KAISER PERMANENTE
COLORADO HMO
MEDICATION REQUEST GUIDELINES

Administered by

Prior Authorization Required Drugs:

a. Drug products, which are listed as **Prior Authorization (PA) required**, require approval when the member presents a prescription to a network pharmacy. To obtain coverage a physician, member or pharmacist may:
   i. Fax a completed **Prior Authorization Request** to MedImpact at (858) 357-2615.
   ii. Contact MedImpact at (800) 788-2949 and provide all necessary information requested.

b. The request will be reviewed by Kaiser Permanente staff according to Medical Exception criteria approved by the Kaiser Permanente Colorado P&T Committee.

c. If the request meets established criteria, the request will be approved and an authorization given.

d. If the request does not meet the criteria established by the P&T Committee, the request will be sent to the health plan physician for further review.

e. Failure to submit a Prior Authorization for a listed drug will result in non-coverage for the health plan member.

f. If the physician wishes to appeal a denied request, he/she may do so by contacting Kaiser Permanente Member Services at (303) 338-3800 for more information.

KAISER PERMANENTE

KAISER COLORADO HMO MR GUIDELINES

ABALOPARATIDE (TYMLOS)

Generic name	Brand name	HICL	GPID	Other
ABALOPARATIDE	TYMLOS		43334	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

1. Must be prescribed by an endocrinology or rheumatology provider
2. No history of osteosarcoma
3. Diagnosis of osteoporosis and meets one of the following criteria, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Patient is considered very high risk for fracture with one of the following:
        i. T-score of -2.5 or less, and 1 or more fragility fractures
        ii. BMD with t-score of -3.5 or less
        iii. History of multiple vertebral compression fractures
        iv. History of multiple fragility fractures
    b. Decline in BMD by more than 2% at hip or more than 2.5% at spine per year, after at least one year of oral alendronate or risedronate, IV zoledronic acid, or denosumab (Prolia), with at least 75% adherence to therapy
    c. T-score remains or has dropped to <-3.5 after at least one year of oral alendronate or risedronate, IV zoledronic acid, or denosumab (Prolia)
    d. Experienced 2 or more fragility fractures while adherent (at least 75% proportion days covered) to oral alendronate or risedronate, IV zoledronic acid, or denosumab (Prolia) for at least one year
    e. Unable to use alendronate or risedronate and IV zoledronic acid due to contraindications or adverse effects, or unable to use denosumab (Prolia) due to contraindications or adverse effects
4. Patient has tried and failed, or has an intolerance or contraindication to, teriparatide injection (Forteo), or the patient travels regularly and is unable to refrigerate teriparatide injection (Forteo) within 36 hours due to travel, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve x2 years.
If initial criteria are not met, do not approve.

RENEWAL CONSIDERATIONS: Do not approve. FDA labeling limits to 2 years.

ePA Questions for Provider Outreach

1. Diagnosis/ICD-10 codes associated with this request:_____
2. Has the patient failed other treatments for this indication? If yes, must list medication, strength, dates of treatment, and reason for discontinuation in Provider Comments section below or attach applicable chart notes.
3. Is there reasoning why alternatives are not suitable (i.e. alendronate tablets, IV zoledronic acid)? If yes, must list reasoning in Provider Comments section below or attach applicable chart notes.
4. Does the patient have history of osteosarcoma?
5. Current T-score: _____ Date: _____
6. Number of fragility fractures patient has had: ___
7. Number of vertebral compression fractures patient has had: ___

RATIONALE

Initial criteria -

- For initial therapy in patients at high risk, there is some evidence that teriparatide could be started first and then followed by an antiresorptive agent (e.g., bisphosphonate) because the bone formation effects of teriparatide may be reduced if started after treatment with an antiresorptive agent. Criteria would allow for use in patients who are at highest risk for fracture prior to starting alternative therapy.
- Patients with history of fragility fracture and BMD with initial t-score in osteoporosis range (<-2.5) but without severe osteoporosis (<-3.5) are generally managed in primary care with use of IV or oral bisphosphonates, with evidence to support use in fracture risk reduction with treatment duration of up to 6-10 years as long as no significant declines in BMD or multiple fragility fractures while on bisphosphonate therapy. Evidence that transition to anabolic agent after use of bisphosphonates may not have as much of a robust response in BMD improvements compared to initial treatment. Therefore, for patients without severe disease or evidence of bisphosphonate failure, continuation of initial therapy is reasonable.
- Based on the landmark pivotal trials for teriparatide and abaloparatide, there is no clinically significant difference in efficacy or recommended treatment durations between teriparatide and abaloparatide for postmenopausal women with osteoporosis.
- There is no head-to-head comparative trial between teriparatide and abaloparatide. Each agent has only been compared to placebo. When compared to placebo, both have demonstrated comparable BMD improvements and fracture reduction with similar treatment durations for efficacy.
- Given similar efficacy and teriparatide being more cost effective, reasonable to preferentially use teriparatide over abaloparatide.
- Both teriparatide and abaloparatide are viable options for treatment of osteoporosis in those with contraindications or intolerances to bisphosphonates when other alternatives (ex. denosumab or romosozumab would also be contraindicated such as in the case of osteonecrosis of the jaw and atypical femur fractures).

Renewal criteria -

- In November 2020, the FDA removed the 2-year lifetime limitation to treatment with teriparatide due to the risk of osteosarcoma:
  - The osteosarcoma warning was based upon studies in rats that high doses (3x greater than human dosing) administered over most of the rats' lifespan (about 24 months) increased the risk of osteosarcoma.
  - Since the teriparatide clinical trials were happening at that time, the trials were terminated early (~19 months).
  - In the 18 years since teriparatide was approved, no increase in osteosarcoma risk has been reported in studies in animals with bone remodeling similar to that in humans (e.g., monkeys).

However osteosarcoma is rare (about 1 in 250,000 adults per year) so would need very large sample sizes.
    - The observed incidence of osteosarcoma during a 15-year post marketing surveillance study was no different than the background incidence rate.
    - Teriparatide has been studied for up to 3 years for the treatment of glucocorticoid-induced osteoporosis.
- Abaloparatide still has 2-year treatment duration in FDA labeling

FDA APPROVED INDICATIONS

FORTEO (teriparatide)

- **Osteoporosis:** Treatment of osteoporosis in postmenopausal females who are at high risk for fracture (defined as history of osteoporotic fracture or multiple risk factors for fracture); treatment to increase bone mass in males with primary or hypogonadal osteoporosis who are high risk for fracture; treatment of males and females with glucocorticoid-induced osteoporosis associated with chronic systemic glucocorticoids with a prednisone dosage of ≥5 mg/day (or equivalent) at a high risk for fracture. May also be used in patients who have failed or are intolerant to other available osteoporosis therapy.

TYMLOS (abaloparatide)

- **Osteoporosis, postmenopausal, fracture risk reduction:** Indicated to reduce risk of vertebral and nonvertebral fractures in postmenopausal women with osteoporosis at high risk for fracture or who failed or intolerant to other available osteoporosis therapy.
- **Osteoporosis, Men at high risk of fracture or who have failed or are intolerant to other osteoporosis therapy:** Indicated to increase bone density in men with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy.

REFERENCES

1. Eastell R, Rosen CJ, Black DM, Cheung AM, Murad MH, Shoback D. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2019;104(5):1595–1622.
2. Tsai JN, Uihlein AV, Lee H, et al. Teriparatide and denosumab, alone or combined, in women with postmenopausal osteoporosis: the DATA study randomized trial. *Lancet* 2013; 382(9886):50–56.
3. Cosman F, Nieves JW, Dempster DW. Treatment sequence matters: anabolic and
4. antiresorptive therapy for osteoporosis. J Bone Miner Res. 2017;32(2):198–202.
5. Miller PD, Lewiecki EM, Krohn K, Schwartz E. Teriparatide: Label changes and identifying patients for long-term use. *Cleveland Clinic Journal of Medicine*. 2021;88(9):489-493. https://www.ccjm.org/content/88/9/489

Creation Date: 05/2022
Effective Date: 02/2024
Reviewed Date: 01/2024
Revised Date: 01/2024

ORENCIA (ABATACEPT)

Generic	Brand	HICL	GPID	Exception/Other
ABATACEPT	ORENCIA	37825		125 mg/mL – Formulary 50 mg/0.4 mL – NF 87.5 mg/0.7 mL – NF

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is currently stable on Orencia
2. Medication is not being used in combination with another biologic
3. Patient has a diagnosis of Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), or Juvenile Idiopathic Arthritis (JIA) and is being prescribed by a CPMG or affiliated rheumatologist

If met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.15].
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria below:

A. Rheumatoid Arthritis (RA)
B. Psoriatic Arthritis (PsA)
C. Juvenile Idiopathic Arthritis (JIA)

A. Rheumatoid Arthritis (RA): All the following must be met:
   1. Patient has a diagnosis of RA and medication is prescribed by CPMG or affiliated rheumatologist
   2. Patient is 18 years of age or older
   3. Medication is not being used in combination with another biologic or advanced small molecule.
   4. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. at least 2 of the following medications: methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
      b. at least 1 TNF inhibitor (e.g., infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F])

If above criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.15].
If above criteria are not met, do not approve.

B. Psoriatic Arthritis (PsA): All the following must be met:
   1. Patient has a diagnosis of PsA, and medication is prescribed by CPMG or affiliated rheumatologist or dermatologist
   2. Patient is 2 years of age or older
   3. Medication is not being used in combination with another biologic or advanced small molecule.

4. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. at least 2 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, leflunomide, sulfasalazine
    b. at least 1 TNF inhibitor (e.g., infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F])
    c. at least one IL-17 inhibitor (secukinumab (Cosentyx)-preferred [F, PA])
    d. IL-12/23 inhibitor (ustekinumab-kfce (Yesintek)-preferred [F, PA])

If above criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.15].
If above criteria are not met, do not approve.

C. Juvenile Idiopathic Arthritis (JIA): All the following must be met:
    1. Patient has a diagnosis of JIA, and medication is prescribed by CPMG or affiliated rheumatologist
    2. Patient is 2 years of age or older
    3. Medication is not being used in combination with another biologic or advanced small molecule.
    4. Patient with failure, intolerance, or contraindication to at least 1 of the following medications, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
        a. Methotrexate
        b. Leflunomide
        c. Hydroxychloroquine
        d. Sulfasalazine

If above criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.15].
If above criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient stable on therapy with abatacept?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Juvenile Idiopathic Arthritis (JIA)]
   QUESTIONS BASED ON DIAGNOSIS SELECTED
   Rheumatoid Arthritis (RA)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

Psoriatic Arthritis (PsA)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

Juvenile Idiopathic Arthritis (JIA)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

FDA APPROVED INDICATIONS: Psoriatic arthritis, Rheumatoid arthritis, Juvenile idiopathic arthritis

REFERENCES

Abatacept (Orencia) 50mg/0.4mL, 87.5mg/0.7mL, 125mg/mL

“Currently stable” means patient is tolerating well, medication appears to be effective, and provider wishes to continue therapy.

GRAPPA 2021 Guidelines:
Coates, L.C., Soriano, E.R., Corp, N. et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nat Rev Rheumatol 18, 465-479 (2022). https://doi.org/10.1038/s41584-022-00798-0

Creation Date:07/27/21
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

ABORTIVE MIGRAINE MEDICATIONS: DIHYDROERGOTAMINES

Generic	Brand	HICL	GPID	Comments
DIHYDROERGOTAMINE MESYLATE (DHE)	TRUDHESA	00155	50931	*Route = Nasal Spray* Non-Formulary tier

GUIDELINES FOR COVERAGE

Must have one of the following diagnoses and meet the diagnosis-specific criteria below:

1. For abortive treatment of migraine headaches with or without aura, must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Patient has a history of failure or intolerance to at least one triptan
   b. Patient has a history of failure or intolerance to dihydroergotamine (Migranal) nasal spray
   c. Patient has a history of failure or intolerance to Zavzpret (zavegepant) nasal spray

   If criteria above are met, then approve indefinitely at GPID, max of 8 per 30 days.
   If criteria are not met, do not approve.

2. For abortive treatment of cluster headaches, must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. The patient is unresponsive or intolerant to high flow oxygen (100%) via non-rebreather mask
   b. The patient is unresponsive or intolerant to sumatriptan nasal spray (formulary), zolmitriptan nasal spray (non-formulary), and/or injectable sumatriptan
   c. Patient has a history of failure or intolerance to dihydroergotamine (Migranal) nasal spray

   If criteria above are met, then approve indefinitely at GPID, max of 8 per 30 days.
   If criteria are not met, do not approve.

RATIONALE

Ensure appropriate criteria are used for the management of requests for DHE nasal spray according to approved indication, dosing, and national treatment guidelines.

Trudhesa, a new intranasal (IN) dihydroergotamine (DHE) product for the acute treatment of migraines with or without aura in adults was approved on September 3, 2021. This is the second IN DHE product for the acute treatment of migraine; Migranal being the first IN DHE product that is generically available. Per the drug company, Trudhesa uses a proprietary delivery device to deliver DHE to the upper nasal space, which allows a lower dose of DHE to be administered and may lower the incidence of adverse

effects. Head-to-head studies between Trudhesa and Migranal have not been performed to show whether this lower dose translates into a difference in efficacy or safety.

** Contraindications & Serious Precautions to DHE nasal spray:*

1) with hemiplegic migraine
2) with migraine with brainstem aura (previously known as basilar artery migraine, basilar migraine and basilar-type migraines)
3) with ischemic heart disease (angina pectoris, history of myocardial infarction, or documented silent ischemia) or to patients who have clinical symptoms or findings consistent with coronary artery vasospasm including Prinzmetal's variant angina
4) with uncontrolled hypertension
5) with concurrent prescriptions for both Dihydroergotamine Mesylate Nasal Spray and either 5-HT1 agonists (e.g., sumatriptan), ergotamine-containing or ergot-type medications or methysergide *should not be used within 24 hours of each other*
6) with concomitant potent CYP 3A4 inhibitors, such as protease inhibitors and macrolide antibiotics, resulting in vasospasm that led to cerebral ischemia and/or ischemia of the extremities. Examples include ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin, troleandomycin, ketoconazole, and itraconazole
7) with concomitant peripheral and central vasoconstrictors (i.e., alpha-adrenergic agonists, vasopressin analogues)
8) with known peripheral arterial disease, sepsis, and following vascular surgery
9) with severely impaired hepatic or renal function

FDA APPROVED INDICATIONS

DHE nasal spray (Migranal and Trudhesa) is an ergot derivative indicated for the acute treatment of migraine headaches with or without aura; not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.

HOW SUPPLIED

INTRANASAL: 4 mg/mL solution

REFERENCES

1. Dihydroergotamine mesylate (Migranal) nasal spray. https://www.bauschhealth.com/Portals/25/Pdf/PI/Migranal-AG-PI.pdf
2. Andersson PG, Jespersen LT. Dihydroergotamine nasal spray in the treatment of attacks of cluster headache. A double-blind trial versus placebo. Cephalalgia. 1986; 6:51-4.
3. https://americanmigrainefoundation.org/resource-library/cluster-headache-treatment-options/
4. The International Headache Society. https://www.ichd-3.org/1-migraine/1-2-migraine-with-aura/1-2-2-migraine-with-brainstem-aura/

Creation date: 5/2020
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

ACORAMIDIS (ATTRUBY)

Generic	Brand	HICL	GPID	Comments
ACORAMIDIS	ATTRUBY	50022		

GUIDELINES FOR COVERAGE

Acoramidis will be approved if ALL the following are met:

1. Patient is aged between 18 and 89 years of age
2. Patient has a diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) documented by positive biopsy demonstrating transthyretin (TTR)-amyloid deposition OR meeting all three of the following:
   a. Diagnosis of heart failure (defined as stage C heart failure (HF) plus New York Heart Association (NYHA class I, II or III), AND either:
      i. Echocardiogram with end-diastolic interventricular septal wall thickness of at least 12mm
      OR
      ii. Cardiac MRI consistent with, or suggestive of, amyloidosis
   b. Pyrophosphate (PYP) scintigraphy cardiac uptake visual score of either:
      i. Grade 2 or 3 using the Perugini Grade 1-3 scoring system
      OR
      ii. Calculated heart-to-contralateral lung (H/CL) ratio of at least 1.5
   c. Absence of a monoclonal gammopathy to rule out light-chain (AL) amyloidosis as determined by meeting the following:
      i. Serum protein electrophoresis (SPEP): no M spike detected, AND
      ii. Kappa/lambda serum free light chains: kappa/lambda free ration within normal limits
      iii. If SPEP and/or kappa lambda serum free light chains are abnormal, serum immunofixation (IFE) is required to be negative (“No monoclonal proteins detected”)
      iv. If results of any of these are unclear such that criteria are not met, a consultation by the Oncology Dept determining that patient does not have AL amyloidosis is adequate to meet this criterion.
3. Patient has medical history of heart failure (HF) with at least 1 of the following:
   a. Hospitalization within the past 2 years for HF
   b. Patient’s oral diuretic dose has doubled in the past 6 months AND/OR has received IV diuretics within the past 6 months
4. Patient has glomerular filtration rate (GFR) of at least 25mL/min and is not requiring dialysis
5. Patient has no history of heart or liver transplantation
6. Patient has no implanted cardiac mechanical assist devices
7. Patient's life expectancy is greater than 1 year
8. Patient has a contraindication or intolerance to tafamidis (Vyndamax/Vyndaqel) or has already tried and had therapeutic failure to it; or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
9. Acoramidis will not be used concurrently with other ATTR medications including tafamidis (Vyndamax, Vyndaqel), inotersen (Tegsedi), or patisiran (Onpattro)

If all the above are met, approve indefinitely.
If any of the above are not met, do not approve.

ePA Questions

1. Does the patient have a diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) documented by positive biopsy demonstrating transthyretin (TTR)-amyloid deposition OR meeting all three of the following:
    A. Diagnosis of heart failure (defined as stage C heart failure (HF) plus New York Heart Association (NYHA class I, II or III), AND either:
        a. Echocardiogram with end-diastolic interventricular septal wall thickness of at least 12mm
        OR
        b. Cardiac MRI consistent with, or suggestive of, amyloidosis
    B. Pyrophosphate (PYP) scintigraphy cardiac uptake visual score of either:
        a. Grade 2 or 3 using the Perugini Grade 1-3 scoring system
        OR
        b. Calculated heart-to-contralateral lung (H/CL) ratio of at least 1.5
    C. Absence of a monoclonal gammopathy to rule out light-chain (AL) amyloidosis as determined by meeting the following:
        a. Serum protein electrophoresis (SPEP): no M spike detected, AND
        b. Kappa/lambda serum free light chains: kappa/lambda free ration within normal limits
        c. If SPEP and/or kappa lambda serum free light chains are abnormal, serum immunofixation (IFE) is required to be negative (“No monoclonal proteins detected”)
        d. If results of any of these are unclear such that criteria are not met, a consultation by the Oncology Dept determining that patient does not have AL amyloidosis is adequate to meet this criterion.
2. Has the patient had prior hospitalization for HF in the past 2 years?
3. Has the patient’s oral diuretic dose doubled in the past 6 months AND/OR has the patient received IV diuretics within the past 6 months?
4. Is the patient requiring dialysis?
5. Lab: glomerular filtration rate (GFR):
6. Date of GFR Lab (MMDDYY):
7. Has the patient had heart or liver transplant?
8. Does the patient have an implanted cardiac mechanical assist device?
9. Is the patient’s life expectancy greater than 1 year?
10. Will the patient use tafamidis (Vyndamax, Vyndaqel), inotersen (Tegsedi), or patisiran (Onpattro) concurrently with acoramidis (Attruby)?

RATIONALE

Per approved label

FDA APPROVED INDICATIONS

Treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization

REFERENCES

1. Gillmore JD, Judge DP, Capelli F, et al. Efficacy and safety of acoramidis in transthyretin amyloid cardiomyopathy. N Engl J Med 2024; 390:132-42.
2. Attruby [package insert]. Palo Alto, CA: BioBridge Pharma; Issued 11/2024.

Creation Date: 1/2025
Effective Date: 2/2025
Reviewed Date: 1/2025
Revised Date: n/a

ACUTE MIGRAINE QUANTITY LIMIT PER COPAY

Generic	Brand	HICL	GPID	Comments
N/A	N/A	N/A	N/A	

- There are limitations on products used to treat migraines to ensure patient safety by minimizing adverse side effects (such as rebound headache) and over-utilization of these products.
- Quantity limits ensure appropriate use and decrease the risk of waste.
- These quantity limits are coded within the PBM and limit the quantities allowed to process for benefit.
- The acute migraine quantity limits are limited per copay (or per rx) and 30-day benefit plans are allowed a certain quantity which is less than for 60-day benefit plans. Prescriptions for these agents do not have refills coded within KPHC as a method of alerting the prescriber that the member might be over-using the medication by triggering a refill request. If the prescriber approves a refill the pharmacy will be able to reprocess the prescription.
- If appropriate and refills are available on the prescription, there is no need for an approval as the pharmacy may reprocess the prescription at any time.

Formulary*	30 Day Plan - Qty/Copay	60 Day Plan - Qty/Copay
D.H.E. 45 Soln 1 mg/ml (dihydroergotamine)	8 ampules (vials)	16 ampules (vials)
D.H.E. 4 mg/mL intranasal solution (dihydroergotamine nasal spray)	8 vials	16 vials
Eletriptan tabs	12 tablets	24 tablets
ERGOMAR SL tabs	12 SL tablets	24 SL tablets
Ergotamine/caffeine tabs (CAFERGOT)	24 tablets	48 tablets
MIGERGOT SUPP (ergotamine/caffeine)	12 suppositories	24 suppositories
Naratriptan tabs	18 tablets	36 tablets
Rizatriptan ODT tabs	18 tablets	36 tablets
Rizatriptan tabs	18 tablets	36 tablets
Sumatriptan 6mg/0.5ml cartridge	8 doses (4 ML)	16 doses (8 ML)
Sumatriptan 6mg/0.5ml PEN injection	8 doses (4 ML)	16 doses (8 ML)
Sumatriptan 6mg/0.5ml SDV Soln (Single Dose Vials)	10 SDV (5 ML)	20 SDV (10 ML)
Sumatriptan nasal spray (6 units per box)	18 units (3 boxes)	36 units (6 boxes)
Sumatriptan tabs	18 tablets	36 tablets
Zolmitriptan tabs	12 tablets	24 tablets
Zolmitriptan nasal spray (6 units per box)	6 units (1 box)	12 units (2 boxes)

Non-Formulary*	30 Day Plan - Qty/Copay	60 Day Plan - Qty/Copay
Acetaminophen-isometheptene-dichloralphenazone caps (MIDRIN)	80 caps / 30 days**	160 caps / 60 days**
Almotriptan tabs	12 tablets	24 tablets
AMERGE tabs	18 tablets	36 tablets
AXERT tabs	12 tablets	24 tablets
CAFERGOT tabs	24 tablets	48 tablets

CAMBIA pack	9 packets	9 packets
ELYXYB (celecoxib) oral solution	9 doses (120mg/dose)	18 doses (120mg/dose)
Diclofenac Potassium powder pack	9 packets	9 packets
FROVA tabs	9 tablets	18 tablets
Frovatriptan tabs	9 tablets	18 tablets
IMITREX 6mg/0.5ml cartridge	8 doses (4 ML)	16 doses (8 ML)
IMITREX 6mg/0.5ml PEN injection	8 doses (4 ML)	16 doses (8 ML)
IMITREX 6 mg/0.5ML SDV Soln (Single Dose Vials)	10 SDV (5 ML)	20 SDV (10 ML)
IMITREX nasal spray (6 units per box)	18 units (3 boxes)	36 units (6 boxes)
IMITREX tabs	18 tablets	36 tablets
Isometheptene-caffeine-acetaminophen tabs (PRODRIN)	80 tabs / 30 days**	80 tabs / 60 days**
MAXALT tabs & TBDP	18 tablets	36 tablets
ONZETRA XSAIL EXHP	8 doses (1 kit)	16 doses (2 kits)
PRODRIN tabs (isometheptene-caffeine-acetaminophen)	80 tabs / 30 days**	80 tabs / 60 days**
RELPAX tabs	12 tablets	24 tablets
RIZAFILM 10mg oral film	18 films	36 films
Sumatriptan 4mg/0.5ml pen INJ (Imitrex)	4 doses (2 ML)	8 doses (4 ML)
Sumatriptan 4mg/0.5ml cartridge (Imitrex)	4 doses (2 ML)	8 doses (4 ML)
TOSYMRA (sumatriptan) 10mg Nasal Spray	18 units (3 boxes)	18 units (3 boxes)
ZEMBRACE SYMTOUCH SOAJ	4 syringes (2 ML)	8 syringes (4 ML)
Zolmitriptan TBDP	12 tablets	24 tablets
ZOMIG nasal spray (6 units per box)	6 units (1 box)	12 units (2 boxes)
ZOMIG tabs & ZMT tabs	12 tablets	24 tablets

RATIONALE
Per Plan.

FDA APPROVED INDICATIONS

REFERENCES
Per Plan.

Creation date: 09/26/2018
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

NON-PREFERRED ADALIMUMAB PA GL

Generic	Brand	HICL	GPID	Notes
ADALIMUMAB	HUMIRA	24800		NF- Comm, Hx, Fed; F- SF
ADALIMUMAB	HUMIRA (CF)	24800		NF- Comm, Hx, Fed; F- SF
ADALIMUMAB-ADBM	CYLTEZO	44481	53841, 53842, 43789, 54205, 55665, 55668	Interchangeable biosimilar, NF- Comm, Hx, Fed; F- SF
ADALIMUMAB-ADAZ	HYRIMOZ	45444	53884, 53875, 53885, 53883, 53891, 53899, 53875, 53887, 53878	NF- Comm, Hx, Fed; F- SF
ADALIMUMAB-BWWD	HADLIMA	45894	46718, 46717, 53846, 53848	NF
ADALIMUMAB-AFZB	ABRILADA	46230	47379, 47378, 47377	NF
ADALIMUMAB-FKJP	HULIO	46685	48318, 48336, 48317	NF
ADALIMUMAB-AQVH	YUSIMRY	47742	53867	NF
ADALIMUMAB-AACF	IDACIO	48528	53387, 53386, 56152	NF
ADALIMUMAB-AATY	YUFLYMA	48955	54213, 54907, 54209, 54908	NF
ADALIMUMAB-RYVK	SIMLANDI	49415	55332, 56016	NF

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:

A. Patient is new to KPCO within the past 90 days and is stable on an adalimumab product.
B. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
C. Patient has one of the following indications and medication is prescribed by the appropriate specialist as noted below:
   1. Patient has a diagnosis of rheumatoid arthritis or subtype, psoriatic arthritis, ankylosing spondylitis or subtype, or polyarticular juvenile idiopathic arthritis and medication is prescribed by a CPMG or affiliated rheumatologist.
   2. The patient is 18 years of age or older with a diagnosis of ulcerative colitis or has a diagnosis of Crohn's Disease at any age and medication is prescribed by a CPMG or affiliated gastroenterologist.
   3. Patient has a diagnosis of psoriasis and medication is prescribed by a CPMG or affiliated dermatologist.
   4. The patient is 18 years of age or older and has a diagnosis of hidradenitis suppurativa and medication is prescribed by a CPMG or affiliated dermatologist.
   5. The patient is 18 years of age order and has a diagnosis of uveitis and medication is prescribed by a CPMG or affiliated rheumatologist or ophthalmologist.

      If criteria are met, approve x1 at GPID, **AND** approve Amjevita indefinitely at HICL.
      If not met, use Initial Criteria for review.

   6. The patient is under 18 years of age and has a diagnosis of ulcerative colitis and medication is prescribed by a CPMG or affiliated gastroenterologist.

7. The patient is under 18 years of age and has a diagnosis of hidradenitis suppurativa and medication is prescribed by a CPMG or affiliated dermatologist.
8. The patient is under 18 years of age and has a diagnosis of uveitis and medication is prescribed by a CPMG or affiliated rheumatologist or ophthalmologist.

If Humira is requested and criteria are met, approve Humira at HICL until the patient turns 18 years of age, and approve Amjevita at HICL indefinitely.
If criteria are not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria:

A. Rheumatoid Arthritis (RA) or subtype
B. Psoriatic Arthritis (PsA)
C. Ankylosing Spondylitis or subtype
D. Uveitis
E. Adults 18 years or older with Ulcerative Colitis (UC)
F. Peds under 18 years with Ulcerative Colitis (UC)
G. Crohn's Disease (CD) and Indeterminate Colitis
H. Psoriasis
I. Hidradenitis Suppurativa (HS)
J. Juvenile Idiopathic Arthritis (JIA)

A. RHEUMATOID ARTHRITIS (RA): All the following must be met:
   1. Patient has a diagnosis of RA or one of the following subtype diagnoses: inflammatory arthritis, inflammatory polyarthritis, or seronegative RA.
   2. Medication is prescribed by a CPMG or affiliated rheumatologist.
   3. Patient is 18 years of age or older.
   4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   5. Patient with failure, intolerance, contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. At least 2 of the following medication: methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
      b. Amjevita

If criteria are met, approve at HICL indefinitely, max 2 pens/syringes per 28 days [MDD 0.08].
If criteria are not met, do not approve.

B. PSORIATIC ARTHRITIS (PsA): All the following must be met:
   1. Patient has a diagnosis of PsA.
   2. Medication is prescribed by a rheumatologist.
   3. Patient is 18 years of age or older.

4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. At least 2 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, leflunomide, sulfasalazine
    b. Amjevita

If criteria are met, approve at HICL indefinitely, max 2 pens/syringes per 28 days [MDD 0.08].
If criteria are not met, do not approve.

C. ANKYLOSING SPONDYLITIS: All the following must be met:
1. Patient has a diagnosis of ankylosing spondylitis or one of the following subtype diagnoses: spondyloarthritis (SpA), axial SpA, nonradiographic axial SpA, radiographic axial SpA, sacroiliitis, undifferentiated spondyloarthropathy, spondyloarthropathy, or enteropathic arthropathy.
2. Medication is prescribed by a rheumatologist.
3. Patient is 18 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient with failure, intolerance, or contraindication to Amjevita, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at HICL indefinitely, max 2 pens/syringes per 28 days [MDD 0.08].
If criteria are not met, do not approve.

D. UVEITIS: All the following must be met:
1. Patient has a diagnosis of uveitis.
2. Medication is prescribed by a rheumatologist or ophthalmologist.
3. Patient is 2 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the

same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. At least 1 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, azathioprine, mycophenolate mofetil, mycophenolic acid, or a calcineurin inhibitor (e.g. cyclosporine, tacrolimus)
   b. Amjevita

If criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.15].
If criteria are not met, do not approve.

E. ADULTS 18 years or older with ULCERATIVE COLITIS (UC): All the following must be met:
   1. Patient has a diagnosis of ulcerative colitis.
   2. Medication is prescribed by a gastroenterologist.
   3. Patient is 18 years of age or older.
   4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   5. Patient with failure, intolerance, or contraindication to Amjevita, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve x1 month (loading dose) max 6 pens/syringes per 28 days [max qty 6; min ds 28], then 2 pens/syringes per 28 days (maintenance dose) indefinitely [MDD 0.08].
If criteria are not met, do not approve.

F. PEDS under 18 years with ULCERATIVE COLITIS (UC): All the following must be met:
   1. Patient has a diagnosis of ulcerative colitis.
   2. Medication is prescribed by a gastroenterologist.
   3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   4. Request is for Humira.

If criteria are met, approve x1 month (loading dose) max 8 pens/syringes per 28 days [max qty 8; min ds 28], then max 4 pens/syringes per 28 days (maintenance dose) until the patient turns 18 years of age [MDD 0.15].
If criteria are not met, do not approve.

G. CROHN'S DISEASE or INDETERMINATE COLITIS: All the following must be met:
   1. Patient has a diagnosis of Crohn’s disease or indeterminate colitis.
   2. Medication is prescribed by a gastroenterologist.
   3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   4. Patient with failure, intolerance, or contraindication to Amjevita, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required

drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve x1 month (loading dose) max 6 pens/syringes per 28 days [max qty 6; min ds 28], then 2 pens/syringes per 28 days (maintenance dose) indefinitely [MDD 0.08].
If criteria are not met, do not approve.

H. PSORIASIS: All the following must be met:
   1. Patient has a diagnosis of moderate to severe psoriasis.
   2. Medication is prescribed by a dermatologist.
   3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Patient has experienced an inadequate response, intolerance, or has a contraindication to a topical corticosteroid or topical calcineurin inhibitor (pimecrolimus, tacrolimus), or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate
      b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one** or contraindication to at least **two** of the following therapies, or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate: Acitretin, Cyclosporine, Methotrexate, Apremilast (Otezla), Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
      c. Amjevita

If criteria are met, approve at HICL, x1 month (loading dose) max 4 pens/syringes per 28 days [max qty 4; min ds 28], then 2 pens/syringes per 28 days (maintenance dose) indefinitely [MDD 0.08].
If criteria are not met, do not approve.

I. HIDRADENITIS SUPPURATIVA (HS): All the following must be met:
   1. Patient has a diagnosis of moderate to severe HS (Hurley stage II-III).
   2. Medication is prescribed by a dermatologist.
   3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   4. Patient with inadequate response, intolerance, or contraindication to the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required

drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

a. At least 3 of the following [medication trials can be within the same drug category], or the patient is noted as Hurley Stage III, making these therapies inappropriate:
    i. Oral antibiotic (8-week trial unless intolerance is documented)
    ii. Topical antibiotic (ex: clindamycin)
    iii. Oral retinoid (isotretinoin, acitretin)
    iv. Intralesional steroid
    v. Hormonal agent (ex: metformin, spironolactone, oral contraceptive for women)
    vi. Laser hair removal
    vii. Infliximab (Inflectra, Remicade, or other biosimilar) infusion
b. Amjevita*

If criteria are met, approve at HICL, x1 month (loading dose) max 6 syringes/pens per 28 days [max qty 6; min ds 28], then 4 syringes/pens per 28 days indefinitely [MDD 0.15].
If criteria are not met, do not approve.

J. JUVENILE IDIOPATHIC ARTHRITIS (JIA): All the following must be met:
1. Patient has a diagnosis of JIA.
2. Medication is prescribed by a rheumatologist.
3. Patient is 2 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient with failure, intolerance, contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. at least 1 of the following medications: methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
    b. Amjevita

If criteria are met, approve at HICL indefinitely, max 2 pens/syringes per 28 days [MDD 0.08].
If criteria are not met, do not approve.

ESCALATION CRITERIA/QTY LIMIT OVERRIDES: Patient must meet New Member or Initial PA Criteria prior to review for Quantity Overrides. Escalation Criteria review only the quantities authorized upon PA approval.

A. Rheumatoid Arthritis (RA) or Psoriatic Arthritis (PsA)
B. Ulcerative Colitis (UC) or Crohn’s Disease
C. Psoriasis
D. Hidradenitis Suppurativa (HS)

A. Patient diagnosis of RA or PsA:
   1. For requests to start on escalated doses (more than 2 pens/syringes per 28 days): Patient must have been on standard maintenance dose of 2 pens/syringes per 28 days for at least 3 months, and provider notes that drug effectiveness lasts only 7-14 days.

      If met, approve max 4 pens/syringes per 28 days x1 year [MDD 0.15].
      If not met, deny and offer maximum 2 pens/syringes per 28 days indefinitely [MDD 0.08].

   2. For requests to continue escalated doses (more than 2 pens/syringes per 28 days): Patient must have been assessed by a rheumatologist in the last 1 year, and the rheumatologist evaluated if the dose can be de-escalated and determined that the escalated dose continues to be medically necessary.

      If met, approve a max of 4 pens/syringes per 28 days x2 years [MDD 0.15].
      If not met, deny and offer maximum 2 pens/syringes per 28 days indefinitely [MDD 0.08].

B. Patient diagnosis of Ulcerative Colitis or Crohn's disease
   1. Documentation by gastroenterology provider of the patient resuming therapy after a gap of 3 months or longer in treatment (to reload).

      If met, approve at HICL x 1 month, max 8 pens/syringes (loading dose) per 28 days [max qty 8; min ds 28], then 2 pens/syringes per 28 days indefinitely [MDD 0.08].
      If not met, deny and offer maximum 2 pens/syringes per 28 days indefinitely [MDD 0.08].

   2. For requests to start on escalated doses (more than 2 pens/syringes per 28 days): Patient must have been on standard maintenance dose of 2 pens/syringes per 28 days with inadequate drug level (less than 12 mcg/mL).

      If met, approve at HICL x1 year, max 4 pens/syringes per 28 days [MDD 0.15].
      If not met, deny and offer maximum 2 pens/syringes per 28 days indefinitely [MDD 0.08].

   3. For requests to continue escalated doses (more than 2 pens/syringes per 28 days): Patient must have been assessed by a gastroenterologist in the last 1 year, and the gastroenterologist evaluated if the dose can be de-escalated and determined that the escalated dose continues to be medically necessary.

      If met, approve at HICL x2 years, max 4 pens/syringes per 28 days [MDD 0.15].
      If not met, deny and offer maximum 2 pens/syringes per 28 days indefinitely [MDD 0.08].

C. Patient diagnosis of Psoriasis:
   1. Documentation by dermatology provider of the patient resuming therapy after a gap of 3 months or longer in treatment (to reload)

      If criteria are met, approve at HICL x1 month, max 4 pens/syringes per 28 days (loading dose) [max qty 4; min ds 28], then 2 pens/syringes per 28 days (maintenance dose) indefinitely [MDD 0.08].
      If not met, deny and offer maximum 2 pens/syringes per 28 days indefinitely [MDD 0.08].

D. Patient diagnosis of Hidradenitis Suppurativa (HS):

1. Documentation by dermatology provider of the patient resuming therapy after a gap of 3 months or longer in treatment (to reload).

   If criteria are met, approve at HICL x1 month, max 6 syringes/pens per 28 days (loading dose) [max qty 6; min ds 28], then 4 syringes/pens per 28 days (maintenance dose) indefinitely [MDD 0.15].
   If not met, deny and offer maximum 4 pens/syringes per 28 days indefinitely [MDD 0.15].

ePA Questions

1. Is the patient stable on therapy with adalimumab?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Will this medication be used in combination with a biologic or advanced small molecule for the same indication?
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Rheumatoid Arthritis (RA) or subtype; Psoriatic Arthritis (PsA); Ankylosing Spondylitis or subtype; Uveitis; Adults 18 years or older with Ulcerative Colitis (UC); Peds under 18 years with Ulcerative Colitis (UC); Crohn's Disease or Indeterminant Colitis; Psoriasis; Hidradenitis Suppurativa (HS); Juvenile Idiopathic Arthritis (JIA)]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Rheumatoid Arthritis or subtype

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg)) are not suitable? If yes, you must list reasoning in Provider Comment section below or attach applicable chart notes.

Psoriatic Arthritis (PsA)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Uveitis

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (azathioprine tablets (50 mg), methotrexate 2.5 mg tablets or 25mg/ml vials, mycophenolate mofetil 250 mg capsules or 500 mg tablets, tacrolimus capsules) are not suitable? If yes, you must list reasoning in Provider Comment section below or attach applicable chart notes.

Psoriasis

1. BSA impacted (%):
2. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (topical steroids; tacrolimus ointment; acitretin capsules (10 mg, 25 mg); cyclosporine capsules (25 mg, 100 mg); methotrexate tablets (2.5 mg) or injection

(25 mg/mL); Otezla tablets) are not suitable? If yes, you must list reasoning in Provider Comment section below or attach applicable chart notes.

Hidradenitis Suppurativa (HS)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Oral antibiotic; Topical antibiotic (ex: clindamycin); Oral retinoid (isotretinoin, acitretin); Intralesional steroid; Hormonal agent (ex: metformin, spironolactone, oral contraceptive for women); Laser hair removal; Infliximab) are not suitable? If yes, you must list reasoning in Provider Comment section below or attach applicable chart notes.

Juvenile Idiopathic Arthritis (JIA)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg)) are not suitable? If yes, you must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE:

*When the brand and biosimilar do not share the same indication for pediatric patients [at time of writing: Uveitis, HS, and UC], if the provider requests brand, noting the formulary preferred biosimilar Amjevita does not have indication, criteria defined by “the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug” shall be considered met for coverage authorization.

Step Therapy through preferred adalimumab product, Amjevita is based on interpretation of CO Revised Statute 10-16-145:

(5) THIS SECTION DOES NOT PROHIBIT:
(a) A CARRIER, AN ORGANIZATION, OR A PBM FROM REQUIRING A COVERED PERSON TO TRY A GENERIC EQUIVALENT DRUG, A BIOSIMILAR DRUG, OR AN INTERCHAGEABLE BIOLOGICAL PRODUCT AS DEFINED BY 42 U.S.C.SEC.262(i)(3), UNLESS THE COVERED PERSON OR COVERED PERSON’S PRESCRIBEING PROVIDER HAS REQUESTED A STEP-THERAPY EXCEPTION AND THE PRESCIBED CRUG MEETS THE CRITERIA FOR A STEP-THERAPY EXCEPTION SPECIFIED IN SUBSECTION (4)(a) OF THIS SECTION;

Compared with a reference product, biosimilars:

- Are made with the same types of living sources
- Are given to the patient in the same way
- Have the same strength, dosage, potential treatment benefits, and potential side effects

REGARDING STEP THERAPY:
Trial and failure of 2 DMARDs is required, as the DMARD classification is not representative of a specific pharmacological class and these medications are pharmacologically unrelated in terms of mechanism of action.

FDA INDICATIONS:

Crohn disease, moderate to severe, induction and maintenance of remission (Humira and adalimumab biosimilars): Treatment of moderately to severely active Crohn disease in adults and pediatric patients ≥6 years of age.

Hidradenitis suppurativa, moderate to severe, refractory: Treatment of moderate to severe hidradenitis suppurativa in adults (Humira and adalimumab biosimilars [except Idacio]) and pediatric patients ≥12 years of age (Humira only).

Juvenile idiopathic arthritis (Humira and adalimumab biosimilars): Treatment (to reduce signs/symptoms) of active polyarticular juvenile idiopathic arthritis (moderate to severe) in pediatric patients ≥2 years of age; may be used alone or in combination with methotrexate.

Plaque psoriasis, moderate to severe (Humira and adalimumab biosimilars): Treatment of chronic plaque psoriasis (moderate to severe) in adults who are candidates for systemic therapy or phototherapy, and when other systemic therapies are less appropriate (with close monitoring and regular follow-up).

Rheumatoid arthritis (Humira and adalimumab biosimilars): Treatment (to reduce signs/symptoms, induce major clinical response, inhibit progression of structural damage, and improve physical function) of active rheumatoid arthritis (moderate to severe) in adults; may be used alone or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs).

Spondyloarthritis (Humira and adalimumab biosimilars):

> Axial spondyloarthritis (eg, ankylosing spondylitis): Treatment (to reduce signs/symptoms) of active ankylosing spondylitis in adults. May also be used off label for nonradiographic axial spondyloarthritis (ACR [Ward 2019]).
>
> Psoriatic arthritis: Treatment (to reduce signs/symptoms, inhibit progression of structural damage, and improve physical function) of psoriatic arthritis (a form of peripheral spondyloarthritis) in adults; may be used alone or in combination with nonbiologic DMARDs. May also be used off label for nonpsoriatic peripheral spondyloarthritis (eg, reactive arthritis, arthritis associated with inflammatory bowel disease) (Mease 2015; Paramarta 2013).

Ulcerative colitis, moderate to severe, induction and maintenance of remission: Treatment of moderately to severely active ulcerative colitis in adults (Humira and adalimumab biosimilars) and pediatric patients ≥5 years of age (Humira only). Note: Efficacy in patients intolerant of or no longer responsive to other tumor necrosis factor blockers has not been established.

Uveitis, noninfectious: Treatment of noninfectious intermediate, posterior, and panuveitis in adults (Humira and adalimumab biosimilars [except Idacio and Yuflyma]) and children ≥2 years of age (Humira only).

References:

1. Currently stable on medication means patient is tolerating well, appears to be effective, and provider wishes to continue.
2. Biosimilars. Overview for Health Care Professionals. https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals. Published 12/31/2022. Accessed 2/3/2023.

Treatment	Relative Contraindications in Psoriasis
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses (ex: systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for psoriasis.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities, active malignancy, and hypersensitivity*
Acitretin	*Caution in women of child potential (cannot consider pregnancy up to 3 years after completion of treatment), pregnancy, lactation, severe hepatic or renal dysfunction, chronically abnormal elevated lipid values, and hypersensitivity*

Created: 01/2021
Effective: 06/2025
Reviewed: 05/2025
Revised: 05/2025

PROAIR RESPICLICK NON-FORMULARY GUIDELINE

Generic	Brand	HICL	GCN	Exception/Other
ALBUTEROL SULFATE	PROAIR RESPICLICK		38212	Non-Formulary - 2ND Preferred

Non-Formulary Criteria: Must meet all the following:
1. Patient does not have an allergy or intolerance to albuterol sulfate.
2. Patient has documented allergy to an inactive ingredient, intolerance (patient states doesn't work as well, tastes bad, etc.), or clinical failure (patient states has to use more puffs or ineffective) to at least one of the following (listed in preferred order), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Proventil HFA authorized generic - 00254-1007-52 or 00781-7296-85
    b. ProAir HFA authorized generic - 00093-3174-31
    c. Ventolin HFA authorized generic - 66993-0019-68

If criteria are met, approve formulary override at NDC-9 level indefinitely.
If criteria are not met, do not approve. [If patient has an allergy or intolerance to albuterol sulfate itself, recommend levalbuterol HFA.]

ePA Questions
1. Does the patient have an allergy or intolerance to albuterol sulfate?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why generic albuterol HFA is not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Health Plan. ProAir Respiclick may be considered after failure of formulary preferred albuterol HFA products. Patients noted to have an allergy to albuterol sulfate should be prescribed levalbuterol.

REFERENCES
1. https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs#:~:text=The%20term%20%E2%80%9Cauthorized%20generic%E2%80%9D%20drug,product%20as%20the%20branded%20product.
2. 00254-1007-52 and 00781-7296-85 is authorized generic for Proventil HFA
3. 00093-3174-31 is authorized generic for ProAir HFA
4. 66993-0019-68 is authorized generic for Ventolin HFA

Creation date: 03/2021
Effective date: 06/2024
Reviewed date: 03/2024
Revised date: 09/2023

ALIROCUMAB (PRALUENT)

Generic	Brand	HICL	GPID	Comments
ALIROCUMAB	PRALUENT PEN	42347	39182, 39184	Nonformulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and stable on therapy.
2. Patient has tried and failed an appropriate dose of, experienced adverse events with, or has an allergy or contraindication to, evolocumab (Repatha), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

   If met, approve x1 year.
   If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of either homozygous familial hypercholesterolemia (HoFH), heterozygous familial hypercholesterolemia (HeFH), or atherosclerotic cardiovascular disease (ASCVD) with a clinical event^^*
2. Has a current LDL level drawn within the last 90 days of greater than or equal to one of the following:
   a) 55 mg/dL for ASCVD at very high risk defined as multiple ASCVD events^^ or 1 ASCVD event and 2 or more high risk conditions (age ≥ 65 years, familial hypercholesterolemia, diabetes, HTN, eGFR 15-59, current smoking)
   b) 70mg/dL for ASCVD not at very high risk
   c) 100 mg/dL for HeFH/HoFH
3. Patient must meet one of the following:
   a) has been taking atorvastatin 80mg or rosuvastatin 40mg daily or statin therapy at the maximally tolerated dose for at least 60 days prior to LDL lab;
   b) has an absolute contraindication to statin therapy (active, decompensated liver disease; nursing female, pregnancy, or plans to become pregnant;
   c) has experienced a hypersensitivity reaction to a statin drug;
   d) has a documented history of CPK>10x ULN or rhabdomyolysis attributed to a statin and not explained by a drug interaction, fall, or prolonged immobility);
   e) is statin intolerant as defined by the National Lipid Association Statin Intolerance Panel**
4. Patient has been taking ezetimibe for at least 60 days prior to LDL lab, or the patient has a contraindication or intolerance to ezetimibe
5. The patient has tried and failed an appropriate dose of, experienced adverse events with, or has an allergy or contraindication to, evolocumab (Repatha), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv)

the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If met, approve at HICL x1 year, max daily dose of 0.08 (2 syringes/pens per 28 days).
If not met, do not approve.

RENEWAL CRITERIA: Must meet ONE of the following:
1. Patient's LDL decreased by at least 20% after starting the PCSK9 inhibitor when compared to pre-PCSK9 inhibitor levels.
2. Patient's LDL is at goal.

If either criterion is met, approve at HICL indefinitely, max daily dose of 0.08 (2 syringes/pens per 28 days).
If neither criterion is met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient stable on alirocumab therapy?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: homozygous familial hypercholesterolemia (HoFH), heterozygous familial hypercholesterolemia (HeFH), or atherosclerotic cardiovascular disease (ASCVD) with a clinical event (must list the clinical event in Provider Comment section below or attach applicable chart notes.]
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (rosuvastatin tablets, atorvastatin tablets, lovastatin tablets, simvastatin tablets, pravastatin tablets; ezetimibe tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
6. Current LDL:
7. Date of LDL lab (MMDDYY):

Renewal Review Questions
1. Current LDL:
2. Date of LDL lab (MMDDYY):
3. LDL Goal:

REFERENCES

*Requires documentation which may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and laboratory data.

^^**Includes**: MI, ACS, CAD with intervention (e.g., PCI, stent, CABG), ischemic non-cardioembolic stroke, PAD with intervention (e.g., stent, surgery); **Excludes**: High CAC score, AAA, CAD finding on diagnostic cath without MI/ACS/intervention, CAD equivalents (e.g. DM, CKD), primary prevention patients regardless of CV risk score

**Inability to tolerate at least 2 statins, with at least one started at the lowest starting daily dose

For primary prevention for a patient who has NOT been noted to have familial hypercholesterolemia, a PCSK9i would not be appropriate. If they have failed statins (even low dose 1-2 days per week) and ezetimibe, we could offer any formulary, unrestricted lipid-lowering therapy.

RATIONALE
Per Health Plan

Creation Date: 3/15/2017
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

FIRDAPSE (AMIFAMPRIDINE)

Generic	Brand	HICL	GPID	Other
AMIFAMPRIDINE PHOSPHATE	FIRDAPSE	36930	28457	Non-formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: All the following must be met:
1. Must be prescribed by a Neurologist or if clinically appropriate, an oncologist
2. Patient must have a diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS)
3. Patient must be age 6 years or older
4. Patient is ambulatory and has weakness that interferes with daily function
5. Has documentation of a baseline clinical muscle strength assessment (examples include either the Quantitative Myasthenia Gravis (QMG) score or the triple-timed up-and-go test (3TUG))
6. Must not have a history of seizure disorder or have active brain metastasis

If initial criteria are met, then approve x 6 months, max dose 10 tablets per day for patients weighing 45kg or more and max dose 5 tablets per day for patients weighing less than 45kg.

RENEWAL CRITERIA: Must meet all the following criteria:
1. Patient has maintained >75% adherence to the medication since last approval
2. The patient's current QMG score or 3TUG test has remained stable or improved compared to baseline
3. Patient is still ambulatory
4. Patient has not developed epileptic seizures

If renewal criteria are met, then approve x 1 year, max dose 10 tablets per day for patients weighing 45kg or more and max dose 5 tablets per day for patients weighing less than 45kg.

ePA Questions for Provider Outreach
INITIAL REVIEW QUESTIONS
1. Is the patient ambulatory with weakness that interferes with daily function?
2. Current Quantitative Myasthenia Gravis (QMG) score:
3. Date of Current Quantitative Myasthenia Gravis (QMG) score (MMDDYY):
4. Current triple-timed up-and-go test (3TUG) score:
5. Date of Current triple-timed up-and-go test (3TUG) score (MMDDYY):
6. Does the patient have history of seizure disorder or active brain metastasis?

RENEWAL REVIEW QUESTIONS
1. Current Quantitative Myasthenia Gravis (QMG) score:
2. Date of Current Quantitative Myasthenia Gravis (QMG) score (MMDDYY):
3. Current triple-timed up-and-go test (3TUG) score:
4. Date of Current triple-timed up-and-go test (3TUG) score (MMDDYY):
5. Is the patient ambulatory?
6. Has the patient developed epileptic seizures?

RATIONALE
Firdapse is a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.

NOTES:
Given serious teratogenicity risk from this medicine, those members with pregnancy potential should be encouraged to have a negative pregnancy test, to be on highly effective contraception (ie IUD or implant) unless there is a valid reason not to and should not be breastfeeding.

FDA APPROVED INDICATIONS
- FIRDAPSE is a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.

REFERENCES
1. Firdapse [Prescribing Information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc: May 2024.

Creation Date:11/2020
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

AMLODIPINE 1 MG/ML SUSPENSION AND SOLUTION - AGE RESTRICTION CRITERIA

Generic	Brand	HICL	GPID	Exception/Other
AMLODIPINE SUSPENSION 1 MG/ML	KATERZIA	45864	46652	Formulary
AMLODIPINE SUSPENSION 1 MG/ML	NORLIQVA	06494	46882	Nonformulary

GUIDELINES FOR COVERAGE

INITIAL AND RENEWAL CRITERIA: ONE of the following criteria must be met:
1. Patient is less than or equal to 10 years old.
2. Patient is using an alternative administration route, such as a gastrostomy tube.
3. Dose cannot be administered by using half, whole or combinations of the amlodipine tablets.
4. Patient cannot swallow tablets whole, halved, or crushed (with or without mixing in apple sauce).

If any criterion is met, approve x1 year.
If no criteria are met, do not approve, and suggest either changing to tablet strengths that can be halved or used in combination, or crushing amlodipine tablets before administration and taking with or without applesauce.

ePA Questions
1. Is the patient using an alternative administration route, such as a gastrostomy tube? If yes, must attach applicable chart notes.
2. Is the patient unable to swallow tablets whole, halved, or crushed (with or without mixing in applesauce)? If yes, must attach applicable chart notes.

RATIONALE
Per Health Plan.

General Clinical Criteria for solutions/suspension
1. Age is less than or equal to 10 years old
2. Presence of gastrostomy
3. Dose does not allow use of halved, whole or combo of tablet
4. Dose does not use whole capsule (cannot “cut” capsules in half)
5. Clinical condition where unable to swallow crushed/opened tablets/capsules (i.e., esophageal stricture)

FDA APPROVAL
1. Treatment of hypertension in patients 6 years of age and older
2. Treatment of Chronic Stable Angina, Vasospastic Angina, or Angiographically documented coronary artery disease in patients without heart failure or an ejection fraction less than 40%
3. Max dose is 10 mg daily

REFERENCES
Per Health Plan

Creation date: 10/2019
Effective date: 10/2024
Reviewed date: 07/2024
Revised date: 07/2024

APALUTAMIDE (ERLEADA)

Generic	Brand	HICL	GPID	Other
APALUTAMIDE	ERLEADA	44773	44446	Non-Formulary

GUIDELINES FOR COVERAGE
Must meet all the following:

1. Patient has a diagnosis of prostate adenocarcinoma
2. Medication is prescribed by an Oncologist
3. Patient does not have a history of seizures or seizure disorder
4. Must have PSA greater than or equal to 2ng/dL
5. Must have a diagnosis of nonmetastatic castration-resistant prostate cancer (M0CRPC) or metastatic castration-sensitive prostate cancer (M1CSPC), and meet all the diagnosis subtype-specific criteria below:
    a. Nonmetastatic Castration Resistant Prostate Cancer (M0CRPC): Must meet all:
        i. No metastasis observable on radiologic scans
        ii. Must have had PSA double in 10 months or less while on at least one ADT (androgen deprivation therapy) including: leuprolide (Eligard, Lupron), goserelin (Zoladex), triptorelin (Trelstar), histrelin (Supprelin, Vantas), degarelix (Firmagon)
        iii. Patient is intolerant of, or has a contraindication to [ex: currently being treated with a strong CYP3A4 inducer that prohibits the use of drug], either of the following; or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
            - Enzalutamide (Xtandi) OR Darolutamide (Nubeqa)

    b. Metastatic Castration Sensitive Prostate Cancer (M1CSPC): Must meet all:
        i. Patient has documented metastatic disease that has not progressed on ADT (androgen deprivation therapy) including: leuprolide (Eligard, Lupron), goserelin (Zoladex), triptorelin (Trelstar), histrelin (Supprelin, Vantas), degarelix (Firmagon)
        ii. Patient with failure, intolerance, or contraindication to all of the following; or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
            1. Abiraterone (Zytiga)
            2. Darolutamide (Nubeqa) OR enzalutamide (Xtandi)
6. Patient has not experienced disease progression on any of the following: enzalutamide (Xtandi), abiraterone acetate (Zytiga, Yonsa), darolutamide (Nubeqa), or docetaxel (Taxotere)

If criteria are met, approve indefinitely at HICL.

If criteria are not met, do not approve. Alternatives include darolutamide [Nubeqa] or enzalutamide [Xtandi] for M0CRPC or abiraterone [Zytiga; preferred], darolutamide [Nubeqa] or enzalutamide [Xtandi] for patients with M1CSPC.

ePA Questions

1. Does the patient a diagnosis of prostate adenocarcinoma?
2. Does the patient have a history of seizures or seizure disorder?
3. Has the patient experienced disease progression on any of the following: enzalutamide (Xtandi), abiraterone acetate (Zytiga, Yonsa), darolutamide (Nubeqa), or docetaxel (Taxotere)?
4. Patient's current PSA value (ng/dL):
5. Date of current PSA (MMDDYY):
6. Diagnosis subtype associated with this request: [check boxes for all diagnosis-subtypes listed in criteria: nonmetastatic castration-resistant prostate cancer (M0CRPC); metastatic castration-sensitive prostate cancer (M1CSPC)]

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   Nonmetastatic Castration-Resistant Prostate Cancer (M0CRPC)

   1. Does the patient have any observable metastasis on radiologic scans?
   2. Has the patient's PSA doubled in 10 months or less while on ADT (androgen deprivation therapy)?
   3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   4. Is there reasoning why alternatives (enzalutamide (Xtandi), darolutamide (Nubeqa)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

   Metastatic Castration-Sensitive Prostate Cancer (M1CSPC)

   1. Has metastatic disease progressed on ADT (androgen deprivation therapy)?
   2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   3. Is there reasoning why alternatives (abiraterone (Zytiga), enzalutamide (Xtandi), darolutamide (Nubeqa)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Per Health Plan.
Enzalutamide is the KPCO preferred agent for nonmetastatic (M0) castration resistant prostate cancer (CRPC), unless CYP-interacting drugs then apalutamide should be used. If the patient has metastatic castration sensitive prostate cancer (mCSPC), KPCO formulary alternatives of abiraterone or docetaxel are preferred.

FDA APPROVED INDICATIONS

Treatment of non-metastatic, castration-resistant prostate cancer (M0CRPC). Treatment of metastatic castration-sensitive prostate cancer (M1CSPC).

REFERENCES

1. Erleada (apalutamide) [prescribing information]. Horsham, PA: Janssen Products, LP; September 2020.
2. NCCN Clinical Practice Guidelines in Oncology. Prostate Cancer v.1.2025. www.nccn.org

Creation Date: 11/2018
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

APROCITENTAN (TRYVIO)

Generic	Brand	HICL	GPID	Comments
APROCITENTAN	TRYVIO	49465		Non-Formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days.
2. Patient has a diagnosis of resistant hypertension and is stable on therapy

If met, approve indefinitely.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:

1. Patient must be 18 years of age or older.
2. Medication must be prescribed by a cardiologist or nephrologist
3. Patient must have a diagnosis of resistant hypertension.
4. Patient has tried and failed, or has an intolerance or contraindication to all of the following or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
    - Thiazide or thiazide-type diuretic
    - ACE inhibitor or angiotensin receptor block (ARB)
    - Calcium channel blocker
    - Beta blocker
    - Aldosterone antagonist
    - Alpha-1 blocker
    - Direct vasodilator
    - Central alpha-agonist or other centrally-acting drug

If initial criteria are met, approve at HICL indefinitely.
If initial criteria are not met, do not approve.

RATIONALE
Aprocitentan should be used for resistant hypertension per its FDA-approved indication and the PRECISION trial. Initially, hypertension should be treated with the drugs listed above as recommended by the current American Heart Association and American College of Cardiology hypertension guidelines. If these fail, aprocitentan can be considered, but it should be last line due to safety concerns, its FDA REMS requirement for monitoring teratogenic risks, and its restriction to specialty pharmacy dispensing only.

FDA APPROVED INDICATIONS

- Treatment of hypertension in combination with other antihypertensive drugs to lower blood pressure in adult patients who are not adequately controlled on other drugs.

REFERENCES

- Tryvio [package insert]. Idorsia Pharmaceuticals US Inc. Radnor, PA. Revised 4/2024.
- Schlaich MP, Bellet M, Weber MA, et al., on behalf of the PRECISION investigators. Dual endothelin antagonist aprocitentan for resistant hypertension (PRECISION): a multicentre, blinded, randomized, parallel-group, phase 3 trial. Lancet 2022;400:1927-37.
- Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2018;71:e127-e248.

Creation Date: 5/2025
Effective Date: 6/2025
Reviewed Date: n/a
Revised Date: n/a

ATOGEPANT (QULIPTA)

Generic	Brand	HICL	GPID	Comments
ATOGEPANT	QULIPTA	47599	51231, 51232, 51236	Oral CGRP antagonist; "Gepant" for preventive tx

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

A. Request is for atogepant (Qulipta) daily for the preventive treatment of migraine
B. Patient must be age 18 or older
C. Patient is not taking another CGRP-directed medication for migraine prevention

D. Must meet diagnosis specific criteria (1 or 2 below)

1. For episodic migraine diagnosis: The patient must meet all the following criteria:
    a. Patient has a diagnosis of episodic migraine (less than 15 migraine days per month)
    b. Patient with failure of (after at least 6-8 weeks at maximally tolerated dose), intolerance to, or contraindication to, at least two medications from different migraine preventive classes; or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
        i. Anticonvulsants: divalproex, valproate, topiramate
        ii. Beta blockers: atenolol, metoprolol, nadolol, propranolol, timolol
        iii. Antidepressants: amitriptyline, nortriptyline, venlafaxine, duloxetine
    c. Meets medication specific criteria below, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
        i. Patient with failure of (after at least two monthly doses), intolerance to, or contraindication to, at least 1 CGRP-mAb [erenumab (Aimovig), eptinezumab (Vyepti), fremanezumab (Ajovy), galcanezumab (Emgality)] for migraine prevention

2. For chronic migraine diagnosis: The patient must meet all the following criteria:
    a. Patient has a diagnosis of chronic migraine (defined as 15 or more headache days [migraine-like or tension-like] per month for the past 3 months, of which at least 8 days are migraines)
    b. Patient with documented intolerance, contraindication, or inadequate response after an adequate trial* to, at least two medications from different migraine preventive classes, or

the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

i. Anticonvulsants: divalproex, valproate, topiramate
ii. Beta blockers: atenolol, metoprolol, nadolol, propranolol, timolol
iii. Antidepressants: amitriptyline, nortriptyline, venlafaxine, duloxetine
iv. Botulinum toxin: onabotulinumtoxinA

c. Meets medication specific criteria below, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    i. Patient with failure of (after at least two monthly doses), intolerance to, or contraindication to, at least 1 CGRP-mAb [erenumab (Aimovig), eptinezumab (Vyepti), fremanezumab (Ajovy), galcanezumab (Emgality)] for migraine prevention

If initial criteria are met, approve x6 months at HICL, max 1 tablet per day.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Request is for atogepant (Qulipta) daily for preventive treatment of migraine
2. Patient is not taking another CGRP-directed medication for migraine prevention
3. Patient has experienced at least one of the following:
    a. At least 30% reduction in migraine days per month
    b. A decrease in MIDAS score by 8 or more points
    c. Fewer migraines or headache attacks by at least 2 days per month with Qulipta therapy
    d. Lessening in migraine severity with Qulipta therapy
    e. Lessening in migraine duration with Qulipta therapy

If renewal criteria are met, approve indefinitely at HICL, max 1 tablet per day.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Ajovy prefilled syringes or auto-injector; divalproex sodium DR or ER tablets, valproic acid capsules (250 mg), topiramate IR tablets; atenolol, metoprolol IR or ER, propranolol IR or ER; amitriptyline, nortriptyline, venlafaxine ER capsules, duloxetine capsules) are

not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient taking another CGRP-directed medication for migraine prevention?

Renewal Review Questions

1. Is the patient taking another CGRP-directed medication for migraine prevention?
2. Has the patient experienced fewer migraines or headache attacks by at least 2 days per month with Qulipta therapy?
3. Has the patient experienced lessening in migraine severity and/or duration with Qulipta therapy?

* *Adequate trials of non-CGRP mAb preventive medication trials FOR MIGRAINE:*

- Oral migraine preventive medication: at least 6-8 weeks at maximally tolerated dose
- OnabotulinumtoxinA: at least two quarterly injections with response assessed 6 months after initiation

Available triptan/ergotamine options:

Generic	Brand	Formulations available
Almotriptan	Axert	Tablet
Eletriptan	Relpax	Tablet
Frovatriptan	Frova	Tablet
Naratriptan	Amerge	Tablet
Rizatriptan	Maxalt/Maxalt MLT	Tablet, ODT
Sumatriptan	Imitrex, Sumavel, Onzetra, Zembrace	Tablet, nasal spray, injection
Zolmitriptan	Zomig/Zomig ZMT	Tablet, ODT, nasal spray
Ergotamine	Ergomar	Sublingual
Ergotamine/caffeine	Cafergot	Tablet, suppository
Dihydroergotamine	Migranal, Trudhesa D.H.E.	Nasal spray, injection

ODT=orally disintegrating tablet

True contraindications to triptan class

- Ischemic coronary artery disease including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina)
- History of stroke or transient ischemic attack
- Peripheral vascular disease
- Ischemic bowel disease
- Uncontrolled hypertension
- Hemiplegic or basilar migraine
- Wolff-Parkinson-White syndrome

Quantity Limits for Novel Oral Migraine Treatment

Medication	Dosage Strength	Maximum quantity limit for 30 days	Notes
Acute migraine indication			
Ubrogepant (Ubrelvy)	50 mg, 100 mg	10	Tablet splitting of the 100 mg tablet has been approved and should be recommended for all patients prescribed to take a

			dose of 50 mg at onset of migraine
Rimegepant (Nurtec ODT)	75 mg	8	Tablet splitting n/a
Zavegepant (Zavzpret)	10 mg	6	Available as a ready-to-use, unit-dose disposable nasal spray device that contains 10 mg of zavegepant. Each carton contains 6 nasal spray units.
Lasmiditan (Reyvow)	50 mg	8	Tablet splitting NOT approved Approved doses to take at onset of migraine are 50 mg, 100 mg, or 200 mg, however, only 50 mg and 100 mg tablet strengths are available
	100 mg	8	
Preventive migraine indication			
Atogepant (Qulipta)	10 mg, 30 mg, 60 mg	30	Tablet splitting of the 60 mg tablet has been approved and should be recommended for all patients prescribed 30 mg daily
Rimegepant (Nurtec ODT)	75 mg	16	Tablet splitting n/a

CGRP-Directed Migraine Medications

Generic (Brand)	Route CGRP "class"	Acute Migraine Approval	Preventive Migraine Approval
Eptinezumab (Vyepti)	IV, CGRP-mAb	X	100 mg or 300 mg Q 3 mo
Erenumab (Aimovig)	SC, CGRP-mAb	X	70 mg or 140 mg Q mo
Fremanezumab (Ajovy)	SC, CGRP-mAb	X	225 mg Q mo, OR 675 mg Q 3 mo
Galcanezumab (Emgality)	SC, CGRP-mAb	X	240 mg loading dose, then 120 mg Q mo
Atogepant (Qulipta)	Oral, CGRP antagonist "gepant"	X	10 mg, 30 mg or 60 mg daily
Rimegepant (Nurtec ODT)	Orally disintegrating tablet, CGRP antagonist "gepant"	75 mg at onset do NOT repeat dose	75 mg every OTHER day
Ubrogepant (Ubrelvy)	Oral, CGRP antagonist "gepant"	50 mg or 100 mg at onset, may repeat in 2 hours	X
Zavegepant (Zavzpret)	Intranasal, CGRP antagonist "gepant"	10 mg at onset do NOT repeat dose	X

RATIONALE

Preventive migraine indication

Rimegepant was the first oral gepant approved for preventive treatment of migraine and this expanded indication came after rimegepant had already been approved for acute treatment of migraine. Atogepant is the second oral gepant approved for the preventive treatment of migraine and this is the only indication for which it is approved for (unlike rimegepant, atogepant does not have an indication for acute migraine treatment).

Preventive indication approvals for both rimegepant and atogepant came after injectable/infused CGRP-mAbs (erenumab, eptinezumab, fremanezumab, galcanezumab). There are no head-to-head clinical trials comparing oral and injectable/infused CGRP directed medications.

In a 2024 Position Statement update from the American Headache Society, CGRP-directed medications are listed as a first-line treatment option for migraine prevention along with older oral migraine preventives and onabotulinumtoxinA (for chronic migraine only).

FDA APPROVED INDICATIONS
Atogepant: Preventive treatment of migraine in adults

REFERENCES
1. Moreno-Ajona D, Pérez-Rodríguez A, Goadsby PJ. Gepants, calcitonin-gene-related peptide receptor antagonists: what could be their role in migraine treatment? Curr Opin Neurol. 2020;33(3):309-315.
2. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache. 2019;59(1):1-18.
3. Ashina M. Migraine. N Engl J Med 2020;383:1866-76.
4. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. 2024 Apr;64(4):333-341.

Creation Date: 08/2020
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD)
TOLVAPTAN (JYNARQUE)

Generic	Brand	HICL	GPID/NDC	Exception/Other
TOLVAPTAN	JYNARQUE PACK		39957, 39958, 39956, 48066, 48068	
TOLVAPTAN	JYNARQUE		59148-0082-13, 59148-0083-13	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all drug specific criteria as follows:

A. JYNARQUE: Must meet all the following criteria:
   1. Prescribed by a nephrologist
   2. Patient has diagnosis of autosomal dominant polycystic kidney disease (ADPKD) confirmed by baseline CT scan or MRI of the kidneys (typical is defined as bilateral/diffuse cyst distribution)
   3. Patient is at high risk of disease progression defined by Mayo ADPKD Classification as "Typical (Class 1) ADPKD" and classified as either 1C, 1D, or 1E
   4. Patient is in one of the following three groups:
      a. Age 18 to 50 years; AND estimated glomerular filtration rate (eGFR) is at least 60 mL/min/1.73m2 AND total kidney volume (TKV) is at least 750 mL
      b. Age 18 to 55 years; AND eGFR is at least 25 to 65 mL/min/1.73m2
      c. Age 56 to 65 years; AND eGFR is at least 25 to 44 mL/min/1.73m2; AND eGFR decline is greater than 2 mL/min/1.73m2 per year

If initial criteria are met, approve x1 year (monitoring for labs is recommended monthly for 18 months).
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet both criteria below:
1. Prescribed by a nephrologist.
2. Prescriber attests to evidence of disease improvement, such as improved eGFR, rate of growth in TKV, and ADPKD Impact Scale.

If renewal criteria are met, approve x1 year (monthly lab monitoring recommended for first 18 months of therapy, and every 3 months thereafter.).
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions:
1. Diagnosis/ICD-10 codes associated with this request: _____
2. Current estimated glomerular filtration rate (eGFR, mL/min/1.73 m2): _____
3. Date of eGFR lab: _____

Renewal Review Questions:
1. Does the prescriber attest to evidence of disease improvement since start of Jynarque therapy, such as improved eGFR, rate of growth in TKV, and ADPKD impact scale?

RATIONALE
KP Regional and National ADPKD treatment guidance
Samsca for hyponatremia must be started in the hospital due to risk of rapid sodium correction and osmotic demyelination [Black Box Warning].

FDA APPROVED INDICATIONS
ADPKD
Hyponatremia

REFERENCES
..\Chebib A Practical Guide for Treatment of ADPKD with Tolvaptan.pdf
Regional ADPKD Clinic for Tolvaptan.ppt
Tolvaptan for Autosomal Dominant Polycystic Kidney Disease.docx

Samsca [package insert]. Tokyo, Japan; Otsuka Pharmaceutical Co., Ltd. 2018.

Creation date: 3/2019
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 5/2021

AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD)
TOLVAPTAN (SAMSCA)

Generic	Brand	HICL	GPID/NDC	Exception/Other
TOLVAPTAN	SAMSCA 15MG TABLETS, SAMSCA 30MG TABLETS		59148-0020-50, 59148-0021-50	Off Label -Ascites, Heart Failure FDA Approved - ADPKD, Hyponatremia

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all drug specific criteria as follows:

A. SAMSCA: Must meet all the following criteria:
   1. Prescribed by a nephrologist
   2. Samsca started or restarted in the hospital for hyponatremia

If initial criteria are met, approve for a total duration of 30 days, max 2 tablets/day.
If initial criteria are not met, do not approve.

RATIONALE

KP Regional and National ADPKD treatment guidance
Samsca for hyponatremia must be started in the hospital due to risk of rapid sodium correction and osmotic demyelination [Black Box Warning].

FDA APPROVED INDICATIONS

ADPKD
Hyponatremia

REFERENCES

..\Chebib A Practical Guide for Treatment of ADPKD with Tolvaptan.pdf
Regional ADPKD Clinic for Tolvaptan.ppt
Tolvaptan for Autosomal Dominant Polycystic Kidney Disease.docx

Samsca [package insert]. Tokyo, Japan; Otsuka Pharmaceutical Co., Ltd. 2018.

Creation date: 3/2019
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 5/2021

AVAPRITINIB (AYVAKIT)

Generic	Brand	HICL	GCN	Exception/Other
AVAPRITINIB	AYVAKIT	46291		Nonformulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA
1. Patient is new to KPCO within the past 90 days and stable on therapy with Ayvakit

If met, approve indefinitely, max 1 tablet/day.
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must meet all of the following criteria:
1. Patient must be 18 years of age or older
2. Patient must have unresectable or metastatic GIST (gastrointestinal stromal tumor) with a PDGFRA D842V mutation
   OR advanced systemic mastocytosis (AdvSM), including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL)
   OR indolent systemic mastocytosis (ISM)

If initial criteria are met, approve indefinitely, max 1 tablet/day.
If initial criteria are not met, do not approve.

ePA Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: unresectable or metastatic GIST (gastrointestinal stromal tumor) with a PDGFRA D842V mutation; advanced systemic mastocytosis (AdvSM), including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL); indolent systemic mastocytosis (ISM)]

RATIONALE
Ensure appropriate use consistent with GIST study population in which avapritinib was evaluated, majority of whom had a PDGFRA D842V mutation. Ensure all FDA indications are included in the PA criteria.

FDA APPROVED INDICATIONS
Treatment of adults with unresectable or metastatic gastrointestinal stromal tumors that harbor a PDGFRA Exon 18 mutation, including PDGFRA D842V mutation.
Treatment of adults with advanced systemic mastocytosis (AdvSM), including aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm, and mast cell leukemia.
Treatment of adults with indolent systemic mastocytosis (ISM).

REFERENCES
1. Avapritinib [Package Insert], Cambridge, MA: Blueprint Medicines Corporation: 2023.

Creation Date: 10/2020
Effective Date: 10/2024
Reviewed Date: 09/2024

Revised Date: 09/2023

AZACITIDINE (ONUREG)

Generic	Brand	HICL	GPID	Exception/Other
AZACITIDINE	ONUREG	26361	48540, 48545	Nonformulary Specialty tier

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all of the following:
1. Patient must be age 18 or older
2. Must be prescribed by an oncology specialist
3. Must have diagnosis of acute myeloid leukemia (AML)
4. Must be in first complete response (CR or CRi, see below) after receiving initial intensive induction therapy (cytarabine + anthracycline) for AML
   - CR=complete response = Blasts <5%, ANC >1000, Platelets ≥100,000, patient currently independent of transfusions
   - CRi = complete response but with incomplete hematologic recovery = all CR criteria met (including current transfusion independence) but with persistent neutropenia (ANC <1000) and/or thrombocytopenia (<100,000)
5. Attained CR/CRi within prior 4 months
6. Must not be a hematopoietic stem cell transplant (HSCT, aka BMT) candidate
7. Does not have an allergy to mannitol or azacitidine

If initial criteria are met, approve at HICL x 1 year, maximum dose #14 tabs per 28 days.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Patient does not have disease relapse of AML (>15% blasts on bone marrow or in blood)
2. Patient has not undergone hematopoietic stem cell transplant (HSCT, aka BMT)

If renewal criteria are met, approve at HICL level x 1 year, maximum dose #14 tabs per 28 days.
If renewal criteria are not met, do not approve.

ePA Questions for Provider Outreach
Initial Review Questions
1. Has the patient achieved complete response (CR or CRi) after initial intensive induction therapy (cytarabine + anthracycline)?
2. Date of complete response (MMDDYY):
3. Current labs:
   a. Labs: Blasts (%):
   b. Blast Lab Date (MMDDYY):
   c. Labs: ANC:
   d. ANC Lab Date (MMDDYY):
   e. Labs: Platelets:
   f. Platelet Lab Date (MMDDYY):
4. Is the patient currently independent of transfusions?
5. Is the patient a candidate for hematopoietic stem cell transplant (HSCT, aka BMT)?
6. Does the patient have an allergy to mannitol or azacitidine?

Renewal Review Questions
1. Does the patient have disease relapse of AML?
2. Has the patient undergone hematopoietic stem cell transplant since starting azacitidine?

RATIONALE
To promote evidence-based, safe use of oral azacitidine in concordance with FDA approval and NCCN guideline recommendations.

FDA APPROVED INDICATIONS
Continued treatment of AML for adults who achieved first CR or CRi following intensive induction chemotherapy and are not able to complete intensive curative therapy.

REFERENCES
1. NCCN Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia v.2.2025. www.nccn.org
2. Onureg Prescribing Information. Summit, NJ. Celgene Corporation. 10/2022
3. NCCN Clinical Practice Guidelines in Oncology. T-Cell Lymphomas v.1.2025. www.nccn.org

Creation Date: 3/2021
Effective Date: 4/2025
Reviewed Date: 3/2025
Revised Date: 3/2024

BACLOFEN ORAL GRANULES (LYVISPAH) - AGE RESTRICTION CRITERIA

Generic	Brand	HICL	GPID	Exception/Other
BACLOFEN ORAL GRANULES	LYVISPAH	01949	51639, 51652, 51638	Formulary

GUIDELINES FOR COVERAGE

INITIAL AND RENEWAL CRITERIA: ONE of the following criteria must be met:
1. Patient is 10 years old or younger.
2. Patient is using an alternative administration route, such as a gastrostomy tube.
3. Dose cannot be obtained by using half, whole, or combination of the baclofen tablets.
4. Patient cannot swallow tablets whole, halved, or crushed (with or without mixing in applesauce)

If any criterion is met, approve x1 year at GPID.
If no criteria are met, do not approve. May suggest using tablet strengths that can be halved or used in combination, or crushing baclofen tablets before administration and taking with or without applesauce.

ePA Questions
1. Is the patient using an alternative administration route, such as a gastrostomy tube? If yes, must attach applicable chart notes.
2. Is the patient unable to swallow tablets whole, halved, or crushed (with or without mixing in applesauce)? If yes, must attach applicable chart notes.

RATIONALE
Per Health Plan.

General Clinical Criteria for solutions/suspension
1. Age is less than or equal to 10 years old
2. Presence of gastrostomy
3. Dose does not allow use of halved, whole or combo of tablet
4. Dose does not use whole capsule (cannot “cut” capsules in half)
5. Clinical condition where unable to swallow crushed/opened tablets/capsules (i.e., esophageal stricture)

FDA APPROVAL
1. Treatment of spasticity resulting from multiple sclerosis particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity; may also be of some value in patients with spinal cord injuries and other spinal cord diseases

Creation Date: 07/2024
Effective Date: 08/2024
Reviewed Date:
Revised Date:

BACLOFEN 25 MG/ 5 ML SUSPENSION - AGE RESTRICTION CRITERIA

Generic	Brand	HICL	GPID	Exception/Other
BACLOFEN SUSPENSION 25 MG/ 5 ML	FLEQSUVY	01949	51885	Formulary (generic)

GUIDELINES FOR COVERAGE

INITIAL AND RENEWAL CRITERIA: ONE of the following criteria must be met:
1. Patient is 10 years old or younger.
2. Patient is using an alternative administration route, such as a gastrostomy tube.
3. Dose cannot be obtained by using half, whole, or combination of the baclofen tablets.
4. Patient cannot swallow tablets whole, halved, or crushed (with or without mixing in applesauce)

If any criterion is met, approve x1 year at GPID.
If no criteria are met, do not approve. May suggest using tablet strengths that can be halved or used in combination, or crushing baclofen tablets before administration and taking with or without applesauce.

ePA Questions
1. Is the patient using an alternative administration route, such as a gastrostomy tube? If yes, must attach applicable chart notes.
2. Is the patient unable to swallow tablets whole, halved, or crushed (with or without mixing in applesauce)? If yes, must attach applicable chart notes.

RATIONALE
Per Health Plan.

General Clinical Criteria for solutions/suspension
1. Age is less than or equal to 10 years old
2. Presence of gastrostomy
3. Dose does not allow use of halved, whole or combo of tablet
4. Dose does not use whole capsule (cannot “cut” capsules in half)
5. Clinical condition where unable to swallow crushed/opened tablets/capsules (i.e., esophageal stricture)

FDA APPROVAL
Treatment of spasticity resulting from multiple sclerosis particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity; may also be of some value in patients with spinal cord injuries and other spinal cord diseases

Creation Date: 07/2024
Effective Date: 08/2024
Reviewed Date:
Revised Date:

BECAPLERMIN

Generic	Brand	HICL	GPID	Exception/Other
BECAPLERMIN	REGRANEX	17028		Nonformulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA
Must meet either criteria 1, or 2-4 below:
1. Prescription is from a hospital discharge per the member, pharmacy or prescriber
   OR all the following:
2. Patient has a diagnosis of diabetes mellitus with lower extremity diabetic neuropathic ulcer
3. Prescription is written by a vascular surgeon, podiatrist or endocrinologist
4. Patient does not have a diagnosis of a neoplasm (i.e., cancer), necrotic tissue, infection or osteomyelitis at site of application

If initial criteria, either 1, or 2-4 are met, then approve for 3 months at HICL, maximum two (2) tubes per month.
If initial criteria are not met, then do not approve.

RENEWAL CRITERIA
1. Patient's wound size has decreased by at least a 30% since starting becaplermin

If renewal criteria are met, then approve at HICL for a period of time necessary to complete a 20 week course, including previous approvals, maximum two (2) tubes per month.
If renewal criteria are not met, then do not approve.

ePA Questions:
Initial Review Questions
1. Is the prescription order for Regranex (becaplermin) from a hospital discharge?
2. Does the patient have a diagnosis of diabetes mellitus with lower extremity diabetic neuropathic ulcer?
3. Does the patient have a neoplasm, necrotic tissue, infection or osteomyelitis at site of application?

Renewal Review Questions
1. Has the treated wound size decreased by at least 30% since starting becaplermin (Regranex)? If yes, must attach applicable chart notes with supportive documentation.

RATIONALE
To ensure use consistent with FDA indication of the treatment of diabetic ulcers.

FDA APPROVED INDICATIONS
Becaplermin is indicated for treatment of lower-extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply. To be used as an adjunct to, and not a substitute for, good ulcer care practices, including initial sharp debridement, pressure relief, and infection control.

REFERENCES
1. Regranex. MedImpact P&T Monograph, February 1999.
2. Regranex Package Insert. McNeil Pharmaceutical, Raritan, New Jersey 08869.
3. MICROMEDEX® Healthcare Series Vol. 108.

Creation date: 11/2016
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2024

BEMPEDOIC ACID (NEXLETOL)

Generic	Brand	HICL	GPID	Exception/Other
BEMPEDOIC ACID	NEXLETOL	46382	47755	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following
1. Diagnosis of heterozygous familial hypercholesterolemia (HeFH) and/or atherosclerotic cardiovascular disease (ASCVD)
2. Current use of, or documented intolerance/contraindication to maximally tolerated statin, ezetimibe, and PCSK9 inhibitor, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception inhibitor
3. Must have a current LDL level drawn within the last 90 days of greater than or equal to one of the following:
    a. 55 mg/dL for ASCVD at very high risk defined as multiple ASCVD events^^, or 1 ASCVD event and 2 or more high risk conditions (age ≥ 65 years, familial hypercholesterolemia, diabetes, HTN, eGFR 15-59, current smoking)
    b. 70 mg/dL for ASCVD not at very high risk
    c. 100 mg/dL for HeFH/HoFH

If initial criteria are met, approve at HICL x 6 months.
If criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following:
1. Current LDL was reduced by at least 10% from baseline after starting Nexletol

If met, approve at HICL indefinitely.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease (ASCVD) with a clinical event (must list the clinical event in Provider Comment section below or attach applicable chart notes.]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (rosuvastatin tablets, atorvastatin tablets, lovastatin tablets, simvastatin tablets, pravastatin tablets; ezetimibe tablets; PCSK9 inhibitor) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
4. Current LDL:
5. Date of LDL lab (MMDDYY):

Renewal Review Questions
1. Current LDL:
2. Date of LDL lab (MMDDYY):

DEFINITIONS:
ASCVD includes acute coronary syndromes (ACS), coronary artery disease (CAD), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)

Statin intolerance is defined as inability to tolerate at least 2 statins, with at least one started at lowest starting daily dose

RATIONALE:
The current American Heart Association/American College of Cardiology cholesterol guideline, as well at the KP National Cholesterol and Cardiac Risk Guideline, recommend medications with established efficacy in reducing the risk of cardiovascular events first-line in the treatment of hyperlipidemia and atherosclerotic cardiovascular disease. Specifically, these agents are statins, ezetimibe, and the PCSK9 inhibitors, the first 2 or which are on formulary. Bempedoic acid only produces a moderate reduction in LDL, much less than statins and PCSK9 inhibitors and on par with ezetimibe. This is our rationale for this prior authorization criteria which will allow its use only after using these alternative agents which are recommended ahead of bempedoic acid in the current AHA/ACC cholesterol guidelines. Bempedoic acid's safety profile is comparable to these other agents, as all are well-tolerated and carry low risk of serious adverse reactions.

FDA APPROVED INDICATIONS
To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with: o established cardiovascular disease (CVD), or o a high risk for a CVD event but without established CVD
Adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with heterozygous familial hypercholesterolemia or atherosclerotic cardiovascular disease, who require additional lowering of LDL-C

REFERENCES
Per Health Plan

Creation date: 10/14/2020
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

BEMPEDOIC ACID (NEXLIZET)

Generic	Brand	HICL	GPID	Exception/Other
BEMPEDOIC ACID/EZETIMIBE	NEXLIZET	46386	47765	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following

1. Diagnosis of heterozygous familial hypercholesterolemia (HeFH) and/or atherosclerotic cardiosvascular disease (ASCVD)
2. Current use of, or documented intolerance/contraindication to maximally tolerated statin, ezetimibe, and PCSK9 inhibitor, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception inhibitor
3. Must have a current LDL level drawn within the last 90 days of greater than or equal to one of the following:
    a. 55 mg/dL for ASCVD at very high risk defined as multiple ASCVD events^^, or 1 ASCVD event and 2 or more high risk conditions (age ≥ 65 years, familial hypercholesterolemia, diabetes, HTN, eGFR 15-59, current smoking)
    b. 70 mg/dL for ASCVD not at very high risk
    c. 100 mg/dL for HeFH/HoFH

If initial criteria are met, approve at HICL x 6 months.
If criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following:

1. Current LDL was reduced by at least 10% from baseline after starting Nexlizet

If met, approve at HICL indefinitely.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease (ASCVD) with a clinical event (must list the clinical event in Provider Comment section below or attach applicable chart notes.]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (rosuvastatin tablets, atorvastatin tablets, lovastatin tablets, simvastatin tablets, pravastatin tablets; ezetimibe tablets; PCSK9 inhibitor) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
4. Current LDL:
5. Date of LDL lab (MMDDYY):

Renewal Review Questions
1. Current LDL:
2. Date of LDL lab (MMDDYY):

DEFINITIONS:
ASCVD includes acute coronary syndromes (ACS), coronary artery disease (CAD), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)

Statin intolerance is defined as inability to tolerate at least 2 statins, with at least one started at lowest starting daily dose

RATIONALE:
The current American Heart Association/American College of Cardiology cholesterol guideline, as well at the KP National Cholesterol and Cardiac Risk Guideline, recommend medications with established efficacy in reducing the risk of cardiovascular events first-line in the treatment of hyperlipidemia and atherosclerotic cardiovascular disease. Specifically, these agents are statins, ezetimibe, and the PCSK9 inhibitors, the first 2 or which are on formulary. Bempedoic acid only produces a moderate reduction in LDL, much less than statins and PCSK9 inhibitors and on par with ezetimibe. This is our rationale for this prior authorization criteria which will allow its use only after using these alternative agents which are recommended ahead of bempedoic acid in the current AHA/ACC cholesterol guidelines. Bempedoic acid's safety profile is comparable to these other agents, as all are well-tolerated and carry low risk of serious adverse reactions.

FDA APPROVED INDICATIONS
To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with: o established cardiovascular disease (CVD), or o a high risk for a CVD event but without established CVD
Adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with heterozygous familial hypercholesterolemia or atherosclerotic cardiovascular disease, who require additional lowering of LDL-C

REFERENCES
Per Health Plan

Creation date: 10/14/2020
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

BENRALIZUMAB (FASENRA)

Generic	Brand	HICL	GPID	Other
BENRALIZUMAB	FASENRA AUTOINJ 30 MG/1 ML	44635	47019	Formulary
BENRALIZUMAB	FASENRA PREFILLED SYRINGES	44635	44088, 55559	Excluded from pharmacy benefit*

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA
1. Patient is new to KPCO within the past 90 days and noted as stable on therapy with Fasenra or Nucala (transitioning to KPCO preferred product Fasenra) for the treatment of asthma or EGPA
2. Medication is prescribed by an Allergist, Pulmonologist, or Rheumatologist
3. Medication is not being used in combination with another biologic for the same indication

If criteria are met, approve autoinjector indefinitely at GPID, max 1 per 28 days [MDD: 0.04].
If criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following diagnoses and meet the diagnosis-specific criteria as follows:

A. EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA, i.e. CHURG-STRAUSS SYNDROME)
B. MODERATE-TO-SEVERE PERSISTENT ASTHMA
C. HEMATOLOGIC HYPEREOSINOPHILIC SYNDROMES

A. DIAGNOSIS OF EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA, i.e. CHURG-STRAUSS SYNDROME): Must meet all the following:
   1. Must be prescribed by an Allergist, Pulmonologist, or Rheumatologist
   2. Medication is not being used in combination with another biologic for the same indication.

If initial criteria are met, approve autoinjector indefinitely at GPID, max 1 per 28 days [MDD: 0.04].
If initial criteria are not met, do not approve.

B. DIAGNOSIS OF MODERATE-TO-SEVERE PERSISTENT ASTHMA: Must meet all the following:
   1. Must be prescribed by an Allergist or Pulmonologist.
   2. Uncontrolled asthma as evidenced by ANY one of the following:
      - Two or more asthma exacerbations requiring systemic corticosteroids (3 or more days each) in the past 12 months
      - one asthma-related hospitalization in the past 12 months
      - Asthma Control Test (ACT) consistently less than 20
   3. Adherent (more than 75% proportion of days covered) to optimized drug therapy (triple drug therapy with high-dose ICS-LABA plus tiotropium (Spiriva Respimat)) for the previous 6 months, OR has contraindications or intolerance to ICS/LABA/tiotropium, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

4. Medication is not being used in combination with another biologic for the same indication.

If initial criteria are met, approve autoinjector indefinitely at GPID, max 1 per 28 days [MDD: 0.04].
If initial criteria are not met, do not approve.

C. DIAGNOSIS OF HEMATOLOGIC HYPEREOSINOPHILIC SYNDROMES: Must meet all the following:
   1. Must be prescribed by a hematologist.
   2. Medication is not being used in combination with another biologic for the same indication.
   3. Absolute eosinophil count of greater than 1.5 cells/µL on 2 occasions more than 1 month apart or tissue showing 20% involvement on bone marrow or other tissue infiltration.
   4. Documented end organ dysfunction caused by this syndrome.
   5. FIP1L1-PDGFRA mut negative.
   6. Patient has been diagnosed for at least 6 months.
   7. Patient has had disease relapse after at least 2 previous trials of systemic corticosteroids in conjunction with hydroxyurea, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, then approve autoinjector at GPID x8 months.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following criteria:
1. Patient previously authorized for coverage of Fasenra for the treatment of asthma.

If met, approve autoinjector indefinitely at GPID, max 1 per 28 days [MDD: 0.04].
If not met, do not approve. [Fasenra for the treatment of hematologic hyper-eosinophilic syndromes is not designed as an open-ended intervention.]

ePA Questions
1. Is the patient using another biologic for the same indication?
2. Is the patient stable on therapy with the requested medication?
3. For patients noted stable on therapy, start date of therapy (MMDDYY):
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Eosinophilic Granulomatosis with Polyangiitis (EGPA, i.e. Churg-Strauss Syndrome); Asthma (Moderate/Severe); Hematologic Hypereosinophilic Syndromes]

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   Moderate/Severe Asthma
   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   2. Is there reasoning why alternatives (triple drug therapy with high-dose ICS-LABA plus tiotropium (Spiriva Respimat)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
   3. Has the patient experienced any of the following (check any/all boxes that apply):

a. Two or more asthma exacerbations requiring systemic corticosteroids (at least 3 days each) in the past 12 months
b. one asthma-related hospitalization in the past 12 months
c. Asthma Control Test (ACT) consistently less than 20

Hematologic Hypereosinophilic Syndromes

1. Has the patient had an absolute eosinophil count of greater than 1.5 cells/μL on 2 occasions more than 1 month apart or tissue showing 20% involvement on bone marrow or other tissue infiltration? If yes, must attach applicable chart notes with supporting documentation.
2. Does the patient have end organ dysfunction caused by this syndrome? If yes, must attach applicable chart notes with supporting documentation.
3. Does the patient have FIP1L1-PDGFRA mutation?
4. Date of diagnosis for this patient (MMDDYY):
5. Has the patient had disease relapse after at least 2 previous trials of systemic corticosteroids in conjunction with hydroxyurea? If yes, must attach applicable chart notes with supporting documentation.

RATIONALE

Per Health Plan and current treatment guidelines.

Benralizumab has anti-eosinophilic activity that makes it a reasonable choice for EGPA in situations where the physician deems it the best choice for EGPA.

*Prefilled syringe forms are excluded from coverage under the prescription benefit as these forms are to be administered by a healthcare professional only. Only autoinjector forms are eligible for review and coverage under the prescription benefit.

FDA APPROVED INDICATIONS

Asthma (Moderate to Severe)

REFERENCES

Table 1: High-dose ICS and High-dose ICS plus LABA combinations for Age ≥12 years

fluticasone/salmeterol DPI (Advair Diskus) 500/50 mcg, 1 inh twice daily
fluticasone/salmeterol MDI (Advair HFA) 230/21 mcg, 2 puffs twice daily
mometasone/formoterol MDI (Dulera) 200/5 mcg, 2 puffs twice daily
ciclesonide MDI (Alvesco) 160 mcg, 2 puffs twice daily
fluticasone MDI (Flovent HFA) 220 mcg, 2 puffs twice daily
Budesonide DPI (Pulmicort Flexhaler) 180 mcg, 4 inh twice daily
Mometasone MDI (Asmanex HFA) 200 mcg, 2 puffs twice daily
Mometasone DPI (Asmanex Twisthaler) 220 mcg, 2 inh twice daily

Creation Date: 09/2021
Effective Date: 06/2025
Revised Date: 01/2025
Reviewed Date: 05/2025

BEXAGLIFLOZIN (BRENZAVVY)

Generic	Brand	HICL	GPID	Comments
BEXAGLIFLOZIN	BRENZAVVY	48644		NF 4th Preferred

GUIDELINES FOR COVERAGE
Must be used for one of the following indications and meet all related criteria as follows:

A. Adults 25 years of age or older with DM2
B. Pediatrics/Young Adults between 10 and 25 years of age with DM2

A. To treat adults 25 years of age or older with type 2 diabetes: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is above, but within 2% of their designated A1c goal
   2. Patient has an eGFR of at least 20 ml/min
   3. Patient has contraindications to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. maximum dose metformin IR and subsequently metformin ER
      b. empagliflozin (Jardiance)
      c. maximum dose sulfonylurea, maximum dose pioglitazone, and all possible combinations thereof unless the patient has one of the following:
         i. h/o bariatric surgery
         ii. BMI ≥ 35 (≥ 30 for Asian American/Pacific Islanders)
         iii. ≥ 5% increase in body weight after 6 months of starting diabetes medications associated with weight gain (i.e. sulfonylurea, insulin, pioglitazone)
         iv. patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day

If all criteria met, approve at HICL x6 months, max 1 tablet per day.
If criteria are not met, do not approve.

B. To treat type 2 diabetes in young adult/pediatric patients between 10 and 25 years of age: Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Patient has contraindications to, is currently using, or has failed maximum doses of metformin IR and subsequently metformin ER
   2. Patient has an eGFR of at least 20 ml/min and has tried and failed, or has an intolerance or contraindication to empagliflozin (Jardiance)
   3. Patient has contraindications to, is currently using, or has failed maximum dose pioglitazone unless the patient has one of the following:

i. h/o bariatric surgery
ii. BMI ≥ 95%ile for age and sex
iii. ≥ 5% increase in body weight after 6 months of starting these medications
iv. patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day

If all criteria met, approve at HICL x6 months, max 1 tablet per day.
If criteria are not met, do not approve.

RENEWAL CRITERIA

1. HgbA1c is either at goal or has decreased by at least 0.5%.

If renewal criteria are met, approve indefinitely at HICL, max 1 tablet per day.
If renewal criteria are not met, do not approve.

RATIONALE

- KP National Diabetes Guidelines recommend using SGLT-2i for people with type 2 diabetes with clinical ASCVD who are already taking metformin to reduce the risk of: (1) cardiovascular events (myocardial infarction or stroke) or cardiovascular death, (2) progression of renal disease and/or (3) death from renal causes, and/or (4) heart failure hospitalizations. The American College of Cardiology (ACC) 2020 Expert Consensus Decision Pathway on Novel Therapies for Cardiovascular Risk Reduction in Patients with Type 2 Diabetes, which is also endorsed by the American Diabetes Association (ADA), recommends SGLT-2i as a first-line treatment in patients with type 2 diabetes and one or more of the following: ASCVD, HFrEF, HFpEF (empagliflozin only), diabetic kidney disease (DKD), or at high risk for ASCVD.
- Preferred order of agents:
  1) Empagliflozin (Jardiance), formulary without PA, is the preferred agent for ASCVD, CKD, and HF due to strength of clinical trial data, range of approved indications, and cost (1/2 tab regimen)
  2) Canagliflozin (Invokana), non-formulary with PA, is the 2nd preferred option for ASCVD, CKD and DM2 patients without compelling indications. due to broad range of indications and cost (1/2 tab regimen).
  3) Dapagliflozin (Farxiga), non-formulary with PA, is the 2nd preferred option for HF, and the 3rd preferred option for ASCVD, CKD and DM2 patients without compelling indications due to broad range of indications but at high cost.
  4) Ertugliflozin (Steglatro), non-formulary with PA, is least preferred due to high cost, paucity of positive clinical trial data, and lack of additional FDA-approved indications. Specifically, ertugliflozin has been studied in patients with type 2 diabetes and ASCVD and did not improve cardiovascular outcomes while all three other SGLT-2i have demonstrated such benefits in this population.
  5) Bexagliflozin (Brenzavvy): non-formulary with PA, is least preferred due to high cost and lack of additional FDA-approved indications.
  6) Sotagliflozin (Inpefa): non-formulary with PA, is 3rd preferred for HF given shorter history of postmarketing safety data compared to other SGLT2i's approved for HF as well as the need to titrate sotagliflozin dose for when others are fixed-dose regimens. Sotagliflozin (Inpefa) is least preferred for glycemic control due to lack of clinical trial data and FDA-approved indication as well as its high cost.
- Jardiance (empagliflozin) is the preferred sodium glucose co-transporter 2 inhibitor (SGLT-2i) at Kaiser Permanente Colorado (KPCO) and can be used effectively and safely with a GFR down to

20 mL/min. In addition, the dose of 12.5 mg (1/2 of 25mg tablet) is an effective dose for all patients regardless of GFR.

- Based on the available evidence, various organizations endorse SGLT-2is use down to lower GFR levels than indicated in product labels:
  - American College of Cardiology Expert Consensus now recommends empagliflozin in GFR ≥ 20 mL/min (2021).
  - National Kidney Foundation recommends SGLT-2is in GFR ≥ 20 mL/min as long as there are no contraindications (2023).
  - American Diabetes Association recognizes SGLT-2is benefits in patients with GFR ≥ 20 mL/min (2023).

FDA APPROVED INDICATIONS for SGLT2 Inhibitors

Empagliflozin (Jardiance)

1. Improve glycemic control in patients with DM2
2. Reduce the risk of CV death in pts with DM2 + CVD
3. Reduce risk of CVD death and HF hospitalizations in pts with HF
4. Reduce risk of sustained eGFR decline, ESRD, CV death and hospitalizations in adults with CKD at risk of progression

Canagliflozin (Invokana)

1. Improve glycemic control in patients with DM2
2. Reduce risk of MACE in pts with DM2 + CVD
3. Reduce the risk of ESRD, doubling of creatinine, CV death, or HF hospitalization in pts with DM2 + diabetic nephropathy

Dapagliflozin (Farxiga)

1. Improve glycemic control in patients with DM2
2. Reduce risk of HF hosp in pts with DM2 + CVD/multiple CV RFs
3. Reduce the risk of CV death and HF hosp in patients with HFrEF NYHA II-IV
4. Reduce risk of sustained eGFR decline, ESRD, CV death, and hospitalization for HF in adults with CKD at risk of progression

Ertugliflozin (Steglatro)

1. Improve glycemic control in patients with DM2

Bexagliflozin (Brenzavvy)

1. Improve glycemic control in patients with DM2

Sotagliflozin (Inpefa)

1. Reduce the risk of CV death and HF hosp in pts with heart failure
2. Reduce the risk of CV death and HF hosp in pts with DM2 + CKD + CV RF(s)

REFERENCES

Medication use in Pediatric/Young Adults:

1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012

3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation date: 01/2024
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

BIMEKIZUMAB (BIMZELX)

Generic	Brand	HICL	GPID	SIZE	Exception/Other
BIMEKIZUMAB	BIMZELX SYRINGE	47629	51344	1	Non-formulary
BIMEKIZUMAB	BIMZELX AUTO INJCT	47629	54888	1	Non-formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on therapy.
2. Patient has a diagnosis of psoriasis, ankylosing spondylitis (AS), axial spondylarthritis, nonradiographic (nr-axSpA), psoriatic arthritis (PSA), hidradenitis suppurativa (HS).
3. Medication is prescribed by a CPMG, affiliated dermatologist, or affiliated rheumatologist.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.

If met, approve indefinitely at HICL, max 2 pens per 56 days [MDD 0.04].
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must meet all the following:

A. Psoriasis
B. Psoriatic Arthritis
C. Ankylosing Spondylitis, Nonradiographic Axial Spondyloarthritis
D. Hidradenitis Suppurativa

A. Psoriasis: All the following must be met:
1. Patient has a diagnosis of moderate to severe psoriasis.
2. Medication is prescribed by a dermatologist.
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Patient has experienced an inadequate response, intolerance, or has a contraindication to a topical corticosteroid or topical calcineurin inhibitor (pimecrolimus, tacrolimus), or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate.
   b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one** or contraindication to at least **two** of the following therapies, or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate: Acitretin, Cyclosporine, Methotrexate, Apremilast (Otezla), Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy.

c. Patient has experienced an inadequate response (after at least 2 months), intolerance, or has a contraindication to all the following:
   - at least one TNF inhibitor (adalimumab (Amjevita) - preferred [F], infliximab (Inflectra) - preferred [F])
   - at least one IL-12/23 inhibitor (ustekinumab-kfce (Yesintek) - preferred [F, PA])
   - at least one IL-17 inhibitor (secukinumab (Cosentyx) - preferred [F, PA])
   - at least one IL-23 inhibitor (guselkumab (Tremfya) [NF, PA], Risankizumab (Skyrizi) [NF, PA])

If criteria are met, approve at HICL, max 2 mL per 28 days [MDD 0.08] x 16 weeks (loading dose), then 2 mL per 56 days [MDD 0.04] (maintenance dose) indefinitely.
If criteria are not met, do not approve.

B. Psoriatic Arthritis: All the following must be met:
1. Patient has a diagnosis of psoriatic arthritis.
2. Medication is being prescribed by a rheumatologist.
3. Patient is 18 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. at least 2 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, leflunomide, sulfasalazine
   b. at least 1 TNF inhibitor (e.g., adalimumab-atto (Amjevita)-preferred [F], infliximab-dyyb (Inflectra)-preferred [F])
   c. at least 1 IL-17 inhibitor (e.g. secukinumab (Cosentyx)-preferred [F, PA])
   d. at least 1 IL-12/23 inhibitor (ustekinumab-kfce (Yesintek)-preferred [F]) unless patient has documented high disease activity
   e. at least 1 IL-23 inhibitor (e.g. guselkumab (Tremfya [NF,PA])
   f. at least 1 JAK inhibitor (e.g. tofacitinib (Xeljanz)-preferred [F])

If criteria are met, approve at HICL, max #1 per 28 days indefinitely.
If criteria are not met, do not approve.

C. Ankylosing Spondylitis or Nonradiographic Axial Spondyloarthritis: All the following must be met:
1. Patient has a diagnosis of ankylosing spondylitis or nonradiographic axial spondyloarthritis.
2. Medication is being prescribed by a rheumatologist.
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
4. Patient has experienced an inadequate response, intolerance, or has a contraindication to, all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the

patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Methotrexate or sulfasalazine, or the patient has documented high disease activity in which these medications would not be suitable treatment
   b. at least 1 TNF inhibitor (e.g., adalimumab-atto (Amjevita)-preferred [F], infliximab-dyyb (Inflectra)-preferred [F])
   c. at least 1 IL-17 inhibitor (e.g. secukinumab (Cosentyx)-preferred [F, PA])
   d. at least 1 JAK inhibitor (e.g. tofacitinib (Xeljanz)-preferred [F])

If criteria are met, approve at HICL max #1 per 28 days indefinitely.
If criteria are not med, do not approve.

D. HIDRADENITIS SUPPURATIVA (HS): All the following must be met:
1. Patient has a diagnosis of moderate to severe HS (Hurley stage II-III).
2. Medication is prescribed by a dermatologist.
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
4. Patient with inadequate response or intolerance to at least 3 of the following [medication trials can be within the same drug category], or the patient is noted as Hurley Stage III, making these therapies inappropriate, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Oral antibiotic (8-week trial unless intolerance is documented)
   b. Topical antibiotic (ex: clindamycin)
   c. Oral retinoid (isotretinoin, acitretin)
   d. Intralesional steroid
   e. Hormonal agent (ex: metformin, spironolactone, oral contraceptive for women)
   f. Laser hair removal
   g. Infliximab (Inflectra, Remicade, or other biosimilar) infusion
5. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least 1 TNF inhibitor (ex: infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F])
6. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least 1 IL-17 inhibitor (ex: secukinumab (Cosentyx)-preferred [F, PA])

If criteria are met, approve at HICL, max 4 mL per 28 days [MDD 0.15] x 16 weeks (loading dose), then 2 mL per 28 days [MDD 0.08] (maintenance dose) indefinitely.
If criteria are not met, do not approve.

ePA Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Psoriasis; Psoriatic Arthritis; Ankylosing Spondylitis or Nonradiographic Axial Spondyloarthritis; Hidradenitis Suppurativa]
2. Is the patient stable on therapy with bimekizumab?
3. For patients noted stable on therapy, start date of therapy (MMDDYY):
4. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

QUESTIONS BASED ON DIAGNOSIS SELECTED

Psoriasis

1. Current BSA (%):
2. Date of BSA assessment (MMDDYY):
3. Has the patient failed other treatments for this indication? If yes, must list the medication(s), strength(s), date(s) of treatment(s), and reasoning for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (topical corticosteroids such as clobetasol; tacrolimus ointment; acitretin capsules (10 mg, 25 mg); cyclosporine capsules (25 mg, 100 mg); methotrexate tablets (2.5 mg) or injection (25 mg/mL); Otezla tablets; Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy; adalimumab-atto (Amjevita), etc.) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Psoriatic Arthritis

1. Has the patient failed other treatments for this indication? If yes, must list the medication(s), strength(s), date(s) of treatment(s), and reasoning for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate tablets (2.5 mg) or injection (25 mg/mL), leflunomide tablets, sulfasalazine tablets, adalimumab-atto (Amjevita), etc.) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Does the patient have documented high disease activity?

Ankylosing Spondylitis or Nonradiographic Axial Spondyloarthritis

1. Has the patient failed other treatments for this indication? If yes, must list the medication(s), strength(s), date(s) of treatment(s), and reasoning for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there a reasoning why alternatives (methotrexate tablets (2.5 mg) or injection (25 mg/mL), sulfasalazine tablets, adalimumab-atto (Amjevita), etc.) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Does the patient have documented high disease activity?

Hidradenitis Suppurativa

1. Does the patient have Hurley Stage II Hidradenitis Suppurativa?
2. Does the patient have Hurley Stage III Hidradenitis Suppurativa?
3. Has the patient failed other treatments for this indication? If yes, must list the medication(s), strength(s), date(s) of treatment(s), and reasoning for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there a reasoning why alternatives (oral antibiotics, topical clindamycin, oral isotretinoin, acitretin, intralesional steroids, laser hair removal, metformin, spironolactone, oral contraceptives (for females), adalimumab-atto (Amjevita), etc.) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Per Health Plan

REFERENCES

Bimekizumab (Bimzelx) 160 mg/1 mL Auto-Injector

"Stable on therapy," means patient is tolerating well, medication appears to be effective, and provider wishes to continue therapy.

Treatment	Relative Contraindications in Psoriasis
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses (ex: systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for psoriasis.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities, active malignancy, and hypersensitivity*
Acitretin	*Caution in women of child potential (cannot consider pregnancy up to 3 years after completion of treatment), pregnancy, lactation, severe hepatic or renal dysfunction, chronically abnormal elevated lipid values, and hypersensitivity*

FDA APPROVED INDICATIONS:

1. Treatment of moderate to severe plaque psoriasis in patients 18 years of age and older
2. Treatment of ankylosing spondylitis in patients 18 years of age and older
3. Treatment of nonradiographic axial spondylarthritis in patients 18 years of age and older
4. Treatment of psoriatic arthritis in patients 18 years of age and older

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

BIRCH TRITERPENES (FILSUVEZ)

Generic	Brand	HICL	GCN	Exception/Other
BIRCH TRITERPENES	FILSUVEZ	48746	53808	

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
5. Patient is age ≥ 6 months and new to KPCO within the past 90 days
6. Patient is currently receiving Filsuvez for the treatment of dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB) and medication is prescribed by a CPMG or affiliated dermatologist.
7. Medication is not being used in combination with Beremagene geperpavec (Vyjuvek) for the same indication.

If criteria are met, approve at GPID for 6 months max 702 grams per 30 days (max 1 tube daily) - [max qty: 702, DS: 30; MDD 23.4 gm].
If criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following diagnoses and meet the diagnosis-specific criteria below:

A. Dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB): All the following must be met:
   1. The patient is age ≥ 6 months and medication is prescribed by a CPMG or affiliated dermatologist.
   2. Medication is not being used in combination with Beremagene geperpavec (Vyjuvek) for the same indication.
   3. The patient's DEB or JEB wounds have not healed despite three months of standard wound care*. If wound pain is causing significant functional impairment, a two-month trial of standard wound care is adequate.
      **Standard wound care for DEB & JEB consists of draining blisters, wound dressings, amelioration of pain and itching, management and prevention of complications including infections, contractures, and pseudosyndactyly, as well as early detection and treatment of squamous cell carcinomas (SCC).*

If criteria are met, approve at GPID for 6 months max 702 grams per 30 days (max 1 tube daily) - [max qty: 702, DS: 30. MDD: 23.4 gm].
If initial criteria are not met, do not approve.

ESCALATION CRITERIA: Must meet all the following:
1. There is documentation by the treating dermatologist of medical necessity for a higher quantity.

If escalation criteria are met, approve at GPID for 6 months.
If escalation criteria are not met, do not approve escalation request, and continue approval quantity for initial criteria.

RENEWAL CRITERIA: Must meet all the following for 1 OR 2 below:
1. For wound(s) not previously treated with Filsuvez (new or untreated wounds):
   a. The patient meets the initial prior authorization criteria for the new or untreated wound(s)

If criteria are met, approve at GPID for 6 months max 702 grams per 30 days (max 1 tube per day) - [max qty: 702, DS: 30; MDD 23.4 gm].
If criteria are not met, do not approve.

2. For wound(s) previously treated with Filsuvez:
   a. The provider attests to, or there is documentation of, wound improvement with the initial course of treatment with Filsuvez.

If criteria are met, approve at GPID for 6 months max 702 grams per 30 days (max 1 tube per day) - [max qty: 702, DS: 30; MDD: 23.4 gm].
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient stable on therapy with the requested medication?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Dystrophic epidermolysis bullosa (DEB); Junctional epidermolysis bullosa (JEB); Other (must provide diagnosis in provider comment section)]
4. Is wound pain causing significant functional impairment?
5. Has the patient failed other treatments for this indication? If yes, must list the treatments, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
6. Will Filsuvez be used in combination with Beremagene geperpavec (Vyjuvek) for the same indication?

Renewal Review Questions
1. Is this request for a wound previously treated with Filsuvez?
2. If previously treated, has the patient's wound improved with the initial treatment course with Filsuvez?

RATIONALE
Birch triterpenes is the only FDA approved therapy for both dystrophic and junctional epidermolysis bullosa which are very rare skin conditions. Patients in the EASE trial were treated for 90 days with a primary outcome of wound closure at day 45. When the data from the EASE trial was assessed for each EB subtype, birch triterpenes was effective for recessive DEB and the clinical trial data did not show treatment benefit with birch triterpenes over placebo for dominant DEB and JEB.

Each tube of birch triterpenes topical gel is for one-time use only. Once the tube is opened, the product should be used immediately (can be used on multiple wounds), and any remaining product discarded.

A one-millimeter layer of birch triterpenes topical gel is applied to the clean wound surface or wound dressing. Birch triterpenes is typically applied every one to four days and applied until the wound was healed. Consider discontinuing therapy if no benefit is seen after 6 weeks.

The quantity limit of one tube per day is set based on the average amount used in the clinical trial but the monthly quantity will depend on the surface area being treated.

For further information, please refer to the Prescribing Information and/or Drug Monograph for Filsuvez.

FDA APPROVED INDICATIONS

Birch triterpenes (Filsuvez) topical gel was FDA approved in December 2023 for the treatment of dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB) in adult and pediatric patients six months of age and older. Birch triterpenes is the second agent to be FDA approved for wounds associated with DEB, it is the first and only agent approved for JEB.

References:
1. Kern JS, Sprecher E, Fernandez MF, et al; EASE investigators. Efficacy and safety of Oleogel-S10 (birch triterpenes) for epidermolysis bullosa: results from the phase III randomized double-blind phase of the EASE study. Br J Dermatol. 2023 Jan 23;188(1):12-21.
2. Filsuvez [Package Insert], Boston, MA: Amryt Pharma; 2024.
3. Heo YA. Birch Bark Extract: A Review in Epidermolysis Bullosa. Drugs. 2023 Sep;83(14):1309-1314.

Creation Date:10/2024
Effective Date: 12/2024
Reviewed Date: 11/2024
Revised Date: 11/2024

BLADDER PAIN SYNDROME (BPS)/INTERSTITIAL CYSTITIS (ICS): PENTOSAN POLYSULFATE SODIUM

Generic	Brand	HICL	GPID	Exception/Other
PENTOSAN POLYSULFATE SODIUM	ELMIRON	08734	41229	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: All the following criteria must be met:
1. The requesting provider is a CPMG Urologist or Uro-gynecologist or an affiliated network Urologist/Uro-Gynecologist with active referral, if needed
2. The patient has a diagnosis of interstitial cystitis (ICS)/ bladder pain syndrome (BPS)
3. Patient has had an eye exam with an Ophthalmologist within the past 365 days
4. Patient less than 65 years of age must have an intolerance to or past failure of a TCA, hydroxyzine, or cimetidine, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve indefinitely at GPID, max daily dose of 1 capsule (100 mg).
If initial criteria are not met, do not approve.

For Quantity Limit overrides: For all requests of pentosan doses over 100 mg/day after meeting Initial Criteria, patient must meet the following:
- The patient has tried pentosan 100 mg/day with some benefit, such as a decrease in pain, urgency and/or frequency

If met, approve requested quantity indefinitely.
If not met, do not approve.

Note: quantity limit of 100mg/day is based on a safety concern regarding an eye condition called maculopathy which can cause a decrease or change in vision and the risk is higher with higher doses.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (amitriptyline tablets, desipramine tablets, nortriptyline capsules; hydroxyzine hcl tablets; OTC cimetidine) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Has the patient had an eye exam with an Ophthalmologist within the past 365 days?

RATIONALE
Ensure appropriate criteria are used for requests of pentosan according to approved indication, dosing, national treatment guidelines and clinical studies.

FDA APPROVED INDICATIONS:
Relief of bladder pain or discomfort due to Interstitial Cystitis

HOW SUPPLIED:
Capsules - 100 mg

Creation date: 07/2020
Effective date: 10/2024
Reviewed date: 09/2024
Revised date: 09/2024

BRAND WHEN GENERIC IS AVAILABLE

Generic	Brand	HICL	GPID	Exception/Other
N/A	N/A	N/A	N/A	

GUIDELINES FOR USE OF BRANDS WHEN A GENERIC IS AVAILABLE (NON-AED)

Brand medications (non-AED) when a generic is available, when not excluded from benefit coverage, will be approved when ALL the following criteria are met, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. An authorized generic is not available
2. Patient has a documented allergic reaction to an inactive ingredient in the generic product (example: dye) not present in the brand name product and other generic equivalents to the brand are not available without the inactive ingredient which caused the allergic reaction
3. Patient has treatment failure, intolerance, or contraindication to at least three other formulary, therapeutic alternatives (Note: In cases where no other alternatives are available, only the generic equivalent needs to have been tried)
4. Patient meets requirements for coverage for generic equivalent, when/if applicable

If 1 through 4 are met, approve the brand indefinitely.
If criteria are not met, do not approve.

GUIDELINES FOR USE OF BRAND ANTIEPILEPTIC DRUGS WHEN A GENERIC IS AVAILABLE

Brand antiepileptic medications when a generic is available, when not excluded from benefit coverage, will be approved when two of the following criteria are met and one of those must be #7, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient is less than 18 years of age
2. Patient has a history of status epilepticus
3. Patient has a history of multiple (more than 1) seizures in one day
4. Patient has a history of a seizure in the past 30 days
5. Patient has a documented allergic reaction to an inactive ingredient in the generic product (example: dye) not present in the brand name product and other generic equivalents to the brand are not available without the inactive ingredient which caused the allergic reaction
6. Patient is currently pregnant
7. An authorized generic is not available

If 1, 2, 3, 4, or 5 AND 7 is met, approve the brand antiepileptic indefinitely.
If 6 AND 7 is met, approve the brand antiepileptic x 1 year.

If criteria are not met, do not approve.

RATIONALE

- Per KPCO Health Plan, Pharmacy Benefits Department
- Excerpted from the BWGA FAQ's Clinicians CO Final 11.15.19 and the BWGA FAQ's Member CO Final 11.18.19 documents created and approved by the KPCO Drug Use Management team
- KPNW BWGA guideline, 2020
- Brand to Generic Antiepileptic FAQ, 2018

Background from CO BWGA documents:

- The FDA requires generic drugs to have the same quality and performance as brand name drugs.
- Patients can expect the same quality, performance, safety, and side-effects with the generic as with the brand-name product. In many cases, the generic is even made by the same company ("authorized generics").
- The nonformulary exception process should not apply for brand medications when the equivalent generic medication is available (BWGA) because they contain the same active ingredients. The exception is in very RARE situations where patients have a documented allergy to a specific inactive ingredient in the equivalent generic medication.

Creation date: 07/2021
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 9/2023

BRODALUMAB (SILIQ)

Generic	Brand	HICL	GPID	SIZE	Exception/Other
BRODALUMAB	SILIQ	44102	43055	1.5	Non-formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is currently stable on therapy.
2. Patient has a diagnosis of psoriasis.
3. Medication is prescribed by a CPMG or affiliated dermatologist.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.

If met, approve at HICL indefinitely, max 2 syringes per 28 days [MDD 0.11].
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of moderate to severe psoriasis.
2. Medication is prescribed by a dermatology provider.
3. The patient is 18 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Patient has experienced an inadequate response, intolerance, or has a contraindication to a topical corticosteroid or topical calcineurin inhibitor (pimecrolimus, tacrolimus), or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate.
   b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least one or contraindication to at least two of the following therapies, or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate: Acitretin, Cyclosporine, Methotrexate, Apremilast (Otezla), Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
   c. Patient has experienced an inadequate response (after at least two months of therapy), intolerance, or has a contraindication to all the following:
      - At least one TNF inhibitor (adalimumab (Amjevita) - preferred [F], infliximab (Inflectra) - preferred [F] - unless the patient has failed an IL-17 inhibitor
      - At least one IL12-23 inhibitor (ustekinumab-kfce (Yesintek) - preferred [F, PA])
      - At least one IL-17 inhibitor (secukinumab (Cosentyx) - preferred [F])
      - At least one IL-23 inhibitor: guselkumab (Tremfya) [NF, PA], risankizumab-rzaa (Skyrizi) [NF, PA]

If criteria are met, approve at HICL, max 3 syringes per 28 days [MDD 0.16] x 1 month (loading dose), then max 2 syringes per 28 days [MDD 0.11] (maintenance dose) indefinitely.
If above criteria are not met, do not approve.

ESCALATION CRITERIA/QTY LIMIT OVERRIDES: Patient must meet New Member or Initial Criteria prior to review for Quantity Overrides. Escalation Criteria review only the quantities authorized upon PA approval.

1. Documentation by dermatology provider of the patient resuming therapy after a gap 3 months or longer in treatment (to reload).

If met, approve at HICL, max 3 syringes per 28 days [MDD 0.16] x 1 month (loading dose), then max 2 syringes per 28 days [MDD 0.11] (maintenance dose) indefinitely.
If not met, deny and offer max 2 syringes per 28 days [MDD 0.11].

ePA Questions

1. Is the patient stable on therapy with brodalumab?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (topical corticosteroids, tacrolimus ointment, acitretin capsules (10 mg, 25 mg), cyclosporine capsules (25 mg, 100 mg), methotrexate tablets (2.5 mg) or injection (25 mg/mL), Otezla tablets, Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy, adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
6. Current BSA (%):
7. Date of BSA assessment (MMDDYY):
8. Does the patient have disease affecting critical areas such as the genitals and/or face?

RATIONALE

Per Health Plan

FDA APPROVED INDICATIONS

1. Siliq: Treatment of moderate to severe plaque psoriasis in adults

REFERENCES

"Currently stable on medication," means patient is tolerating well, medication appears to be effective, and provider wishes to continue therapy.

Treatment	Relative Contraindications for Psoriasis
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses (ex: systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for psoriasis.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities, active malignancy, and hypersensitivity*

Acitretin	*Women of child potential (cannot consider pregnancy up to 3 years after completion of treatment), pregnancy, lactation, severe hepatic or renal dysfunction, chronically abnormal elevated lipid values, and hypersensitivity*

Creation Date: 11/2019
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

BUCCAL FILM DIAZEPAM (LIBERVANT)

Generic	Brand	HICL	GPID	Exception/Other
DIAZEPAM 5 MG BUCCAL FILM	LIBERVANT	01615	55633	Nonformulary
DIAZEPAM 7.5 MG BUCCAL FILM	LIBERVANT	01615	55635	Nonformulary
DIAZEPAM 10 MG BUCCAL FILM	LIBERVANT	01615	55636	Nonformulary
DIAZEPAM 12.5 MG BUCCAL FILM	LIBERVANT	01615	55637	Nonformulary
DIAZEPAM 15 MG BUCCAL FILM	LIBERVANT	01615	55638	Nonformulary

GUIDELINES FOR COVERAGE

Must meet all the following:

1. The requesting provider is a CPMG or affiliated network neurologist or epileptologist.
2. Patient is between 2 and 5 years of age.
3. Patient has a diagnosis of generalized and/or focal (partial) epilepsy and is on a stable regimen of antiseizure medicine.
4. Patient is experiencing seizure activity that necessitates acute treatment and is different from the patient's usual epilepsy pattern. At least one of the following diagnoses must be present:
    a. Acute repetitive seizures
    b. Intermittent seizure episodes
    c. Seizure clusters
    d. Prolonged convulsive seizures (at least 3 min or longer)
5. The patient has tried and failed, or has an intolerance or allergy to diazepam rectal gel, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at GPID indefinitely, max 2 cartons per 30 days [MDD: 0.14].
If criteria are not met, do not approve.

NOTE: Libervant should NOT be used in combination with Diastat rectal gel.

ePA Questions

1. Does the patient have a diagnosis of generalized and/or focal (partial) epilepsy?
2. Is the patient on a stable regimen of antiseizure medications?
3. Is the patient experiencing seizure activity that necessitates acute treatment and is different from the patient's usual epilepsy pattern?
4. Which of the following is the patient experiencing: [check boxes for all diagnoses: Acute repetitive seizures; Intermittent seizure episodes; Seizure clusters; Prolonged convulsive seizures (at least 3 min or longer)]
5. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
6. Is there reasoning why alternatives (diazepam rectal gel) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

The class of medicines used for the treatment of acute repetitive seizures or clusters has expanded in recent years. The first treatment to be FDA-approved was Diazepam rectal (Diastat®) in 2005 and is indicated for the management of select, refractory participants 2 years of age or older with epilepsy on stable regimens of antiepileptic drugs, who require intermittent use of diazepam to control episodes of increased seizure activity. Diazepam buccal film is the latest FDA approved medicine indicated for acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from usual seizure pattern in epilepsy participants between the ages of 2 and 5 years. Other treatment options FDA approved for this indication but with differing age guidelines include diazepam intranasal (Valtoco®) for patients 6 years of age or older and midazolam intranasal (Nayzilam®) for patients 12 years of age or older. All four agents carry the same contraindication of acute narrow-angle glaucoma. Clinical guidelines from both the American Epilepsy Society and Neurocritical Care Society recommend diazepam rectal and midazolam intranasal (off-label) for acute convulsive seizure management when parenteral benzodiazepines are not available. These guidelines were also published prior to the approval of midazolam and diazepam intranasal as well as the diazepam buccal film therapies and did not specifically identify rescue use and non-hospital settings. As of this writing, the Epilepsy Foundation of America is actively working to develop consensus on best practices for rescue therapies.

FDA APPROVED INDICATIONS

Libervant: Indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age.

REFERENCES

1. Libervant [package insert]. Warren, NJ: Aquestive Therapeutics, Inc.; 2024
2. Valtoco [package insert]. San Diego, CA: Neurelis, Inc.; 2023.
3. Nayzilam [package insert]. Smyrna, GA: UCB, Inc.; 2023.
4. Diastat [package insert]. Bridgewater, NJ: Bausch Health US LLC; 2023.
5. Gidal B, Klein P, Hirsch LJ. Seizure clusters, rescue treatments, seizure action plans: Unmet needs and emerging formulations. Epilepsy & Behavior 2020;112:1-10.

Creation Date: 07/2024
Effective Date: 08/2024
Reviewed Date:
Revised Date:

BUPRENORPHINE PATCH

Generic	Brand	HICL	GPID	Exception/Other
BUPRENORPHINE	BUTRANS PATCH	23438		Formulary (generic)

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

1. Patient is 18 years of age or older
2. Patient has a chronic pain diagnosis
3. Medication is not being used for treatment of opioid use disorder
4. Patch is being used x1 as part of a micro-dosing strategy to transition to sublingual buprenorphine; or the patient's daily opioid dose is 80 MME or less and the patient has one of the following:
   a) History of or active substance use disorder (including not limited to opioid use disorder, alcohol use disorder, amphetamine use disorder, cocaine use disorder, benzodiazepine use disorder)
   b) High risk of opioid misuse or abuse
   c) History of or active chronic pulmonary condition (untreated obstructive sleep apnea, COPD, chronic O2 requirement)
   d) Failed one of the following formulary alternatives or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      i) Morphine SR tablets, Fentanyl patches, methadone tablets

   If initial criteria are met as part of a micro-dosing strategy, approve x1 fill only. If initial criteria are met for any other use, approve indefinitely at HICL.
   If initial criteria are not met, do not approve.

ePA Questions for Provider Outreach

1. Diagnosis associated with this request: [check boxes for possible diagnoses listed in criteria: treatment of chronic pain; treatment of opioid use disorder]

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   Treatment Of Chronic Pain

   1. Is the patch being used one time only as part of a micro-dosing strategy to transition to sublingual buprenorphine?
   2. Patient's total daily opioid dose (MME):
   3. Does the patient have any of the following conditions (check any/all boxes that apply):
      a. History of or active substance use disorder (including not limited to opioid use disorder, alcohol use disorder, amphetamine use disorder, cocaine use disorder, benzodiazepine use disorder)
      b. High risk of opioid misuse or abuse
      c. History of or active chronic pulmonary condition (untreated obstructive sleep apnea, COPD, chronic O2 requirement)
   4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

5. Is there reasoning why alternatives (Morphine SR tablets, Fentanyl patches, methadone tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

FDA APPROVED INDICATIONS
Pain management: Management of pain severe enough to require around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Creation Date: 07/2023
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

CABOTEGRAVIR (VOCABRIA)

Generic	Brand	HICL	GPID	Exception/Other
CABOTEGRAVIR SODIUM	VOCABRIA	46411		Non-Formulary Oral cabotegravir is an option for starting Cabenuva treatment of HIV. It can also be used in instances where patients have missed a scheduled Cabenuva administration to restart therapy.

GUIDELINES FOR COVERAGE

INITIAL CRITERIA
Must meet all the following:
1. Patient must be 12 years of age or older
2. Must be prescribed by an Infectious Disease provider
3. Patient has HIV and the virus shows no evidence of resistance to integrase strand inhibitors (INSTIs - raltegravir, dolutegravir, elvitegravir, bictegravir, cabotegravir) or nonnucleoside reverse-transcriptase inhibitors (NNRTIs - efavirenz, delavirdine, nevirapine, rilpivirine)
4. Patient has no history of treatment failure (i.e., failure to consistently suppress viral load to undetectable levels) with previous HIV regimens
5. Current HIV viral suppression is documented by an HIV-1 RNA less than 50 copies per mL for at least the past 6 months
6. Patient has had no treatment interruptions lasting two weeks or more in the past 6 months

If initial criteria are met, approve at HICL x3 fills only x1 year.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA
Must meet the following:
1. Patient has not missed more than 2 scheduled administrations of cabotegravir/rilpivirine (Cabenuva) by 7 days or more in the past 12 months.

If met, approve at HICL x3 fills only x1 year.
If not met, do not approve.

ePA questions for Provider Outreach
INITIAL REVIEW QUESTIONS
1. Does the patient's virus show evidence of resistance to integrase strand inhibitors (INSTIs – raltegravir, dolutegravir, elvitegravir, bictegravir, cabotegravir) or nonnucleoside reverse-transcriptase inhibitors (NNRTIs – efavirenz, delavirdine, nevirapine, rilpivirine)?
2. Does the patient have history of treatment failure (i.e. failure to consistently suppress viral load to undetectable levels) with previous HIV regimens?
3. 2 most recent HIV-1 RNA Lab values (copies per mL):
    a. Lab 1:
    b. Lab 2:
4. Dates of HIV-1 RNA Lab values (MMDDYY):
    a. Date of Lab 1:
    b. Date of Lab 2:

5. How many treatment interruptions lasting two weeks or more has the patient had in the past 6 months?

RENEWAL REVIEW QUESTIONS

1. How many scheduled administrations of cabotegravir/rilpivirine (Cabenuva) has the patient missed by 7 days or more in the past 12 months?

RATIONALE

Per Health Plan.

FDA APPROVED INDICATIONS

HIV-1 infection:
Preexposure prophylaxis: Oral: As oral lead-in to assess tolerability of cabotegravir prior to administration of IM cabotegravir or as oral bridging therapy for missed cabotegravir injections.

Treatment: Oral: Short-term treatment of HIV-1 infection (in combination with rilpivirine) in adults and adolescents ≥12 years of age weighing ≥35 kg who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known or suspected resistance to cabotegravir or rilpivirine, as an oral lead-in to assess tolerability of cabotegravir prior to initiating IM cabotegravir and rilpivirine, or an oral bridging therapy for missed cabotegravir injections.

REFERENCES

NNRTI - nonnucleoside reverse transcriptase inhibitor
INSTI - integrase strand transfer inhibitor

Vocabria (cabotegravir) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; March 2022.

Creation Date: 07/2021
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2024

CANAGLIFLOZIN (INVOKANA)

Generic	Brand	HICL	GPID	Comments
CANAGLIFLOZIN	INVOKANA	40171		NF 1st Preferred – 0.5 tab of 300mg (150mg/day)

GUIDELINES FOR COVERAGE
Must be used for one of the following indications and meet all related criteria as follows:

E. Adults 25 years of age or older with DM2 and ASCVD
C. Adults 25 years of age or older with DM2 with Nephropathy
D. Adults 25 years of age or older with DM2 without ASCVD or diabetic nephropathy
E. Pediatrics/Young Adults between 10 and 25 years of age with DM2

A. To treat adults 25 years of age or older with type 2 diabetes and established atherosclerotic cardiovascular disease (ASCVD) [acute coronary syndromes (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)]: Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    1. Patient has contraindication or intolerance to, is currently using, or has failed maximum doses of metformin IR and/or metformin ER, or the patient's A1c is at goal and SGLT-2i is more appropriate for ASCVD, CKD and/or HF benefit
    2. Patient has an eGFR of at least 20 ml/min and has tried and failed, or has an intolerance or contraindication to empagliflozin (Jardiance)

If all criteria met, approve at HICL indefinitely, max 0.5 tablet per day.
If criteria are not met, do not approve.

B. To treat adults 25 years of age or older with type 2 diabetes with nephropathy: Must meet all the following:
    1. eGFR is at least 20 ml/min, and eGFR is less than 60 ml/min and/or urinary albumin-to-creatinine ratio greater than 300
    2. The patient has contraindication to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
        a. Maximum doses of metformin IR and/or metformin ER, or the patient’s A1c is at goal and SGLT-2i is more appropriate for ASCVD, CKD and/or HF benefit
        b. ACE-I or ARB
        c. empagliflozin (Jardiance)

If all criteria met, approve at HICL indefinitely, max 0.5 tablet per day.
If criteria are not met, do not approve.

C. To treat adults 25 years of age or older with type 2 diabetes without ASCVD or diabetic nephropathy: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is above, but within 2% of their designated A1c goal
   2. Patient has an eGFR of at least 20 ml/min
   3. Patient has contraindications to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. maximum dose metformin IR and subsequently metformin ER
      b. empagliflozin (Jardiance)
      c. maximum dose sulfonylurea, maximum dose pioglitazone, and all possible combinations thereof unless the patient has one of the following:
         i. h/o bariatric surgery
         ii. BMI ≥ 35 (≥ 30 for Asian American/Pacific Islanders)
         iii. ≥ 5% increase in body weight after 6 months of starting diabetes medications associated with weight gain (i.e. sulfonylurea, insulin, pioglitazone)
         iv. patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day

If all criteria met, approve at HICL x6 months, max 0.5 tablet per day.
If criteria are not met, do not approve.

D. To treat type 2 diabetes in young adult/pediatric patients between 10 and 25 years of age: Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Patient has contraindications to, is currently using, or has failed maximum doses of metformin IR and subsequently metformin ER
   2. Patient has an eGFR of at least 20 ml/min and has tried and failed, or has an intolerance or contraindication to empagliflozin (Jardiance)
   3. Patient has contraindications to, is currently using, or has failed maximum dose pioglitazone unless the patient has one of the following:
      a. h/o bariatric surgery
      b. BMI ≥ 95%ile for age and sex
      c. ≥ 5% increase in body weight after 6 months of starting these medications
      d. patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day

If all criteria met, approve at HICL x6 months, max 0.5 tablet per day.
If criteria are not met, do not approve.

RENEWAL CRITERIA

1. HgbA1c is either at goal or has decreased by at least 0.5%.

If renewal criteria are met, approve indefinitely at HICL, max 0.5 tablet per day.
If renewal criteria are not met, do not approve.

RATIONALE

- KP National Diabetes Guidelines recommend using SGLT-2i for people with type 2 diabetes with clinical ASCVD who are already taking metformin to reduce the risk of: (1) cardiovascular events (myocardial infarction or stroke) or cardiovascular death, (2) progression of renal disease and/or (3) death from renal causes, and/or (4) heart failure hospitalizations. The American College of Cardiology (ACC) 2020 Expert Consensus Decision Pathway on Novel Therapies for Cardiovascular Risk Reduction in Patients with Type 2 Diabetes, which is also endorsed by the American Diabetes Association (ADA), recommends SGLT-2i as a first-line treatment in patients with type 2 diabetes and one or more of the following: ASCVD, HFrEF, HFpEF (empagliflozin only), diabetic kidney disease (DKD), or at high risk for ASCVD.
- Preferred order of agents:
    1) Empagliflozin (Jardiance), formulary without PA, is the preferred agent for ASCVD, CKD, and HF due to strength of clinical trial data, range of approved indications, and cost (1/2 tab regimen)
    2) Canagliflozin (Invokana), non-formulary with PA, is the 2nd preferred option for ASCVD, CKD and DM2 patients without compelling indications. due to broad range of indications and cost (1/2 tab regimen).
    3) Dapagliflozin (Farxiga), non-formulary with PA, is the 2nd preferred option for HF, and the 3rd preferred option for ASCVD, CKD and DM2 patients without compelling indications due to broad range of indications but at high cost.
    4) Ertugliflozin (Steglatro), non-formulary with PA, is least preferred due to high cost, paucity of positive clinical trial data, and lack of additional FDA-approved indications. Specifically, ertugliflozin has been studied in patients with type 2 diabetes and ASCVD and did not improve cardiovascular outcomes while all three other SGLT-2i have demonstrated such benefits in this population.
    5) Bexagliflozin (Brenzavvy): non-formulary with PA, is least preferred due to high cost and lack of additional FDA-approved indications.
    6) Sotagliflozin (Inpefa): non-formulary with PA, is 3rd preferred for HF given shorter history of postmarketing safety data compared to other SGLT2i's approved for HF as well as the need to titrate sotagliflozin dose for when others are fixed-dose regimens. Sotagliflozin (Inpefa) is least preferred for glycemic control due to lack of clinical trial data and FDA-approved indication as well as its high cost.
- Jardiance (empagliflozin) is the preferred sodium glucose co-transporter 2 inhibitor (SGLT-2i) at Kaiser Permanente Colorado (KPCO) and can be used effectively and safely with a GFR down to 20 mL/min. In addition, the dose of 12.5 mg (1/2 of 25mg tablet) is an effective dose for all patients regardless of GFR.
- Based on the available evidence, various organizations endorse SGLT-2is use down to lower GFR levels than indicated in product labels:
    - American College of Cardiology Expert Consensus now recommends empagliflozin in GFR ≥ 20 mL/min (2021).

- National Kidney Foundation recommends SGLT-2is in GFR ≥ 20 mL/min as long as there are no contraindications (2023).
- American Diabetes Association recognizes SGLT-2is benefits in patients with GFR ≥ 20 mL/min (2023).

FDA APPROVED INDICATIONS for SGLT2 Inhibitors

Empagliflozin (Jardiance)

1. Improve glycemic control in patients with DM2
2. Reduce the risk of CV death in pts with DM2 + CVD
3. Reduce risk of CVD death and HF hospitalizations in pts with HF
4. Reduce risk of sustained eGFR decline, ESRD, CV death and hospitalizations in adults with CKD at risk of progression

Canagliflozin (Invokana)

1. Improve glycemic control in patients with DM2
2. Reduce risk of MACE in pts with DM2 + CVD
3. Reduce the risk of ESRD, doubling of creatinine, CV death, or HF hospitalization in pts with DM2 + diabetic nephropathy

Dapagliflozin (Farxiga)

Improve glycemic control in patients with DM2
Reduce risk of HF hosp in pts with DM2 + CVD/multiple CV RFs
Reduce the risk of CV death and HF hosp in patients with HFrEF NYHA II-IV
Reduce risk of sustained eGFR decline, ESRD, CV death, and hospitalization for HF in adults with CKD at risk of progression

Ertugliflozin (Steglatro)

Improve glycemic control in patients with DM2

Bexagliflozin (Brenzavvy)

Improve glycemic control in patients with DM2

Sotagliflozin (Inpefa)

Reduce the risk of CV death and HF hosp in pts with heart failure
Reduce the risk of CV death and HF hosp in pts with DM2 + CKD + CV RF(s)

REFERENCES

Medication use in Pediatric/Young Adults:

1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class

were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation date: 09/26/18
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

EPIDIOLEX (CANNABIDIOL)

Generic	Brand	HICL	GPID	Exception/Other
CANNABIDIOL	EPIDIOLEX	45006	45169	

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on cannabidiol (Epidiolex)
2. Patient has a diagnosis of Lennox-Gastaut Syndrome, Dravet Syndrome, or Tuberous Sclerosis and is being managed by a CPMG or affiliated neurologist or epileptologist

If New Member Criteria are met, approve indefinitely.
If New Member Criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria below:

A. Lennox-Gastaut syndrome (LGS)
B. Dravet syndrome (DS)
C. Tuberous Sclerosis Complex (TSC)

A. To treat Lennox-Gastaut Syndrome (LGS): All the following must be met:
   1. Medication is prescribed by a CPMG or affiliated neurologist or epileptologist.
   2. Patient is 1 year of age or older.
   3. This medication will be used as adjunctive therapy with at least one other anti-seizure drug.
   4. The patient is stable on cannabidiol (Epidiolex), or the patient has failed a valproic acid derivative, and lamotrigine, and either topiramate or rufinamide, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

      If initial criteria are met, approve indefinitely.
      If initial criteria are not met, do not approve.

B. To treat Dravet Syndrome (DS): All the following must be met:
   1. Medication is prescribed by a CPMG or affiliated neurologist or epileptologist.
   2. Patient is 1 year of age or older.
   3. The patient is stable on cannabidiol (Epidiolex), or the patient has failed a valproic acid derivative product and clobazam, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve indefinitely.
If initial criteria are not met, do not approve.

C. To treat Tuberous Sclerosis Complex (TSC) associated seizures: All the following must be met:
   1. Medication is prescribed by a CPMG or affiliated neurologist or epileptologist.
   2. Patient has a diagnosis of TSC either by confirmed genetic testing or meeting clinical criteria for definitive diagnosis outline by the 2012 International Tuberous Sclerosis Complex Consensus Group.
   3. Patient is 1 year of age or older.
   4. Patient is treatment refractory to optimal dosing of at least two antiepileptic drugs (AEDs) that are appropriate for the epilepsy diagnosis.
   5. Patient has experienced the following over the past 4 weeks:
      a. At least 8 seizures
      b. At least 1 focal seizure ocurring in at least 3 of the 4 weeks
   6. This medication will be used as adjunctive therapy with at least one other anti-seizure drug.

   If initial criteria are met, approve indefinitely.
   If initial criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with cannabidiol (Epidiolex)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Lennox-Gastaut syndrome (LGS); Dravet syndrome (DS); Tuberous Sclerosis Complex (TSC)]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Lennox-Gastaut syndrome (LGS)
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (divalproex sodium DR (12 hr) or ER (24 hr) tablets, divalproex sodium sprinkle caps (125 mg), valproic acid capsules (250 mg); lamotrigine IR, ER, or chewable tablets; topiramate IR tablets or sprinkle capsules (25 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Will the medication be used as adjunctive therapy with at least one other anti-seizure drug?

Dravet syndrome (DS)
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (divalproex sodium DR (12 hr) or ER (24 hr) tablets, divalproex sodium sprinkle caps (125 mg), valproic acid capsules (250 mg); clobazam tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Tuberous Sclerosis Complex (TSC)
1. Does the patient have a diagnosis of TSC either by confirmed genetic testing or meeting clinical criteria for definitive diagnosis outline by the 2012 International Tuberous Sclerosis Complex Consensus Group? If yes, must attach applicable chart notes.
2. Will the medication be used as adjunctive therapy with at least one other anti-seizure drug?

3. Is the patient treatment refractory to optimal dosing of at least two antiepileptic drugs (AEDs) that are appropriate for the epilepsy diagnosis? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. How many seizures has the patient experienced in the past 4 weeks?
5. How many focal seizures has the patient experienced each week in the past 4 weeks? (#, #, #, #)

RATIONALE
Ensure appropriate use consistent with FDA indication.

FDA APPROVED INDICATIONS
Treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or Tuberous Sclerosis Complex (TSC) in patients ≥1 year of age.

REFERENCES
1. Epidiolex [Package Insert], Carlsbad, CA: Greenwich Biosciences, Inc.; 2024.
2. Northrup H, Krueger DA; International Tuberous Sclerosis Complex Consensus Group. Tuberous sclerosis complex diagnostic criteria update: recommendations of the 2012 International Tuberous Sclerosis Complex Consensus Conference. Pediatr Neurol. 2013;49(4):243-254. doi:10.1016/j.pediatrneurol.2013.08.001

Creation date: 11/28/2018
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

XCOPRI (CENOBAMATE)

Generic	Brand	HICL	GPID	Exception/Other
CENOBAMATE	XCOPRI	46241	47409, 47413, 47414, 47394, 47395, 47416, 49574, 47396, 47397, 55041	

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on cenobamate (Xcopri)
2. Patient has a diagnosis of Partial Onset Seizures and is being managed by a CPMG or affiliated neurologist or epileptologist

If New Member Criteria are met, approve indefinitely.
If New Member Criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Medication is prescribed by a CMPG or affiliated neurologist or epileptologist
2. Patient is 18 years of age or older. [This drug has not been studied in pediatric populations.]
3. Patient has a diagnosis of partial onset seizures (also known as focal onset aware or impaired awareness)
4. The patient is stable on cenobamate (Xcopri), or the patient has failed at least **2** of the medications, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event:
   - Carbamazepine [preferred formulary]
   - Lacosamide [preferred formulary]
   - Lamotrigine [preferred formulary]
   - Levetiracetam [preferred formulary]
   - Oxcarbazepine [preferred formulary]
   - Topiramate [preferred formulary]
   - Zonisamide [preferred formulary]
   - Valproic acid derivative [formulary]
   - Felbamate [formulary]
   - Gabapentin [formulary]
   - Phenobarbital [formulary]
   - Phenytoin [formulary]
   - Pregabalin [formulary]
   - Primidone [formulary]
   - Brivaracetam (Briviact) [non-formulary]
   - Eslicarbazepine (Aptiom) [non-formulary]
   - Tiagabine [non-formulary]
   - Vigabatrin [non-formulary]

If met, approve indefinitely at HICL.
If not met, do not approve.

ePA Questions

1. Is the patient stable on therapy with cenobamate (Xcopri)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: partial onset seizures (also known as focal onset aware or impaired awareness)]
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (carbamazepine ER tablets (100 mg, 200 mg, 400 mg), carbamazepine IR tablets (200 mg), carbamazepine chewable tablets (100 mg); divalproex sodium DR (12 hr) or ER (24 hr) tablets, divalproex sodium sprinkle caps (125 mg), valproic acid capsules (250 mg); lacosamide tablets; lamotrigine IR, ER, or chewable tablets; levetiracetam IR or ER tablets; oxcarbazepine tablets (150 mg, 300 mg, 600 mg); topiramate IR tablets or sprinkle capsules (25 mg); zonisamide capsules; felbamate tablets (400 mg, 600 mg) or suspension; gabapentin capsules (100 mg, 300 mg, 400 mg); pregabalin capsules; primidone tablets; Dilantin 30 mg capsules, phenytoin ER capsules (100 mg) or chewable tablets (50 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

FDA APPROVED INDICATIONS

Xcopri is indicated for the treatment of partial-onset seizures in adult patients.

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Creation Date: 07/2023
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date:

CGRP MONOCLONAL ANTIBODY INHIBITORS
AIMOVIG

Generic	Brand	HICL	GPID	Comments
ERENUMAB	AIMOVIG	44923	46116 140mg, 44753 70mg	Acts on receptor

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet the following:
A. Patient is new to KPCO within the past 90 days
B. Patient is stable on CGRP-mAb for migraine prevention

If New Member criteria are met for migraine prevention, approve current therapy x 3 months (to allow time for consideration of formulary preferred alternatives then must meet Initial Criteria for ongoing coverage).
If New Member criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet the following:
A. Patient is not taking another CGRP-directed medication for migraine prevention
B. Must meet drug and diagnosis specific criteria (1 or 2) below:

1. For Episodic Migraine diagnosis: The patient must meet all the following criteria:
   a. Patient has a diagnosis of episodic migraine (less than 15 migraine days per month)
   b. Patient with failure of (after at least 6-8 weeks at maximally tolerated dose), intolerance to, or contraindication to, at least two medications from different migraine preventive classes, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      i. Anticonvulsants: divalproex, valproate, topiramate
      ii. Beta blockers: atenolol, metoprolol, nadolol, propranolol, timolol
      iii. Antidepressants: amitriptyline, nortriptyline, venlafaxine, duloxetine
   c. Meets medication specific criteria below, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      i. Patient has tried and failed one CGRP-mAb that acts on the ligand (examples: fremanezumab (Ajovy), galcanezumab (Emgality), eptinezumab (Vyepti))

      If initial criteria are met, then approve at HICL x 6-months.

If initial criteria are not met, do not approve. If patient has not tried and failed a CGRP-mAb that acts on the ligand, deny and recommend Ajovy 225 mg monthly or 675 mg every 3 months.

2. For Chronic Migraine diagnosis: The patient must meet all the following criteria:
   a. Patient has a diagnosis of chronic migraine (defined as 15 or more headache days [migraine-like or tension-like] per month for the past 3 months, of which at least 8 days are migraines)
   b. Patient has documented intolerance, contraindication, or inadequate response after an adequate trial* to at least two medications from different migraine preventive classes, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      i. Anticonvulsants: divalproex, valproate, topiramate
      ii. Beta blockers: atenolol, metoprolol, nadolol, propranolol, timolol
      iii. Antidepressants: amitriptyline, nortriptyline, venlafaxine, duloxetine
      iv. Botulinum toxin: onabotulinumtoxinA
   c. Meets medication specific criteria below, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      i. Patient has tried and failed a CGRP-mAb that acts on the ligand (examples: fremanezumab (Ajovy), galcanezumab (Emgality), eptinezumab (Vyepti)

      If initial criteria are met, then approve at HICL x 6-months.
      If initial criteria are not met, do not approve. If patient has not tried and failed a CGRP-mAb that acts on the ligand, deny and recommend Ajovy 225 mg monthly or 675 mg every 3 months.

RENEWAL CRITERIA: Review based on diagnosis specific criteria:

A. For episodic or chronic migraine indications: All the following criteria must be met:
   1. Patient is not taking another CGRP-directed medication for migraine prevention.
   2. Patient has experienced at least one of the following:
      a. Fewer migraines or headache attacks by at least 2 days per month with Aimovig therapy
      b. Lessening in migraine severity with Aimovig therapy
      c. Lessening in migraine duration with Aimovig therapy

   If criteria are met, then approve Aimovig at HICL indefinitely.
   If criteria are not met, do not approve.

** Adequate trials of non-CGRP mAb preventive medication trials FOR MIGRAINE:*

- Oral migraine preventive medicaton: at least 6-8 weeks at maximally tolerated dose
- OnabotulinumtoxinA: at least two quarterly injections with response assessed 6 months after initiation

CGRP-Directed Migraine Medications

Generic (Brand)	Route CGRP "class"	Acute Migraine Approval	Preventive Migraine Approval
Eptinezumab (Vyepti)	IV, CGRP-mAb	X	100 mg or 300 mg Q 3 mo
Erenumab (Aimovig)	SC, CGRP-mAb	X	70 mg or 140 mg Q mo
Fremanezumab (Ajovy)	SC, CGRP-mAb	X	225 mg Q mo, OR 675 mg Q 3 mo
Galcanezumab (Emgality)	SC, CGRP-mAb	X	240 mg loading dose, then 120 mg Q mo
Atogepant (Qulipta)	Oral, CGRP antagonist "gepant"	X	10 mg, 30 mg or 60 mg daily
Rimegepant (Nurtec ODT)	Orally disintegrating tablet, CGRP antagonist "gepant"	75 mg at onset do NOT repeat dose	75 mg every OTHER day
Ubrogepant (Ubrelvy)	Oral, CGRP antagonist "gepant"	50 mg or 100 mg at onset, may repeat in 2 hours	X
Zavegepant (Zavzpret)	Intranasal, CGRP antagonist "gepant"	10 mg at onset do NOT repeat dose	X

ePA Questions for Provider Outreach

1. Diagnosis/ICD-10 codes associated with this request: _____
2. Has the patient failed other treatments for this indication? If yes, must list medication, strength, dates of treatment, and reason for discontinuation in Provider Comments section below or attach applicable chart notes.
3. Is there reasoning why alternatives are not suitable (i.e. Ajovy prefilled syringes or auto-injector; divalproex sodium DR or ER tablets, valproic acid capsules (250 mg); topiramate IR tablets; atenolol, metoprolol IR or ER, propranolol IR or ER; amitriptyline, nortriptyline; venlafaxine ER capsules; Botox)? If yes, must list reasoning in Provider Comments section below or attach applicable chart notes.

RATIONALE

Ensure appropriate criteria are used for the management of requests for all CGRP inhibitors according to approved indication and national treatment guidelines. There are minimal head-to-head studies with other treatments for migraine prophylaxis. In addition, in a 2024 Position Statement update from the American Headache Society, CGRP-directed medications are listed as a first-line treatment option for migraine prevention along with older oral migraine preventives and onabotulinumtoxinA (for chronic migraine only). When initially approved, data with CGRP-mAbs was limited to healthy subjects as patients with cardiovascular comorbidities were excluded from the clinical trials. To date, there have been no significant safety concerns identified in this patient population from open-label and real-world clinical trials.

^^ Original intent of C.1 was to allow patients who were previously stable on Emgality and in May/June 2021 were converted to Ajovy (KP's preferred agent) which resulted in a loss of stability (migraines returned while on Ajovy) to be able to convert back to Emgality. This has been updated to include Aimovig so patients who had been stable and achieved migraine reduction on Aimovig, who have tried Ajovy but failed, are able to easily transition back to Aimovig without significant delay in care that could result in further worsening of migraines.

Results from erenumab trials did not show the 140 mg monthly dose to be superior to 70 mg monthly, however, both 70 mg monthly and 140 mg monthly are FDA approved doses.

FDA APPROVED INDICATIONS
Preventive treatment of migraine in adults

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Creation date: 11/2018
Effective date: 02/2025

Reviewed date: 01/2025
Revised date: 01/2025

CGRP MONOCLONAL ANTIBODY INHIBITORS
EMGALITY

Generic	Brand	HICL	GPID	Comments
GALCANEZUMAB	EMGALITY	45281	46397, 40418, 40419	Acts on ligand

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet the following:

A. Patient is new to KPCO within the past 90 days
B. Either the patient is stable on CGRP-mAb for migraine prevention, or the patient is in an active cluster headache and prior cluster headaches were treated with Emgality 300 mg

If New Member criteria are met for migraine prevention, approve current therapy at GPID x 3 months (to allow time for consideration of formulary preferred alternatives then must meet Initial Criteria for ongoing coverage).
If New Member criteria are met for cluster headache, approve Emgality 100 mg x 2 months (to allow time for consideration of formulary preferred alternatives then must meet Initial Criteria for ongoing coverage).
If New Member criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet the following:

A. Patient is not taking another CGRP-directed medication for migraine prevention
B. Must meet drug and diagnosis specific criteria (1, 2, or 3) below:

1. For Episodic Migraine diagnosis: The patient must meet all the following criteria:
   a. Patient has a diagnosis of episodic migraine (less than 15 migraine days per month)
   b. Patient with failure of (after at least 6-8 weeks at maximally tolerated dose), intolerance to, or contraindication to, at least two medications from different migraine preventive classes, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      i. Anticonvulsants: divalproex, valproate, topiramate
      ii. Beta blockers: atenolol, metoprolol, nadolol, propranolol, timolol
      iii. Antidepressants: amitriptyline, nortriptyline, venlafaxine, duloxetine
   c. Meets medication specific criteria below, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

i. Galcanezumab (Emgality) 120 mg: Patient has tried and failed, or has a contraindication to, at least one CGRP-mAb that acts on the ligand (examples: fremanezumab (Ajovy), eptinezumab (Vyepti))

If initial criteria are met, then approve at GPID x 6-months.
If initial criteria are not met, do not approve. If patient has not tried and failed a CGRP-mAb that acts on the ligand, deny and recommend Ajovy 225 mg monthly or 675 mg every 3 months.

ii. Galcanezumab (Emgality) 100 mg: Do not approve. No indication.

2. For Chronic Migraine diagnosis: The patient must meet all the following criteria:
   a. Patient has a diagnosis of chronic migraine (defined as 15 or more headache days [migraine-like or tension-like] per month for the past 3 months, of which at least 8 days are migraines)
   b. Patient has documented intolerance, contraindication, or inadequate response after an adequate trial* to at least two medications from different migraine preventive classes, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      i. Anticonvulsants: divalproex, valproate, topiramate
      ii. Beta blockers: atenolol, metoprolol, nadolol, propranolol, timolol
      iii. Antidepressants: amitriptyline, nortriptyline, venlafaxine, duloxetine
      iv. Botulinum toxin: onabotulinumtoxinA
   c. Meets medication specific criteria below, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

      i. Galcanezumab (Emgality) 120 mg: Patient has tried and failed, or has a contraindication to, at least one CGRP-mAb that acts on the ligand (examples: fremanezumab (Ajovy), eptinezumab (Vyepti))

      If initial criteria are met, then approve at GPID x 6-months.
      If initial criteria are not met, do not approve. If patient has not tried and failed a CGRP-mAb that acts on the ligand, deny and recommend Ajovy 225 mg monthly or 675 mg every 3 months.

      ii. Galcanezumab (Emgality) 100 mg: Do not approve. No indication.

3. For Episodic Cluster Headache diagnosis: The patient must meet all the following criteria:

a. Patient has not received coverage approval for Emgality in the past for cluster headache (if they have, use renewal criteria)
b. Patient has a diagnosis of episodic cluster headache (cluster attacks that occur in periods lasting from 7 days to 1 year, with remission periods greater than 3 months between attacks)
c. Patient does not have a diagnosis of chronic cluster headache (cluster attacks that occur for one year or longer without remission, or with remission periods lasting less than 3 months)
d. Request is for galcanezumab (Emgality) 100 mg/mL syringes and patient is not using another CGRP-mAb or oral CGRP antagonist (ubrogepant, rimegepant, atogepant, etc.)
e. Patient has documented intolerance, contraindication, or inadequate response to at least 2 other acute/abortive medication/therapy trials (including triptans, oxygen, intranasal dihydroergotamine, and intranasal lidocaine) and at least 2 standard cluster headache therapies (lithium, verapamil, melatonin, prednisone, occipital nerve block, topiramate, valproate, memantine), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

If initial criteria are met, then approve at GPID x2 months (2 doses of 300 mg Q month).
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Review based on diagnosis specific criteria in either A or B below:

A. For episodic or chronic migraine indications: All the following criteria must be met:
   1. Patient is not taking another CGRP-directed medication for migraine prevention
   2. Patient has experienced at least one of the following:
      a. Fewer migraines or headache attacks by at least 2 days per month with Emgality therapy
      b. Lessening in migraine severity with Emgality therapy
      c. Lessening in migraine duration with Emgality therapy

   If criteria are met, then approve Emgality at GPID indefinitely.
   If criteria are not met, do not approve.

B. For episodic cluster headache indication: All the following criteria must be met:
   1. Request is for galcanezumab (Emgality) 100 mg/ml syringes
   2. Patient's prior cluster headache period for which galcanezumab (Emgality) was approved to treat has resolved, and the patient is now in a new cluster headache period
   3. Patient had an adequate response to galcanezumab (Emgality) 300 mg monthly for cluster headache (adequate response: at least 30% reduction in cluster headache frequency from baseline after 4 weeks)
   4. Patient has not used consecutive monthly doses of Emgality in the last two months [Note: galcanezumab (Emgality) should not be used for more than 2 months total per cluster headache period]

   If criteria are met, then approve at GPID x 2 months (2 doses of 300 mg Q month).
   If criteria are not met, do not approve.

** Adequate trials of non-CGRP mAb preventive medication trials FOR MIGRAINE:*

- Oral migraine preventive medicaton: at least 6-8 weeks at maximally tolerated dose
- OnabotulinumtoxinA: at least two quarterly injections with response assessed 6 months after initiation

CGRP-Directed Migraine Medications

Generic (Brand)	Route CGRP "class"	Acute Migraine Approval	Preventive Migraine Approval
Eptinezumab (Vyepti)	IV, CGRP-mAb	X	100 mg or 300 mg Q 3 mo
Erenumab (Aimovig)	SC, CGRP-mAb	X	70 mg or 140 mg Q mo
Fremanezumab (Ajovy)	SC, CGRP-mAb	X	225 mg Q mo, OR 675 mg Q 3 mo
Galcanezumab (Emgality)	SC, CGRP-mAb	X	240 mg loading dose, then 120 mg Q mo
Atogepant (Qulipta)	Oral, CGRP antagonist "gepant"	X	10 mg, 30 mg or 60 mg daily
Rimegepant (Nurtec ODT)	Orally disintegrating tablet, CGRP antagonist "gepant"	75 mg at onset do NOT repeat dose	75 mg every OTHER day
Ubrogepant (Ubrelvy)	Oral, CGRP antagonist "gepant"	50 mg or 100 mg at onset, may repeat in 2 hours	X
Zavegepant (Zavzpret)	Intranasal, CGRP antagonist "gepant"	10 mg at onset do NOT repeat dose	X

RATIONALE

Ensure appropriate criteria are used for the management of requests for all CGRP inhibitors according to approved indication and national treatment guidelines. There are minimal head-to-head studies with other treatments for migraine prophylaxis. In addition, in a 2024 Position Statement update from the American Headache Society, CGRP-directed medications are listed as a first-line treatment option for migraine prevention along with older oral migraine preventives and onabotulinumtoxinA (for chronic migraine only). When initially approved, data with CGRP-mAbs was limited to healthy subjects as patients with cardiovascular comorbidities were excluded from the clinical trials. To date, there have been no significant safety concerns identified in this patient population from open-label and real-world clinical trials.

^^ Original intent of C.1 was to allow patients who were previously stable on Emgality and in May/June 2021 were converted to Ajovy (KP's preferred agent) which resulted in a loss of stability (migraines returned while on Ajovy) to be able to convert back to Emgality. This has been updated to include Aimovig so patients who had been stable and achieved migraine reduction on Aimovig, who have tried Ajovy but failed, are able to easily transition back to Aimovig without significant delay in care that could result in further worsening of migraines.

FDA APPROVED INDICATIONS

Preventive treatment of migraine in adults
Episodic cluster headache treatment (Emgality 100 mg only)

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Creation date: 11/2018
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

CIMZIA (CERTOLIZUMAB)

Generic	Brand	HICL	GPID	Exception/Other
CERTOLIZUMAB	CIMZIA	35554	99615, 23471	Non-Formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on therapy.
2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
3. Patient has one of the following indications and medication is prescribed by the appropriate specialist as noted:
    a. Patient has a diagnosis of rheumatoid arthritis (RA), psoriatic arthritis (PsA), or ankylosing spondylitis or subtype and medication is prescribed by a CPMG or affiliated rheumatologist.
    b. The patient has a diagnosis of Crohn's disease and medication is prescribed by a CPMG or affiliated gastroenterologist.
    c. The patient has a diagnosis of psoriasis and medication is prescribed by a CPMG or affiliated dermatologist.

If met, approve indefinitely.
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria:

A. Rheumatoid Arthritis (RA)
B. Psoriatic Arthritis (PsA)
C. Ankylosing Spondylitis or subtype
D. Crohn's Disease
E. Psoriasis

A. RHEUMATOID ARTHRITIS: All the following must be met:
    1. Patient has a diagnosis of RA.
    2. Medication is prescribed by a rheumatologist.
    3. Patient is 18 years of age or older.
    4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
    5. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
        a. At least 2 of the following medications: methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
        b. At least 1 TNF inhibitor (e.g., infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F])
        c. At least 2 of the following:

- JAK inhibitor (e.g., tofacitinib (Xeljanz)-preferred [F])
- IL-6 inhibitor (e.g., tocilizumab (Tyenne)-preferred [F, PA])
- Abatacept (Orencia) [F, PA]

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

B. PSORIATIC ARTHRITIS (PsA): All the following must be met:
1. Patient has a diagnosis of PsA.
2. Medication is prescribed by a rheumatologist or dermatologist.
3. Patient is 18 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. At least 2 of the following medications, or the patient has documented high disease activity in which the medications below would not be suitable treatment: methotrexate, leflunomide, sulfasalazine
   b. At least 1 TNF inhibitor (e.g., infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F])
   c. At least 1 IL-17 inhibitor (e.g., secukinumab (Cosentyx) [F, PA])
   d. At least 1 IL-23 inhibitor (e.g., guselkumab (Tremfya) [NF, PA])
   e. At least 1 of the following:
      - IL-12/23 inhibitor (ustekinumab-kfce (Yesintek) preferred [F, PA])
      - abatacept (Orencia) [F, PA]
      - JAK inhibitor (e.g., tofacitinib (Xeljanz) [F])

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

C. ANKYLOSING SPONDYLITIS: All the following must be met:
1. Patient has a diagnosis of ankylosing spondylitis or one of the following subtype diagnoses: spondyloarthritis (SpA), axial SpA, nonradiographic axial SpA, radiographic axial SpA, sacroiliitis, undifferentiated spondyloarthropathy, spondyloarthropathy, or enteropathic arthropathy.
2. Medication must be prescribed by a rheumatologist.
3. Patient is 18 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the

same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. At least 1 TNF inhibitor (e.g., infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F])
   b. At least 1 IL-17 inhibitor (e.g. secukinumab (Cosentyx) [F, PA])
   c. At least 1 JAK inhibitor (e.g. tofacitinib (Xeljanz)-preferred]

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

D. CROHN'S DISEASE: All the following must be met:
   1. Patient has a diagnosis of Crohn's disease or indeterminant colitis with Crohn's features.
   2. Medication is prescribed by a gastroenterologist.
   3. Patient is 18 years of age or older.
   4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   5. Patient with failure, intolerance, or contraindication to at least one TNF inhibitor (e.g. infliximab [F], and adalimumab (Amjevita) [F], or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

E. PSORIASIS: All the following must be met:
   1. Patient has a diagnosis of moderate to severe psoriasis.
   2. Medication is prescribed by a dermatologist.
   3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Patient has experienced an inadequate response, intolerance, or has a contraindication to a topical corticosteroid or topical calcineurin inhibitor (pimecrolimus, tacrolimus), or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or past biologic therapy within the past 4 months, making these therapies inappropriate
      b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one** or contraindication to at least **two** of the following therapies, or the patient is

reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate: Acitretin, Cyclosporine, Methotrexate, Apremilast (Otezla), Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy

c. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one TNF inhibitor ([adalimumab (adalimumab (Amjevita) -preferred [F], infliximab (Inflectra) -preferred [F])
d. Patient has experienced an inadequate response, intolerance, or has a contraindication to an IL12-23 inhibitor (ustekinumab-kfce (Yesintek) - preferred [F, PA])
e. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one IL-17 inhibitor (secukinumab (Cosentyx) - preferred [F, PA]]
f. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one IL-23 inhibitor [guselkumab (Tremfya) or risankizumab-rzaa (Skyrizi)]

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

ePA Questions

1. Is the patient stable on therapy with certolizumab?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Will this medication be used in combination with a biologic or advanced small molecule for the same indication?
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Rheumatoid Arthritis (RA); Psoriatic Arthritis (PsA); Ankylosing Spondylitis or subtype; Crohn's Disease; Psoriasis]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Rheumatoid Arthritis

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); infliximab; Xeljanz 10 mg tablets - half tablet twice daily; adalimumab-atto (Amjevita)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Psoriatic Arthritis (PsA)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); infliximab; Xeljanz 10 mg tablets - half tablet twice daily; adalimumab-atto (Amjevita)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Ankylosing Spondylitis or Subtype

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.

2. Is there reasoning why alternatives (infliximab (Inflectra), adalimumab-atto (Amjevita), etc.) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Crohn's Disease (CD)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (infliximab (Inflectra), adalimumab-atto (Amjevita), etc.) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Psoriasis

1. BSA impacted (%):
2. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (topical steroids; tacrolimus ointment; acitretin capsules (10 mg, 25 mg); cyclosporine capsules (25 mg, 100 mg); methotrexate tablets (2.5 mg) or injection (25 mg/mL); Otezla tablets; infliximab (Inflectra); adalimumab-atto (Amjevita), etc.) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

REFERENCES

"Stable on therapy" means patient is tolerating well, appears to be effective and provider wishes to continue.

Treatment	Relative Contraindications for Psoriasis
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses (ex: systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for psoriasis.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities, active malignancy, and hypersensitivity*
Acitretin	*Caution in women of child potential (cannot consider pregnancy up to 3 years after completion of treatment), pregnancy, lactation, severe hepatic or renal dysfunction, chronically abnormal elevated lipid values, and hypersensitivity*

Created: 11/2020
Effective: 06/2025
Reviewed: 05/2025
Revised: 05/2025

COMBINATION INHALED CORTICOSTEROID AND LONG-ACTING BETA-AGONIST FLUTICASONE-SALMETEROL (ADVAIR HFA)

Generic	Brand	HICL	GPID	Exception/Other
FLUTICASONE PROPION/SALMETEROL	ADVAIR HFA		97135, 97136, 97137	Formulary

GUIDELINES FOR COVERAGE

Must have one of the following indications and meet all indication-specific criteria:

A. Diagnosis of Asthma or Asthma with COPD
B. Diagnosis of COPD

A. Diagnosis of Asthma or Asthma with COPD: Must meet ONE of the following Step Therapy requirements, or the provider submitted justification and supporting clinical documentation that states one of the following: i) provider attests that the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to budesonide or formoterol] to brand or generic Symbicort HFA.
2. Patient has tried and failed or has contraindications [inability to use dry powder due to poor inspiratory force or severe milk protein allergy] to brand or generic Advair Diskus, or patient is less than 12 years of age and is unable to manipulate brand or generic Advair Diskus device.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

B. Diagnosis of COPD: Must meet a, and b, c, or d below, or the provider submitted justification and supporting clinical documentation that states one of the following: i) provider attests that the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed or has contraindications to at least one LAMA/LABA combination inhaler [formulary option: Stiolto Respimat], or one LAMA [formulary option: Spiriva Respimat 2.5 mcg] and one LABA [formulary option: Striverdi Respimat].
2. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to budesonide or formoterol] to brand or generic Symbicort HFA.
3. Patient is less than 12 years of age and is unable to manipulate brand or generic Advair Diskus device.
4. Patient has tried and failed or has contraindications [inability to use dry powder due to poor inspiratory force or severe milk protein allergy] to brand or generic Advair Diskus.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Asthma or Asthma with COPD; COPD]

QUESTIONS BASED ON DIAGNOSIS SELECTED
Asthma or Asthma with COPD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

COPD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA, Stiolto Respimat, Spiriva Respimat) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Health Plan.

- Wixela Inhub (generic Advair Diskus) and Breyna (generic Symbicort) HFA are first- and second-line KPCO formulary ICS/LABA medications
- Advair HFA is the third-line ICS/LABA on formulary. Dulera HFA, AirDuo or Breo Ellipta should only be considered in patients who are not candidates for Wixela Inhub, Breyna HFA, and Advair HFA.
- Patients on high dose ICS/LABA for asthma [Advair HFA 230/21 mcg 2 inhalations BID, Dulera HFA 200/5 mcg 2 inhalations BID, Breo Ellipta 200/25 mcg 1 inhalation QD and AirDuo 232/14 mcg 2 inhalations BID] are only candidates for Wixela Inhub or Advair HFA. Symbicort/Breyna HFA is not available in a high ICS dose formulation based on FDA approved dosing.
- For COPD management, initial therapy consist of regular treatment with a long-acting bronchodilator, either LAMA and/or LABA.
- Formoterol based inhalers, Symbicort/Breyna HFA (40.8gms/4 inhalers per 90 days) and Dulera HFA (52gms/4 inhalers per 90 days), have a quantity limit to avoid medication overuse (≥ 2 rescue doses per week indicates poorly controlled asthma and need to address therapy) with SMART therapy.

FDA APPROVED INDICATIONS
See individual medications.

REFERENCES
Per Health Plan.

Creation date: 03/18/2019
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2024

COMBINATION INHALED CORTICOSTEROID AND LONG-ACTING BETA-AGONIST FLUTICASONE-SALMETEROL (AIRDUO)

Generic	Brand	HICL	GCN	Exception/Other
FLUTICASONE PROPION/SALMETEROL	AIRDUO		48494, 48495, 48489, 42957, 42958, 42956	Nonformulary

GUIDELINES FOR COVERAGE

Must have one of the following indications and meet all indication-specific criteria:

A. Diagnosis of Asthma or Asthma with COPD
B. Diagnosis of COPD

A. Diagnosis of Asthma or Asthma with COPD: Must meet ONE of the following Step Therapy Requirements, or the provider submitted justification and supporting clinical documentation that states one of the following: i) provider attests that the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to budesonide or formoterol] to brand or generic Symbicort HFA.
2. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to fluticasone or salmeterol, milk protein allergy, concomitant use of strong CYP3A4 inhibitor] to brand or generic Advair Diskus.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

B. Diagnosis of COPD: Must meet a, and b, c, or d below, or the provider submitted justification and supporting clinical documentation that states one of the following: i) provider attests that the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed or has contraindications to at least one LAMA/LABA combination inhaler [formulary option: Stiolto Respimat], or one LAMA [formulary option: Spiriva Respimat 2.5 mcg] and one LABA [formulary option: Striverdi Respimat].
2. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to budesonide or formoterol] to brand or generic Symbicort HFA.

3. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to fluticasone or salmeterol, milk protein allergy, concomitant use of strong CYP3A4 inhibitor] to brand or generic Advair Diskus.
4. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to fluticasone or salmeterol, concomitant use of strong CYP3A4 inhibitor] to Advair HFA.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Asthma or Asthma with COPD; COPD]

QUESTIONS BASED ON DIAGNOSIS SELECTED
Asthma or Asthma with COPD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

COPD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA, Stiolto Respimat, Spiriva Respimat) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Health Plan.

- Wixela Inhub (generic Advair Diskus) and Breyna (generic Symbicort) HFA are first- and second-line KPCO formulary ICS/LABA medications
- Advair HFA is the third-line ICS/LABA on formulary. Dulera HFA, AirDuo or Breo Ellipta should only be considered in patients who are not candidates for Wixela Inhub, Breyna HFA, and Advair HFA.
- Patients on high dose ICS/LABA for asthma [Advair HFA 230/21 mcg 2 inhalations BID, Dulera HFA 200/5 mcg 2 inhalations BID, Breo Ellipta 200/25 mcg 1 inhalation QD and AirDuo 232/14 mcg 2 inhalations BID] are only candidates for Wixela Inhub or Advair HFA. Symbicort/Breyna HFA is not available in a high ICS dose formulation based on FDA approved dosing.
- For COPD management, initial therapy consist of regular treatment with a long-acting bronchodilator, either LAMA and/or LABA.
- Formoterol based inhalers, Symbicort/Breyna HFA (40.8gms/4 inhalers per 90 days) and Dulera HFA (52gms/4 inhalers per 90 days), have a quantity limit to avoid medication overuse (≥ 2 rescue doses per week indicates poorly controlled asthma and need to address therapy) with SMART therapy.

FDA APPROVED INDICATIONS
See individual medications.

REFERENCES
Per Health Plan.

Creation date: 03/18/2019
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2024

COMBINATION INHALED CORTICOSTEROID AND LONG-ACTING BETA-AGONIST FLUTICASONE-VILANTEROL (BREO ELLIPTA)

Generic	Brand	HICL	GCN	Exception/Other
FLUTICASONE/VILANTEROL	BREO ELLIPTA	40319	34647, 35808, 54747	Nonformulary

GUIDELINES FOR COVERAGE

Must have one of the following indications and meet all indication-specific criteria:

A. Diagnosis of Asthma or Asthma with COPD
B. Diagnosis of COPD

A. Diagnosis of Asthma or Asthma with COPD: Must meet ONE of the following Step Therapy requirements, or the provider submitted justification and supporting clinical documentation that states one of the following: i) provider attests that the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to fluticasone or salmeterol, milk protein allergy, concomitant use of strong CYP3A4 inhibitor] to brand or generic Advair Diskus.
2. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to budesonide or formoterol] to brand or generic Symbicort HFA.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

B. Diagnosis of COPD: Must meet a, and b, c, or d below, or the provider submitted justification and supporting clinical documentation that states one of the following: i) provider attests that the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed or has contraindications to at least one LAMA/LABA combination inhaler [formulary option: Stiolto Respimat], or one LAMA [formulary option: Spiriva Respimat 2.5 mcg] and one LABA [formulary option: Striverdi Respimat].
2. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to budesonide or formoterol] to brand or generic Symbicort HFA.
3. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to fluticasone or salmeterol, milk protein allergy, concomitant use of strong CYP3A4 inhibitor] to brand or generic Advair Diskus.
4. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to fluticasone or salmeterol, concomitant use of strong CYP3A4 inhibitor] to Advair HFA.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Asthma or Asthma with COPD; COPD]

QUESTIONS BASED ON DIAGNOSIS SELECTED
Asthma or Asthma with COPD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

COPD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA, Stiolto Respimat, Spiriva Respimat) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Health Plan.

- Wixela Inhub (generic Advair Diskus) and Breyna (generic Symbicort) HFA are first- and second-line KPCO formulary ICS/LABA medications
- Advair HFA is the third-line ICS/LABA on formulary. Dulera HFA, AirDuo or Breo Ellipta should only be considered in patients who are not candidates for Wixela Inhub, Breyna HFA, and Advair HFA.
- Patients on high dose ICS/LABA for asthma [Advair HFA 230/21 mcg 2 inhalations BID, Dulera HFA 200/5 mcg 2 inhalations BID, Breo Ellipta 200/25 mcg 1 inhalation QD and AirDuo 232/14 mcg 2 inhalations BID] are only candidates for Wixela Inhub or Advair HFA. Symbicort/Breyna HFA is not available in a high ICS dose formulation based on FDA approved dosing.
- For COPD management, initial therapy consist of regular treatment with a long-acting bronchodilator, either LAMA and/or LABA.
- Formoterol based inhalers, Symbicort/Breyna HFA (40.8gms/4 inhalers per 90 days) and Dulera HFA (52gms/4 inhalers per 90 days), have a quantity limit to avoid medication overuse (≥ 2 rescue doses per week indicates poorly controlled asthma and need to address therapy) with SMART therapy.

FDA APPROVED INDICATIONS
See individual medications.

REFERENCES
Per Health Plan.

Creation date: 03/18/2019
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2024

COMBINATION INHALED CORTICOSTEROID AND LONG-ACTING BETA-AGONIST MOMETASONE-FORMOTEROL (DULERA)

Generic	Brand	HICL	GCN	Exception/Other
MOMETASONE/FORMOTEROL	DULERA		28766, 28767	Nonformulary

GUIDELINES FOR COVERAGE

Must have one of the following indications and meet all indication-specific criteria:

A. Diagnosis of Asthma or Asthma with COPD
B. Diagnosis of COPD

A. Diagnosis of Asthma or Asthma with COPD: Must meet ONE of the following Step Therapy requirements, or the provider submitted justification and supporting clinical documentation that states one of the following: i) provider attests that the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to fluticasone or salmeterol, milk protein allergy, concomitant use of strong CYP3A4 inhibitor] to brand or generic Advair Diskus.
2. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to budesonide or formoterol] to brand or generic Symbicort HFA.

If criteria are met, approve indefinitely at HICL.
If criteria are not met, do not approve.

B. Diagnosis of COPD: Must meet criteria a, and b, c, or d below, or the provider submitted justification and supporting clinical documentation that states one of the following: i) provider attests that the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed or has contraindications to at least one LAMA/LABA combination inhaler [formulary option: Stiolto Respimat], or one LAMA [formulary option: Spiriva Respimat 2.5 mcg] and one LABA [formulary option: Striverdi Respimat].
2. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to budesonide or formoterol] to brand or generic Symbicort HFA.
3. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to fluticasone or salmeterol, milk protein allergy, concomitant use of strong CYP3A4 inhibitor] to brand or generic Advair Diskus.
4. Patient has tried and failed or has contraindications [allergy (anaphylaxis, hives) to fluticasone or salmeterol, concomitant use of strong CYP3A4 inhibitor] to Advair HFA.

If criteria are met, approve indefinitely at HICL.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Asthma or Asthma with COPD; COPD]

QUESTIONS BASED ON DIAGNOSIS SELECTED
Asthma or Asthma with COPD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

COPD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA, Stiolto Respimat, Spiriva Respimat) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Health Plan.

- Wixela Inhub (generic Advair Diskus) and Breyna (generic Symbicort) HFA are first- and second-line KPCO formulary ICS/LABA medications
- Advair HFA is the third-line ICS/LABA on formulary. Dulera HFA, AirDuo or Breo Ellipta should only be considered in patients who are not candidates for Wixela Inhub, Breyna HFA, and Advair HFA.
- Patients on high dose ICS/LABA for asthma [Advair HFA 230/21 mcg 2 inhalations BID, Dulera HFA 200/5 mcg 2 inhalations BID, Breo Ellipta 200/25 mcg 1 inhalation QD and AirDuo 232/14 mcg 2 inhalations BID] are only candidates for Wixela Inhub or Advair HFA. Symbicort/Breyna HFA is not available in a high ICS dose formulation based on FDA approved dosing.
- For COPD management, initial therapy consist of regular treatment with a long-acting bronchodilator, either LAMA and/or LABA.
- Formoterol based inhalers, Symbicort/Breyna HFA (40.8gms/4 inhalers per 90 days) and Dulera HFA (52gms/4 inhalers per 90 days), have a quantity limit to avoid medication overuse (≥ 2 rescue doses per week indicates poorly controlled asthma and need to address therapy) with SMART therapy.

FDA APPROVED INDICATIONS
See individual medications.

REFERENCES
Per Health Plan.

Creation date: 03/18/2019
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2024

COMT-INHIBITOR: OPICAPONE (ONGENTYS)

Generic	Brand	HICL	GPID	Comments
OPICAPONE	ONGENTYS	45536	45838, 47967	Nonformulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient must be age 18 or older
2. Must be prescribed by a Neurologist or given in consultation with a neurologist
3. Must have a diagnosis of Parkinson's disease
4. Patient is experiencing at least 2 hours 'off' time per day despite maximally tolerated levodopa/carbidopa
5. Patient has failed two of the following adjunct drugs prescribed in combination with levodopa/carbidopa, unless contraindicated or clinically significant adverse effects are experienced, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a) COMT inhibitor: entacapone (Comtan®, Stalevo® or their generics) AND
   b) MAO-B inhibitor: selegiline OR
   c) Dopamine agonist: ropinirole, pramipexole

If initial criteria are met, then approve at GPID x6 months.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following:
1. Patient has shown improvement of symptoms since starting on the drug

If renewal criteria above are met, then approve at GPID indefinitely.
If renewal criteria above are not met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient experiencing at least 2 hours "off" time per day despite maximally tolerated levodopa/carbidopa?
2. Has the patient failed other treatments for this indication? If yes, must list the medication(s), strength, date(s) of treatment, and reasoning for discontinuation in the Provider Comment section below or attach applicable chart notes.
3. Is there a reasoning why alternatives (levodopa/carbidopa, entacapone, selegiline, ropinirole, pramipexole, etc.) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Has the patient shown improvement of symptoms since starting on opicapone (Ongentys)?

RATIONALE
Ensure appropriate use consistent with FDA indication.

FDA APPROVED INDICATIONS

Ongentys is indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

Appendix A: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
COMT Inhibitors		
carbidopa/levodopa/ entacapone	PO: Dose should be individualized based on therapeutic response; doses may be adjusted by changing strength or adjusting interval. Fractionated doses are not recommended and only 1 tablet should be given at each dosing interval.	1,200 mg/day (divided doses)
entacapone	PO: 200 mg with each dose of levodopa/carbidopa	1,600 mg/day (divided doses)
tolcapone	PO: 100 mg 3 times daily, as adjunct to levodopa/carbidopa	300 mg/day
MAO-B Inhibitors		
rasagiline	PO: Monotherapy or adjunctive therapy (not including levodopa): 1 mg once daily. Adjunctive therapy with levodopa: Initial: 0.5 mg once daily; may increase to 1 mg once daily based on response and tolerability.	1 mg/day
selegiline	PO: monotherapy or adjunctive therapy (not including levodopa): 5mg twice daily. Adjunctive therapy with levodopa: 5mg twice daily.	5mg twice daily (not to exceed 10mg/day)
Dopamine Agonists		
pramipexole	PO: Initial dose: 0.125 mg 3 times daily, increase gradually every 5 to 7 days; maintenance (usual): 0.5 to 1.5 mg 3 times daily	4.5 mg/day (divided doses)
pramipexole ER	PO: Initial dose: 0.375 mg once daily; increase gradually not more frequently than every 5 to 7 days to 0.75 mg once daily and then, if necessary, by 0.75 mg per dose	4.5 mg/day
ropinirole	PO: Recommended starting dose: 0.25 mg 3 times/day. Based on individual patient response, the dosage should be titrated with weekly increments: Week 1: 0.25 mg 3 times/day; total daily dose: 0.75mg; week 2: 0.5 mg 3 times/day; total daily dose: 1.5 mg; week 3: 0.75 mg 3 times/day; total daily dose: 2.25 mg; week 4: 1 mg 3 times/day; total daily dose: 3 mg. After week 4, if necessary, daily dosage may be increased by 1.5 mg/day on a weekly basis up to a dose of 9 mg/day, and then by up to 3 mg/day weekly to a total of 24 mg/day.	24 mg/day (divided doses)
ropinirole ER	PO: Initial dose: 2 mg once daily for 1 to 2 weeks, followed by increases of 2 mg/day at weekly or longer intervals based on therapeutic response and tolerability	24 mg/day

Appendix B: Contraindications/Boxed Warnings

- Contraindication(s):
  - Concomitant use of non-selective MAO inhibitors.
  - History of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms.
- Boxed warning(s): none reported

Appendix C: General Information

- Off time/episodes represent a return of PD symptoms (bradykinesia, rest tremor or rigidity) when the L-dopa treatment effect wears off after each dosing interval.
- PD symptoms, resulting from too little levodopa (L-dopa), are in contrast with dyskinesia which typically results from too much L-dopa. The alterations between "on" time (the time when PD symptoms are successfully suppressed by L-dopa) and "off" time is known as "motor fluctuations".
- The addition of carbidopa to L-dopa prevents conversion of L-dopa to dopamine in the systemic circulation and liver.

REFERENCES

1. Ongentys Prescribing Information. San Diego, CA: Neurocrine Biosciences, Inc.; December 2023. Available at: https://www.ongentyshcp.com/pdf/ONGENTYS-full-Prescribing-Information.pdf

2. Pahwa MD, Factor SA, Lyons KE, et al. Practice Parameter: Treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review): [RETIRED] Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2006 Apr;66:983-995.
3. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and Movement Disorder Society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease. Mov Disord. 2018 Aug;33(8):1248-1266.

Creation Date: 01/2021
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 09/2023

CORTICOTROPIN

Generic	Brand	HICL	GPID	Exception/Other
CORTICOTROPIN VIALS	ACTHAR GEL, CORTROPHIN	02830	26016	Brand Acthar - Formulary Generic Cortrophin - NF

Length of approval applies to Federal Group

GUIDELINES FOR COVERAGE

Must have one of the following indications and meet all indication-specific criteria below:

A. INFANTILE SPASMS
B. MULTIPLE SCLEROSIS
C. ANY/ALL OTHER DIAGNOSES – NOT COVERED

A. TO TREAT INFANTILE SPASMS: Must meet ALL the following:
   1. Patient has a diagnosis of infantile spasms
   2. Request is for Acthar (Cortrophin does NOT have FDA approval for infantile spasms)
   3. The corticotropin must NOT be administered within a medical office setting. It must be administered in a home setting by non-healthcare persons
   4. Patient is less than 2 years old

If criteria are met, approve for 28 days, at NDC-9 (63004-8710), maximum of 8 vials (each 5mL vial contains 400 units) [applies to FEDERAL Group].
If criteria are not met, do not approve.

B. TO TREAT ACUTE EXACERBATION OF MULTIPLE SCLEROSIS: Must meet the following:
   1. Patient has a diagnosis of multiple sclerosis
   2. Request is for Cortrophin (preferred corticotropin product outside of infantile spasms)
   3. The corticotropin must NOT be administered within a medical office setting. It must be administered in a home setting by non-healthcare persons
   4. Must be prescribed by Neurology
   5. Must meet ONE of the following criteria as follows, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Patient has a contraindication (documented hypersensitivity) to prednisone, methylprednisolone, and dexamethasone
      b. Patient failed at least a 3-day course of PO prednisone of at least 500mg daily, with or without a short PO prednisone taper afterwards, for this current exacerbation
      c. Patient failed at least a 7-day course of IV or PO dexamethasone of at least 8mg daily, with or without a short PO prednisone or dexamethasone taper afterwards, for this current exacerbation
      d. Patient failed at least a 3-day course of IV methylprednisolone of at least 500mg daily, with or without a short oral prednisone taper afterwards, for this current exacerbation

If criteria are met, approve 120 units/day at NDC-9 (62559-0860) for up to 21 days (each 5mL vial contains 400 units) [applies to FEDERAL Group].
If criteria are not met, do not approve.

C. Any/all other indications are not covered. [Per Lexi-Comp - although FDA approved for other indications, there is little evidence to support the use of corticotropin and relevant national guidelines do not recommend the use of corticotropin.]

ePA Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Infantile Spasms; Multiple Sclerosis]

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   Infantile Spasms

   1. Will the medication be administered in a home setting by non-healthcare persons?

   Multiple Sclerosis (MS)

   1. Will the medication be administered in a home setting by non-healthcare persons?
   2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   3. Is there reasoning why alternatives (prednisone, methylprednisolone, and dexamethasone) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Ensure appropriate therapeutic use of this long acting corticotropin formulation.
The recommended regimen for use in infantile spasms is a daily dose of 150 units/m2 (divided into twice daily intramuscular injections of 75 units/ m2) for a 2 week treatment period then a gradual taper over a 2-week period. A suggested taper schedule is 30 units/ m2 every morning for 3 days, 15 units/ m2 every morning for 3 days, 10 units/ m2 every morning for 3 days, and then 10 units/ m2 every other morning for 6 days.
8 vials per 28 days supply based on dosage of 150 units/m2/day with an estimate of 0.7m2 body surface area, estimated maximum for a child less than 40 pounds (two years old).
The American Academy of Neurology guidelines for treatment of infantile spasms state that response is usually within 2 weeks and current clinical data is insufficient to determine optimum dosage and duration.
Questcor states that the H.P. Acthar Gel vial expires 28 days after initial puncture, when stored under ideal conditions (per USP standard guidelines).

Contraindications to Acthar

A. concomitant use of live or live attenuated vaccines when receiving immunosuppressive corticotropin dose (also a contraindication to prednisone and methylprednisolone)
B. congenital infection in infants
C. congestive heart failure
D. hypertension, uncontrolled
E. intravenous administration
F. ocular herpes simplex infection
G. osteoporosis
H. peptic ulcers, history or presence of
I. primary adrenocortical insufficiency or adrenocortical hyperactivity
J. scleroderma

K. sensitivity to porcine protein
L. surgery, recent
M. systemic fungal infection (also a contraindication to prednisone, methylprednisolone and dexamethasone)

FDA APPROVED INDICATIONS

Brand corticotrophin	FDA approved indictions
Acthar Gel	• Monotherapy for the treatment of infantile spasms in infants and chidren under 2 years of age • Treatment of exacerbations of MS in adults • May be used for the following disorders and disease: rheumatic, collagen, dermatologic, allergic states, ophthalmic, respiratory, and edematous state
Purified Cortrophin Gel	• Nervous system (acute MS exacerbation), rheumatic disorders, collagen disease, dermatologic diseases, allergic states, ophthalmic diseases, respiratory disease, and edmatous states.

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3. Thompson AJ, Kennard C, Swash M, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. Neurology. 1989;39(7):969-71.
4. Abbruzzese G, Gandolfo C, and Loeb C. “Bolus” methylprednisolone versus ACTH in the treatment of multiple sclerosis. Ital J Neurol Sci. 1983 Jun;4(2):169-72.

Creation date: 07/25/2018
Effective date: 10/2024
Reviewed date: 07/2024
Revised date: 07/2024

DABRAFENIB (TAFINLAR)

Generic	Brand	HICL	GPID	Comments
DABRAFENIB	TAFINLAR	40360	34723, 34724	Nonformulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA

1. Patient is new to KPCO within the past 90 days and is stable on therapy.

   If met, approve based on the following:
   - For adjuvant setting: Approve for duration needed to complete a total of 12 months of adjuvant treatment, max 4 per day.
   - For unresectable or metastatic setting: Approve x indefinitely, max 4 per day.

   If not met, review by Initial Criteria below.

INITIAL CRITERIA: Must meet all the following criteria:

A. Must be prescribed by an oncologist
B. Must have a BRAF V600 activating mutation positive tumor
C. Must meet the diagnosis-specific criteria below:
   1. Cutaneous Melanoma (Adjuvant Setting)
      a. Must be requested in the adjuvant treatment setting

      If initial criteria above are met, approve at HICL x 12 months, max 4 per day.
      If initial criteria are not met, do not approve.

   2. Cutaneous Melanoma (Unresectable or Metastatic Setting): Must meet criteria a and b, plus either c or d below:
      a. Must be requested in unresectable or metastatic (advanced) setting
      b. Must have confirmed brain metastasis, or the patient has tried and is unable to tolerate vemurafenib (Zelboraf) due to unacceptable toxicities despite adequate dose reductions, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception
      c. Patient has not received BRAF-targeted therapy in the past (other than possible vemurafenib with intolerable toxicities as noted in C.2.b.)
      d. Patient previously demonstrated clinical benefit from BRAF-targeted therapy (ex: vemurafenib (Zelboraf), dabrafenib (Tafinlar), encorafenib (Braftovi)) and may benefit from rechallenge with a BRAF-inhibitor (dabrafenib) after other (non BRAF targeted) therapies.

      If initial criteria above are met, approve at HICL x indefinitely, max 4 per day.
      If initial criteria are not met, do not approve. Use specific notations below for denial as applicable:
      - If initial criteria are met other than C.2.b, deny noting patient must use vemurafenib.

3. Non-small cell lung cancer
   a. Must be requested in the unresectable or metastatic setting
   b. Must have BRAF V600E mutation positive tumor

   If initial criteria above are met, approve at HICL x indefinitely, max 4 per day.
   If initial criteria are not met, do not approve.

4. Thyroid cancer
   a. Must be requested in the locally advanced or metastatic setting
   b. Must have anaplastic thyroid cancer
   c. Must have BRAF V600E mutation positive tumor

   If initial criteria above are met, approve at HICL x indefinitely, max 4 per day.
   If initial criteria are not met, do not approve.

5. Solid tumors
   a. Must be requested in the unresectable or metastatic setting
   b. Must have BRAF V600E mutation positive tumor
   c. Must have progressed through prior treatment and have no satisfactory alternative treatment options

   If initial criteria above are met, approve at HICL x indefinitely, max 4 per day.
   If initial criteria are not met, do not approve.

RENEWAL CRITERIA

1. Request for continued coverage is in the unresectable or metastatic setting only. [No indication for treatment beyond 12 months in the adjuvant setting.]
2. Patient's disease has not progressed since treatment initiation, or the treating provider believes patient is deriving significant clinical benefit to justify treatment continuation [Note: provider does not need to prove lack of progression via imaging. Clinical evaluation suffices.]

   If renewal criteria are met, approve at HICL x indefinitely, max 4 per day.
   If renewal criteria are not met, do not approve.

RATIONALE

FDA labeling
Steering use toward preferred products

FDA APPROVED INDICATIONS

Melanoma (adjuvant, unresectable/metastatic), NSCLC (metastatic), anaplastic thyroid cancer (locally advanced, metastatic), solid tumors (unresectable, metastatic) with BRAF V600 activating mutations.

Creation Date: 3/2020
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

DAPAGLIFLOZIN (FARXIGA)

Generic	Brand	HICL	GPID	Comments
DAPAGLIFLOZIN	FARXIGA	40137		NF 2nd Preferred

GUIDELINES FOR COVERAGE
Must be used for one of the following indications and meet all related criteria as follows:

A. General criteria for any/all requests
B. Adults 25 years of age or older with DM2 and ASCVD
D. Adults 25 years of age or older with DM2 with Nephropathy
E. Adults 18 years of age or older with Heart Failure
F. Adults 18 years of age or older with CKD (without type 2 diabetes)
G. Adults 25 years of age or older with DM2 without ASCVD, Nephropathy, or Heart Failure
H. Pediatrics/Young Adults between 10 and 25 years of age with DM2

A. General criteria for any/all requests:
   - Request must be for generic dapagliflozin [authorized generic available].

If not met, do not approve.

B. To treat adults 25 years of age or older with type 2 diabetes and established atherosclerotic cardiovascular disease (ASCVD) [acute coronary syndromes (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)]: Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Patient has contraindication or intolerance to, is currently using, or has failed maximum doses of metformin IR and/or metformin ER, or the patient's A1c is at goal and SGLT-2i is more appropriate for ASCVD, CKD and/or HF benefit
   2. Patient has an eGFR of at least 20 ml/min and has tried and failed, or has an intolerance or contraindication to empagliflozin (Jardiance)

If all criteria met, approve at HICL indefinitely, max 1 tablet per day.
If criteria are not met, do not approve.

C. To treat adults 25 years of age or older with type 2 diabetes with nephropathy: Must meet all the following:
   1. eGFR is at least 20 ml/min, and eGFR is less than 60 ml/min and/or urinary albumin-to-creatinine ratio greater than 300
   2. The patient has contraindication to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to

lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Maximum doses of metformin IR and/or metformin ER, or the patient's A1c is at goal and SGLT-2i is more appropriate for ASCVD, CKD and/or HF benefit
   b. ACE-I or ARB
   c. empagliflozin (Jardiance)

If all criteria met, approve at HICL indefinitely, max 1 tablet per day.
If criteria are not met, do not approve.

D. To treat adults 18 years of age or older with HF (with or without type 2 diabetes): Must meet all the following:
   1. NYHA Class II-IV
   2. Patient has eGFR of at least 25 ml/min
   3. Has contraindications to, is currently using, or has failed all of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. ACE-I or ARB or ARNI (Entresto)
      b. Beta blocker
      c. Aldosterone antagonist (e.g., spironolactone, eplerenone)
      d. empagliflozin (Jardiance)

If all criteria met, approve at HICL indefinitely, max 1 tablet per day.
If criteria are not met, do not approve.

E. To treat adults 18 years of age or older with CKD (without type 2 diabetes): Must meet all the following:
   1. eGFR of at least 20 ml/min, and eGFR is less than 60 ml/min and/or Urinary albumin-to-creatinine ratio of at least 300
   2. Has contraindications to, is currently using or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. ACE-I or ARB
      b. empagliflozin (Jardiance)

If all criteria met, approve at HICL indefinitely, max 1 tablet per day.
If criteria are not met, do not approve.

F. To treat adults 25 years of age or older with type 2 diabetes without ASCVD, nephropathy, or HF: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is above, but within 2% of their designated A1c goal
   2. Patient has an eGFR of at least 20 ml/min
   3. Patient has contraindications to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. maximum dose metformin IR and subsequently metformin ER
      b. empagliflozin (Jardiance)
      c. maximum dose sulfonylurea, maximum dose pioglitazone, and all possible combinations thereof unless the patient has one of the following:
         i. h/o bariatric surgery
         ii. BMI ≥ 35 (≥ 30 for Asian American/Pacific Islanders)
         iii. ≥ 5% increase in body weight after 6 months of starting diabetes medications associated with weight gain (i.e. sulfonylurea, insulin, pioglitazone)
         iv. patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day

If all criteria met, approve at HICL x6 months, max 1 tablet per day.
If criteria are not met, do not approve.

G. To treat type 2 diabetes in young adult/pediatric patients between 10 and 25 years of age: Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Patient has contraindications to, is currently using, or has failed maximum doses of metformin IR and subsequently metformin ER
   2. Patient has an eGFR of at least 20 ml/min and has tried and failed, or has an intolerance or contraindication to empagliflozin (Jardiance)
   3. Patient has contraindications to, is currently using, or has failed maximum dose pioglitazone unless the patient has one of the following:
      a. h/o bariatric surgery
      b. BMI ≥ 95%ile for age and sex
      c. ≥ 5% increase in body weight after 6 months of starting these medications
      d. patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day

If all criteria met, approve at HICL x6 months, max 1 tablet per day.
If criteria are not met, do not approve.

RENEWAL CRITERIA
1. HgbA1c is either at goal or has decreased by at least 0.5%.

If renewal criteria are met, approve indefinitely at HICL, max 1 tablet per day.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Adults 25 years of age or older with DM2 and ASCVD; Adults 25 years of age or older with DM2 with Nephropathy; Adults 18 years of age or older with Heart Failure; Adults 18 years of age or older with CKD (without type 2 diabetes); Adults 25 years of age or older with DM2 without ASCVD, Nephropathy, or Heart Failure; Pediatrics/Young Adults between 10 and 25 years of age with DM2]
   QUESTIONS BASED ON DIAGNOSIS SELECTED
   Adults 25 years of age or older with DM2 and ASCVD
   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); Jardiance tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
   3. Lab: Current eGFR:
   4. Date of eGFR lab (MMDDYY):

   Adults 25 years of age or older with DM2 with Nephropathy
   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); Jardiance tablets; losartan tablets; lisinopril, benazepril, captopril) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
   3. Lab: Current eGFR:
   4. Date of eGFR lab (MMDDYY):
   5. Lab: Current Albumin to Creatinine Ratio:
   6. Date of Albumin to Creatinine lab (MMDDYY):

   Adults 18 years of age or older with Heart Failure
   1. Patient's NYHA Functional Class (1-4):
   2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   3. Is there reasoning why alternatives (Jardiance tablets; losartan tablets; lisinopril, benazepril, captopril; Entresto tablets; atenolol tablets, metoprolol IR/ER tablets, bisoprolol tablets, carvedilol tablets, labetalol tablets, acebutolol capsules, propranolol ER capsules (60 mg, 80 mg, 120 mg, 160 mg) or IR tablets; spironolactone tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
   4. Lab: Current eGFR:
   5. Date of eGFR lab (MMDDYY):

   Adults 18 years of age or older with CKD (without type 2 diabetes)
   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

2. Is there reasoning why alternatives (Jardiance tablets; losartan tablets; lisinopril, benazepril, captopril) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Lab: Current eGFR:
4. Date of eGFR lab (MMDDYY):
5. Lab: Current Albumin to Creatinine Ratio:
6. Date of Albumin to Creatinine lab (MMDDYY):

Adults 25 years of age or older with DM2 without ASCVD, Nephropathy, or Heart Failure

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); glipizide, glimepiride, glyburide (1.25 mg. 2.5 mg, 5 mg) immediate-release tablets; pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Lab: Current eGFR:
4. Date of eGFR lab (MMDDYY):
5. Lab: Current A1c:
6. Date of A1c (MMDDYY):
7. Patient's current BMI:
8. Has the patient had bariatric surgery?

Pediatrics/Young Adults between 10 and 25 years of age with DM2

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Lab: Current eGFR:
4. Date of eGFR lab (MMDDYY):
5. Lab: Current A1c:
6. Date of A1c (MMDDYY):
7. Patient's current BMI:
8. Has the patient had bariatric surgery?

Renewal Review Questions

1. Lab: Current A1c:
2. Date of A1c (MMDDYY):

RATIONALE

- KP National Diabetes Guidelines recommend using SGLT-2i for people with type 2 diabetes with clinical ASCVD who are already taking metformin to reduce the risk of: (1) cardiovascular events (myocardial infarction or stroke) or cardiovascular death, (2) progression of renal disease and/or (3) death from renal causes, and/or (4) heart failure hospitalizations. The American College of Cardiology (ACC) 2020 Expert Consensus Decision Pathway on Novel Therapies for Cardiovascular Risk Reduction in Patients with Type 2 Diabetes, which is also endorsed by the American Diabetes Association (ADA), recommends SGLT-2i as a first-line treatment in patients with type 2 diabetes and one or more of the following: ASCVD, HFrEF, HFpEF (empagliflozin only), diabetic kidney disease (DKD), or at high risk for ASCVD.

- Preferred order of agents:
  1) Empagliflozin (Jardiance), formulary without PA, is the preferred agent for ASCVD, CKD, and HF due to strength of clinical trial data, range of approved indications, and cost (1/2 tab regimen)
  2) Canagliflozin (Invokana), non-formulary with PA, is the 2nd preferred option for ASCVD, CKD and DM2 patients without compelling indications. due to broad range of indications and cost (1/2 tab regimen).
  3) Dapagliflozin (Farxiga), non-formulary with PA, is the 2nd preferred option for HF, and the 3rd preferred option for ASCVD, CKD and DM2 patients without compelling indications due to broad range of indications but at high cost.
  4) Ertugliflozin (Steglatro), non-formulary with PA, is least preferred due to high cost, paucity of positive clinical trial data, and lack of additional FDA-approved indications. Specifically, ertugliflozin has been studied in patients with type 2 diabetes and ASCVD and did not improve cardiovascular outcomes while all three other SGLT-2i have demonstrated such benefits in this population.
  5) Bexagliflozin (Brenzavvy): non-formulary with PA, is least preferred due to high cost and lack of additional FDA-approved indications.
  6) Sotagliflozin (Inpefa): non-formulary with PA, is 3rd preferred for HF given shorter history of postmarketing safety data compared to other SGLT2i's approved for HF as well as the need to titrate sotagliflozin dose for when others are fixed-dose regimens. Sotagliflozin (Inpefa) is least preferred for glycemic control due to lack of clinical trial data and FDA-approved indication as well as its high cost.
- Jardiance (empagliflozin) is the preferred sodium glucose co-transporter 2 inhibitor (SGLT-2i) at Kaiser Permanente Colorado (KPCO) and can be used effectively and safely with a GFR down to 20 mL/min. In addition, the dose of 12.5 mg (1/2 of 25mg tablet) is an effective dose for all patients regardless of GFR.
- Based on the available evidence, various organizations endorse SGLT-2is use down to lower GFR levels than indicated in product labels:
  - American College of Cardiology Expert Consensus now recommends empagliflozin in GFR ≥ 20 mL/min (2021).
  - National Kidney Foundation recommends SGLT-2is in GFR ≥ 20 mL/min as long as there are no contraindications (2023).
  - American Diabetes Association recognizes SGLT-2is benefits in patients with GFR ≥ 20 mL/min (2023).

FDA APPROVED INDICATIONS for SGLT2 Inhibitors

Empagliflozin (Jardiance)

1. Improve glycemic control in patients with DM2
2. Reduce the risk of CV death in pts with DM2 + CVD
3. Reduce risk of CVD death and HF hospitalizations in pts with HF
4. Reduce risk of sustained eGFR decline, ESRD, CV death and hospitalizations in adults with CKD at risk of progression

Canagliflozin (Invokana)

1. Improve glycemic control in patients with DM2
2. Reduce risk of MACE in pts with DM2 + CVD
3. Reduce the risk of ESRD, doubling of creatinine, CV death, or HF hospitalization in pts with DM2 + diabetic nephropathy

Dapagliflozin (Farxiga)

1. Improve glycemic control in patients with DM2
2. Reduce risk of HF hosp in pts with DM2 + CVD/multiple CV RFs
3. Reduce the risk of CV death and HF hosp in patients with HFrEF NYHA II-IV
4. Reduce risk of sustained eGFR decline, ESRD, CV death, and hospitalization for HF in adults with CKD at risk of progression

Ertugliflozin (Steglatro)
1. Improve glycemic control in patients with DM2

Bexagliflozin (Brenzavvy)
1. Improve glycemic control in patients with DM2

Sotagliflozin (Inpefa)
1. Reduce the risk of CV death and HF hosp in pts with heart failure
2. Reduce the risk of CV death and HF hosp in pts with DM2 + CKD + CV RF(s)

REFERENCES

Medication use in Pediatric/Young Adults:
1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation date: 09/26/18
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

JESDUVROQ (DAPRODUSTAT)

Generic	Brand	HICL	GCN	Comments
DAPRODUSTAT	JESDUVROQ	48668		

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA
3. Patient is new to KPCO within the past 90 days and stable on therapy.

If met, approve indefinitely at HICL, max #3 per day.
If not met, Use Initial Criteria for review.

INITIAL CRITERIA: Must meet all the following:
1. The patient has a diagnosis of anemia due to chronic kidney disease (CKD).
2. The patient is 18 years of age or older.
3. Therapy is prescribed by a nephrologist.
4. The patient has been receiving dialysis for at least 4 months.
5. The patient has an eGFR of less than 60mL/min/1.73m2 corresponding to stage 3, 4, or 5 chronic kidney disease (CKD).
6. Patient has a hemoglobin level less than 12 g/dL.
7. Medication will not be used in combination with an erythropoiesis-stimulating agent (ESA) (e.g., Epogen, Procrit).

If met, approve at HICL x24 weeks, max #3 per day.
If not met, do not approve.

RENEWAL CRITERIA: Must meet one of the following:
1. The patient has a hemoglobin level of greater than or equal to 10 g/dL.
2. The patient's hemoglobin level has increased by at least 2 g/dL from their baseline level.

If met, approve indefinitely at HICL, max #3 per day.
If not met, do not approve.

RATIONALE
Ensure appropriate use consistent with FDA indication.

FDA APPROVED INDICATIONS
Indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months.

REFERENCES
Jesduvroq [Prescribing Information]. Durham, NC: GlaxoSmithKline; February 2023.

Creation Date: 11/2023
Effective Date: 12/2024
Reviewed Date: 11/2024
Revised Date:

DARIDOREXANT (QUVIVIQ)

Generic	Brand	HICL	GPID	Comments
DARIDOREXANT	QUVIVIQ	47751		Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all General Criteria and all Age Criteria in applicable age section

A. **General Criteria for All Requests:** Must meet all the following:
   1. Medication is prescribed by Behavioral Health or Sleep Medicine provider
   2. Patient must be age 18 or older
   3. Diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance
   4. Potential factors contributing to sleep disturbances have been addressed (e.g., inappropriate sleep hygiene, sleep environment issues and co-morbid conditions contributing to insomnia)
   5. Patient has no history of narcolepsy

B. **Age 65 Years or Older:** Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to trazodone
   2. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to ramelteon or OTC melatonin
   3. Trial and failure of, contraindication, or intolerance to lemborexant (Dayvigo) and/or Suvorexant (Belsomra)

   If initial criteria are met, approve at HICL indefinitely, max daily dose of 1 tablet.
   If initial criteria are not met, do not approve.

C. **Age Less Than 65 Years:** Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to trazodone
   2. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to ramelteon or OTC melatonin
   3. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to at least ONE of the following sedative-hypnotic alternatives: zolpidem (F), zaleplon (NF), eszopiclone (NF)

4. Trial and failure of, contraindication, or intolerance to lemborexant (Dayvigo) and/or Suvorexant (Belsomra)

   If initial criteria are met, approve at HICL indefinitely, max daily dose of 1 tablet.
   If initial criteria are not met, do not approve.

ePA Questions

1. Have factors that could contribute to sleep disturbances been addressed (e.g., inappropriate sleep hygiene, sleep environment issues and co-morbid conditions contributing to insomnia)?
2. Does the patient have history of narcolepsy?
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (OTC melatonin, trazodone, zolpidem IR tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

FDA APPROVED INDICATIONS

Dayvigo (lemborexant) and Belsomra (suvorexant), and Quviviq (daridorexant) are indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

REFERENCES

Per Health Plan

Creation Date: 03/2021
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

DAROLUTAMIDE (NUBEQA)

Generic	Brand	HICL	GPID	Other
DAROLUTAMIDE	NUBEQA	45909	46746	Non-Formulary

GUIDELINES FOR COVERAGE
Must meet all the following:

5. Patient has a diagnosis of prostate adenocarcinoma
6. Medication is prescribed by an Oncologist
7. Must have PSA greater than or equal to 2ng/dL
8. Patient has not experienced disease progression on any of the following: enzalutamide (Xtandi), abiraterone acetate (Zytiga, Yonsa), apalutamide (Erleada), or docetaxel (Taxotere)
9. Must have a diagnosis of nonmetastatic castration-resistant prostate cancer (M0CRPC) or metastatic castration-sensitive prostate cancer (M1CSPC), and meet all the diagnosis subtype-specific criteria below:
    a. Nonmetastatic Castration Resistant Prostate Cancer (M0CRPC): Must meet all:
        i. No metastasis observable on radiologic scans
        ii. Must have had PSA double in 10 months or less while on at least one ADT (androgen deprivation therapy) including: leuprolide (Eligard, Lupron), goserelin (Zoladex), triptorelin (Trelstar), histrelin (Supprelin, Vantas), degarelix (Firmagon)
    b. Metastatic Castration Sensitive Prostate Cancer (M1CSPC): Must meet all:
        i. Patient has documented metastatic disease that has not progressed on ADT (androgen deprivation therapy) including: leuprolide (Eligard, Lupron), goserelin (Zoladex), triptorelin (Trelstar), histrelin (Supprelin, Vantas), degarelix (Firmagon)
        ii. The patient is intolerant of, or has a contraindication to, abiraterone (Zytiga), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve indefinitely at HICL.
If criteria are not met, do not approve. Alternative is abiraterone [Zytiga] for patients with M1CSPC.

ePA Questions

1. Does the patient a diagnosis of prostate adenocarcinoma?
2. Lab: Current PSA:
3. Date of PSA Lab (MMDDYY):
4. Has the patient experienced disease progression on any of the following: enzalutamide (Xtandi), abiraterone acetate (Zytiga, Yonsa), darolutamide (Nubeqa), or docetaxel (Taxotere)?
5. Diagnosis subtype associated with this request: [check boxes for all diagnosis-subtypes listed in criteria: nonmetastatic castration-resistant prostate cancer (M0CRPC); metastatic castration-sensitive prostate cancer (M1CSPC)]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Nonmetastatic Castration-Resistant Prostate Cancer (M0CRPC)

1. Does the patient have any observable metastasis on radiologic scans?
2. Has the patient's PSA doubled in 10 months or less while on ADT (androgen deprivation therapy)?

Metastatic Castration-Sensitive Prostate Cancer (M1CSPC)

1. Has metastatic disease progressed on ADT (androgen deprivation therapy)?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (abiraterone (Zytiga)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Per Health Plan.
Enzalutamide is the KPCO preferred agent for nonmetastatic (M0) castration resistant prostate cancer (CRPC), unless history of seizures then darolutamide or apalutamide should be used. If the patient has metastatic castration sensitive prostate cancer (mCSPC), KPCO formulary alternatives of abiraterone or docetaxel are preferred.

FDA APPROVED INDICATIONS

Treatment of non-metastatic, castration-resistant prostate cancer (M0CRPC). Treatment of metastatic castration-sensitive prostate cancer (M1CSPC, in combination with docetaxel if darolutamide).

REFERENCES

1. Nubeqa (darolutamide) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; July 2019.
2. NCCN Clinical Practice Guidelines in Oncology. Prostate Cancer v.1.2025. www.nccn.org

Creation Date: 11/2018
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

DASATINIB

Generic	Brand	HICL	GPID	Other
DASATINIB	SPRYCEL	33855		Formulary, 2nd generation TKI

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA
1. Patient is new to KPCO within the past 90 days, patient is stable on therapy, and the medication has been prescribed by an oncologist.

If met, approve indefinitely.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet the following criteria based on diagnosis below:

A. Chronic Phase of Chronic Myeloid Leukemia (CML)
B. Accelerated or Blast Phase of Chronic Myeloid Leukemia (CML)
C. Acute Lymphoblastic Leukemia (ALL)
D. Gastrointestinal Stromal Tumor (GIST)
E. Chordoma
F. Chondrosarcoma
G. Melanoma
H. Myeloid/Lymphoid Neoplasms with Eosinophilia

A. **CML - Chronic Phase: Must meet all the following:**
   1. Medication is prescribed by a CPMG or affiliated oncologist.
   2. Must not have any of the following BCR-ABL1 mutations: T315I/A, F317L/V/I/C or V299L
   3. Patient must have Philadelphia Chromosome (aka BCR-ABL)
   4. Patients meets ONE of the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Patient has tried and failed imatinib (Gleevec) with an inadequate response that is not due to patient nonadherence.
      b. Patient has a documented intolerance to imatinib (Gleevec) not alleviated by dose reductions (≤200 mg/day [adult] or 260mg/m^2 [peds; if this calculates to >200mg/day use adult dose cutoff])
      c. Patient has a contraindication to imatinib (Gleevec)
      d. Patient has Intermediate or High Sokal Score (0.8 or greater)

If criteria are met, approve indefinitely.
If criteria are not met, do not approve [direct to imatinib (Gleevec) as appropriate].

B. **CML - Accelerated or Blast Phase: Must meet all the following:**
   1. Medication is prescribed by a CPMG or affiliated oncologist.
   2. Patient must have Philadelphia Chromosome (aka BCR-ABL)

3. Must have Accelerated Phase or Blast Phase CML
4. Must not have any of the following BCR-ABL1 mutations: T315I/A, F317L/V/I/C or V299L

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

C. **Acute Lymphoblastic Leukemia (ALL): Must meet all the following:**
1. Medication is prescribed by a CPMG or affiliated oncologist.
2. Patient must have Philadelphia Chromosome (aka BCR-ABL)
3. Must not have any of the following BCR-ABL1 mutations: T315I/A, F317L/V/I/C or V299L

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

D. **Gastrointestinal Stromal Tumor (GIST): Must meet all the following:**
1. Medication is prescribed by a CPMG or affiliated oncologist.
2. Patient must have metastatic or unresectable GIST.
3. Patient must have PDGFRA D842V mutation or other PDGFRA exon 18 mutation conferring resistance to imatinib (NCCN Category 1 recommendation).
4. Patient has had disease progression, documented intolerance, or contraindications to avapritinib (Ayvakit), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

E. **Chordoma**
1. Medication is prescribed by a CPMG or affiliated oncologist.
2. Patient has metastatic chordoma, or chordoma that is not amenable to localized therapies (e.g. radiation or surgery).
3. Patient has tried and failed, or has intolerance or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Imatinib (Gleevec)
   b. Sunitinib (Sutent)

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

F. **Chondrosarcoma**
1. Medication is prescribed by a CPMG or affiliated oncologist.
2. Patient has metastatic chondrosarcoma, or disease that is not amenable to localized therapies (e.g., radiation, surgery and/or locally administered ablative therapy).
3. Patient has tried and failed, or has intolerance or contraindication to pazopanib (Votrient), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

G. **Melanoma**
1. Medication is prescribed by a CPMG or affiliated oncologist.
2. Patient must have metastatic melanoma with disease progression or intolerance to one prior line of therapy.
3. Patient must have activating KIT mutation.
4. Patient must not have known KIT amplification, or KIT exon 17 mutation (e.g., D816H).
5. Patient must not have had disease progression on imatinib.
6. Patient must have attempted therapy with, and have a documented intolerance to imatinib (Gleevec) not alleviated by dose reductions (≤200 mg/day [adult] or 260mg/m^2 [peds; if this calculates to >200mg/day use adult dose cutoff]), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

H. **Other myeloid/lymphoid neoplasms with Eosinophilia and tyrosine kinase gene mutations: Must meet all the following:**
1. Must be prescribed by a CPMG or affiliated oncologist.
2. Patient must have a myeloid or lymphoid neoplasm with eosinophilia.
3. Patient must have ABL1 mutation/rearrangement.

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

ePA Questions

1. Is the patient stable on therapy with dasatinib (Sprycel)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Chronic Phase of Chronic Myeloid Leukemia (CML); Accelerated or Blast Phase of Chronic Myeloid Leukemia (CML); Acute Lymphoblastic Leukemia (ALL); Gastrointestinal Stromal Tumor (GIST); Chordoma; Chondrosarcoma; Melanoma; Myeloid/Lymphoid Neoplasms with Eosinophilia]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Chronic Phase of Chronic Myeloid Leukemia (CML)

1. Is the patient Philadelphia Chromosome (aka BCR-ABL) positive?
2. Does the patient have any of the following BCR-ABL1 mutations? Please check any/all that apply: T315I/A, F317L/V/I/C, V299L, None
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (imatinib (Gleevec) tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
5. Sokal Score:
6. Date of Sokal Score (MMDDYY):

Accelerated or Blast Phase of Chronic Myeloid Leukemia (CML)

1. Is the patient Philadelphia Chromosome (aka BCR-ABL) positive?
2. Does the patient have any of the following BCR-ABL1 mutations? Please check any/all that apply: T315I/A, F317L/V/I/C, V299L, None
3. Please check the box that applies to this patient's phase of CML: Chronic, Accelerated, Blast

Acute Lymphoblastic Leukemia (ALL)

1. Is the patient Philadelphia Chromosome (aka BCR-ABL) positive?
2. Does the patient have any of the following BCR-ABL1 mutations? Please check any/all that apply: T315I/A, F317L/V/I/C, V299L, None

Gastrointestinal Stromal Tumor (GIST)

1. Does the patient have metastatic or unresectable GIST?
2. Does the patient have any relevant mutations associated with this diagnosis? If yes, please note which one(s) in Provider Comment section below or attach applicable chart notes.
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (imatinib (Gleevec) tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Chordoma

1. Does the patient have metastatic chordoma, or chordoma that is not amenable to localized therapies (e.g. radiation or surgery)?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (Imatinib (Gleevec) tablets; Sunitinib (Sutent) capsules) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Chondrosarcoma

1. Does the patient have metastatic chondrosarcoma, or disease that is not amenable to localized therapies (e.g., radiation, surgery and/or locally administered ablative therapy)?

2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (pazopanib (Votrient) tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Melanoma

1. Does the patient have metastatic melanoma with disease progression?
2. Does the patient have any relevant mutations associated with this diagnosis? If yes, please note which one(s) in Provider Comment section below or attach applicable chart notes.
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (imatinib (Gleevec) tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Myeloid/Lymphoid Neoplasms with Eosinophilia

1. Does the patient have any relevant mutations associated with this diagnosis? If yes, please note which one(s) in Provider Comment section below or attach applicable chart notes.

REFERENCES

1. NCCN Clinical Practice Guidelines in Oncology Chronic Myeloid Leukemia v.2.2024 www.nccn.org
2. NCCN Clinical Practice Guidelines in Oncology Acute Lymphoblastic Leukemia v.4.2023 www.nccn.org
3. NCCN Clinical Practice Guidelines in Oncology Gastrointestinal Stromal Tumors (GISTs) v.1.2024 www.nccn.org
4. NCCN Clinical Practice Guidelines in Oncology Bone Cancer v.2.2024 www.nccn.org
5. NCCN Clinical Practice Guidelines in Oncology Melanoma: Cutaneous v.2.2024 www.nccn.org
6. NCCN Clinical Practice Guidelines in Oncology Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions v.1.2024 www.nccn.org

Creation Date: 11/2019
Effective Date: 06/2024
Reviewed Date: 05/2024
Revised Date: 05/2024

DEFLAZACORT (EMFLAZA)

Generic	Brand	HICL	GPID	Exception/Other
DEFLAZACORT	EMFLAZA 18MG	11668	43012	GSN 77113 Non-Formulary
DEFLAZACORT	EMFLAZA 22.75MG/ML SUSP	11668	43016	GSN 77117 Non-Formulary
DEFLAZACORT	EMFLAZA 30MG	11668	23762	GSN 27605 Non-Formulary
DEFLAZACORT	EMFLAZA 36MG	11668	43015	GSN 77116 Non-Formulary
DEFLAZACORT	EMFLAZA 6MG	11668	23761	GSN 27604 Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: All the following must be met:
1. Patient is at least 2 years old.
2. Patient has a diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by genetic testing.
3. Medication is prescribed by a neurologist.
4. Patient has tried prednisone or prednisolone for at least 6 months, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve at HICL indefinitely.
If initial criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Duchenne Muscular Dystrophy (DMD) confirmed by genetic testing]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (prednisone, prednisolone) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Prednisone is recommended as the first-line corticosteroid for use in patients with DMD. Prednisone and deflazacort are considered comparable in efficacy with regards to improving muscle strength and function in patients with DMD.

The American Academy of Neurology concluded that prednisone may be associated with a greater weight gain within the first 12 months of treatment (5 kg vs. 2 kg, respectively), with no significant difference in weight gain observed with longer-term use. Deflazacort treatment, however, may be associated with an increased risk of cataracts compared to prednisone. These differences have been

supported by a Cochrane Review noting very low quality of evidence. Deflazacort may be associated with less weight gain than prednisone in the short-term, but differences in weight gain with long-term use as well as any differences in other side effects, such as behavior changes, risk for fractures, cataracts, or effects on glucose control are not clearly known.

A 2022 study in 196 boys with DMD compared efficacy and safety outcomes of three different corticosteroid dosing regimens: daily prednisone, daily deflazacort, and intermittent prednisone. Across measures of motor function, both daily prednisone and daily deflazacort were more effective than intermittent prednisone and the daily regimens did not differ significantly.

FDA APPROVED INDICATIONS
Treatment of Duchenne muscular dystrophy (DMD) in patients 2 years and older

REFERENCES
KP InterRegional Practice Recommendations for Deflazacort final 20170822
Guglieri M, Bushby K, McDermott MP, et al. Effect of Different Corticosteroid Dosing Regimens on Clinical Outcomes in Boys With Duchenne Muscular Dystrophy: A Randomized Clinical Trial. JAMA. 2022 Apr 19;327(15):1456-1468.

Created: 9/26/2018
Effective: 04/2025
Last revised: 05/2024
Last reviewed: 03/2025

DESMOPRESSIN (NOCDURNA)

Generic	Brand	HICL	GPID	Comments
DESMOPRESSIN	NOCDURNA	02841	35296, 37509	Nonformulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

1. Patient must be age 18 years or older
2. Must have a diagnosis of nocturia due to nocturnal polyuria that has been confirmed with a 24-hour urine collection and the patient meets one of the following:
   a. The nocturnal urine volume exceeds 20% of the total 24-hour urine volume if the patient is less than 65 years of age
   b. The nocturnal urine volume exceeds 33% of the total 24-hour urine volume if the patient is 65 years of age or older
3. Patient awakens at least two times per night to void
4. Must have baseline sodium (Na) level within the past 30 days that is within normal limits (135 -145 mmol/L)
5. Requested dose does not exceed 27.7 mcg per day for women or 55.3 mcg per day for men
6. Patient has tried and failed, or had an intolerance to, desmopressin oral tablets and oral solution, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

If initial criteria are met, approve at GPID x1 year, max 1 tab per day.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:

1. Patient has shown improvement or decrease in nocturia episodes since starting on the drug
2. Patient has routine monitoring for serum sodium levels with normal level (135 -145 mmol/L) since initiating therapy and within the past 6 months

If renewal criteria are met, approve at GPID indefinitely, max 1 tab per day.
If renewal criteria are not met, do not approve.

RATIONALE

Desmopressin acetate has a black box warning regarding potential for hyponatremia. Serum sodium levels should be normal prior to prescribing and should be remeasured within 7 days and one month after starting. Patient 65 years or older should be monitored more frequently since they are at higher risk of hyponatremia. Desmopressin SL tablets have only been studied in adult patients.

FDA APPROVED INDICATIONS

Desmopressin SL tablets (Nocdurna) is FDA approved for treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

QUANTITY LIMITS: 1 SL tablet per day (either strength)

REFERENCES:

1. Nocdurna [package insert]. Parsippany, NJ: Ferring Pharmaceuticals: 2018.

Creation Date: 1/2022
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

DIACOMIT (STIRIPENTOL)

Generic	Brand	HICL	GPID	Exception/Other
STIRIPENTOL	DIACOMIT	35461		Nonformulary, Specialty Tier with Quantity Limit

GUIDELINES FOR COVERAGE

All the following must be met:
1. Medication is prescribed by a CMPG or affiliated neurologist or epileptologist.
2. Patient has a diagnosis of Dravet Syndrome (DS).
3. Patient is 6 months and older (weighing 15 lb or more).
4. The patient must be taking clobazam [stiripentol is not indicated for monotherapy and should be prescribed concurrently with clobazam].
5. The patient is stable on stiripentol (Diacomit), or the patient has failed all the following medications, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. a valproic acid derivative
   b. Epidiolex [Nonformulary requires Prior Authorization]

If initial criteria are met, approve at HICL indefinitely, max 6 capsules/packets per day.
If initial criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with stiripentol (Diacomit)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (clobazam tablets; divalproex sodium DR (12 hr) or ER (24 hr) tablets, divalproex sodium sprinkle caps (125 mg), valproic acid capsules (250 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Ensure appropriate use consistent with FDA indication.

FDA APPROVED INDICATIONS
Treatment of seizures associated Dravet syndrome (DS) in patients ≥2 years of age taking clobazam.
There are no clinical data to support the use of DIACOMIT as monotherapy in Dravet syndrome .

NOTES:
Given serious teratogenicity risk from this medicine, those members with pregnancy potential should be encouraged to have a negative pregnancy test, to be on highly effective contraception (ie IUD or implant) unless there is a valid reason not to and should not be lactating.

REFERENCES

Diacomit [Package Insert], Beauvais, France: Biocodex; 2022.

Creation date: 11/18/2020
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

DIFICID (FIDAXOMICIN)

Generic	Brand	HICL	GPID	Exception/Other
FIDAXOMICIN 40 MG/ML SUSP	DIFICID	37674	47769	
FIDAXOMICIN TABLETS	DIFICID	37674	30035	

GUIDELINES FOR USE

INITIAL CRITERIA: Must meet all of the following:

1. Patient has a diagnosis of *C. difficile* infection
2. Patient is intolerant to vancomycin or has had no improvement/worsening of symptoms during a 6-12 week regimen consisting of standard dose treatment (e.g. at least 125 mg four times daily for 10-14 days) with a gradual reduction in dosing frequency over the following 4-10 weeks, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If all the above are met, approve x1 fill, max qty: 20 tablets (max 150 mL if request is for susp).
If all the above are not met, do not approve.

RENEWAL CRITERIA: Must meet all of the following:

1. Diagnosis of *C. difficile* infection
2. Previous course of fidaxomicin resolved symptoms of C. difficile infection
3. Patient with C. difficile infection (relapse or recurrence) after course of Dificid
4. Patient did not have any improvement in symptoms while previously taking oral vancomycin, or the patient has a contraindication or intolerance to vancomycin, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If all the above are met, approve x1 fill, max qty: 20 tablets (max 150 mL if request is for susp).
If all the above are not met, do not approve.

ePA Questions

Initial Review Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (vancomycin) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions

1. Does the patient have C. difficile infection (relapse or recurrence) after one course of Dificid?
2. Did a previous course of fidaxomicin resolve symptoms of C. difficile infection?

3. Is there reasoning why alternatives (vancomycin) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
To ensure appropriate utilization of Dificid.

Renewal criteria considerations: If a patient receives vancomycin initially, improves, and then when vancomycin stops their symptoms return, AND the patient has the same issue with Dificid (things improve, only to return after Dificid course ends), then the two drugs have both shown to work, but not long-term. Dificid should not be given long-term in that case, go back to vancomycin. For cases where the patient's symptoms did not improve or worsened while on vancomycin initially, and a course of Dificid worked in that patient, only to have symptoms return upon end of Dificid course, then it is reasonable to renew.

FDA APPROVED INDICATIONS
Treatment of C. difficile infection

REFERENCES

Creation date: 11/2021
Effective date: 12/2024
Reviewed date: 11/2024
Revised date: 11/2024

DIHYDROERGOTAMINE NASAL SRAY - STEP THERAPY

Generic	Brand	HICL	GPID	Comments
DIHYDROERGOTAMINE MESYLATE (DHE) NASAL SPRAY	MIGRANAL	00155	24732	GENERIC ONLY - formulary

Step Therapy Criteria

Patient has tried and failed, or had an intolerance/allergy to any triptan product, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If met, override restriction only for generic dihydroergotamine nasal spray (Migranal) at GPID-G indefinitely.
If not met, do not approve.

RATIONALE
Per Health Plan

REFERENCE
Note: this product does have a quantity limit per fill applied to it. The claims system will first perform the step therapy look back for preferred drug use with the below HICLs in the claim history. Once the step therapy criteria are met, the system will apply the quantity limit to the claim, ensuring the quantities above the limit do not pay:

Generic Name	HICL Code
RIZATRIPTAN BENZOATE	18535
SUMATRIPTAN SUCCINATE	6587
NARATRIPTAN HCL	13266
SUMATRIPTAN	12779
ZOLMITRIPTAN	12958
ELETRIPTAN HYDROBROMIDE	23093
SUMATRIPTAN-NAPROXEN SODIUM	35534
ALMOTRIPTAN MALATE	21894
FROVATRIPTAN SUCCINATE	22988
SUMATRIPTAN SUCCINATE & CAMPHOR-MENTHOL	43394

Since Migranal is available as a generic, the Brand Migranal will remain non-formulary.

Creation date: 01/2024
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

DPP-4 INHIBITOR - JANUVIA

Generic	Brand	HICL	GPID	Exception/Other
SITAGLIPTIN	JANUVIA	34126	97400, 97398, 97399	Non-formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following diagnoses and meet all diagnosis-specific criteria below:

A - DM2 in adults older than 25 years old
B - DM2 in pediatrics/young adults age 10 to 25 years

A. To treat type 2 diabetes in adults older than 25 years of age: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is within 1% or less from their designated goal
   2. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
   3. If on insulin, unable to adjust insulin regimen to achieve better control
   4. Patient has tried and failed or has an intolerance or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. maximum dose metformin, maximum dose sulfonylurea, maximum dose pioglitazone, Jardiance, and all possible combinations thereof
      b. sitagliptin (Zituvio)

      If initial criteria are met, approve at HICL x6 months.
      If initial criteria are not met, do not approve.

B. To treat type 2 diabetes in young adult/pediatric patients 10 years of age to less than 25 years of age: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is within 1% or less from their designated goal
   2. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
   3. Patient has contraindications to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. maximum dose metformin, maximum dose pioglitazone, Jardiance, and all possible combinations thereof

b. sitagliptin (Zituvio)

If initial criteria are met, approve at HICL x6 months.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
2. Most recent HgbA1c is at goal

If renewal criteria are met, approve at HICL x12 months.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: DM2 in Adults Older Than 25 Years Old, DM2 in Pediatrics/Young Adults Age 10 to 25 Years]

QUESTIONS BASED ON DIAGNOSIS SELECTED

DM2 in Adults Older Than 25 Years Old
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); glipizide, glimepiride, glyburide (1.25 mg. 2.5 mg, 5 mg) immediate-release tablets; pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

DM2 in Pediatrics/Young Adults Age 10 to 25 Years
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

Renewal Review questions
1. Current A1c lab (%):
2. Date of A1c lab (MMDDYY):
3. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

RATIONALE

- DPP-4 inhibitors [i.e., linagliptin (Tradjenta), alogliptin (Nesina), sitagliptin (Zituvio, Januvia), saxagliptin (Onglyza)] are not considered first- or second-line medications for the treatment of type 2 diabetes due to minimal A1c lowering (0.5% to 0.7%), lack of positive outcomes data (i.e., ASCVD, CKD, HF), undetermined long-term safety and high cost compared to other agents.
- SGLT-2 inhibitors (such as empagliflozin and canagliflozin) are preferred over DPP-4 inhibitors due to extra benefits in HF, chronic kidney disease, and ASCVD.
- Kaiser Permanente does not promote combination medications [i.e., Jentadueto (linagliptin/metformin)] and are excluded from coverage (not eligible for NF review) for several reasons:
  - lack of medical advantage
  - ease of dosage adjustment and discontinuation of a single medication
  - ease of identification and management of a side effect or an allergy of a single medication

FDA APPROVED INDICATIONS

All DPP-4 inhibitors are indicated to improve glycemic control in adults with type 2 diabetes mellitus

REFERENCES

Medication use in Pediatric/Young Adults:

1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation date: 09/26/2018
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

DPP-4 INHIBITOR - NESINA

Generic	Brand	HICL	GPID	Comments
ALOGLIPTIN	NESINA	39968	34085, 34076	Non-formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following diagnoses and meet all diagnosis-specific criteria below:

A - DM2 in adults older than 25 years old
B - DM2 in pediatrics/young adults age 10 to 25 years

A. To treat type 2 diabetes in adults older than 25 years of age: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is within 1% or less from their designated goal
   2. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
   3. If on insulin, unable to adjust insulin regimen to achieve better control
   4. Patient has contraindications to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. maximum dose metformin, maximum dose sulfonylurea, maximum dose pioglitazone, Jardiance, and all possible combinations thereof
      b. sitagliptin (Zituvio)

      If initial criteria are met, approve at HICL x6 months.
      If initial criteria are not met, do not approve.

B. To treat type 2 diabetes in young adult/pediatric patients 10 years of age to less than 25 years of age: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is within 1% or less from their designated goal
   2. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
   3. Patient has contraindications to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. maximum dose metformin, maximum dose pioglitazone, Jardiance, and all possible combinations thereof
      b. sitagliptin (Zituvio)

If initial criteria are met, approve at HICL x6 months.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
2. Most recent HgbA1c is at goal

If renewal criteria are met, approve at HICL x12 months.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: DM2 in Adults Older Than 25 Years Old, DM2 in Pediatrics/Young Adults Age 10 to 25 Years]

QUESTIONS BASED ON DIAGNOSIS SELECTED

DM2 in Adults Older Than 25 Years Old
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); glipizide, glimepiride, glyburide (1.25 mg. 2.5 mg, 5 mg) immediate-release tablets; pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

DM2 in Pediatrics/Young Adults Age 10 to 25 Years
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

Renewal Review questions
1. Current A1c lab (%):
2. Date of A1c lab (MMDDYY):
3. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

RATIONALE
- DPP-4 inhibitors [i.e., linagliptin (Tradjenta), alogliptin (Nesina), sitagliptin (Zituvio, Januvia), saxagliptin (Onglyza)] are not considered first- or second-line medications for the treatment of type

2 diabetes due to minimal A1c lowering (0.5% to 0.7%), lack of positive outcomes data (i.e., ASCVD, CKD, HF), undetermined long-term safety and high cost compared to other agents.
- SGLT-2 inhibitors (such as empagliflozin and canagliflozin) are preferred over DPP-4 inhibitors due to extra benefits in HF, chronic kidney disease, and ASCVD.
- Kaiser Permanente does not promote combination medications [i.e., Jentadueto (linagliptin/metformin)] and are excluded from coverage (not eligible for NF review) for several reasons:
  - lack of medical advantage
  - ease of dosage adjustment and discontinuation of a single medication
  - ease of identification and management of a side effect or an allergy of a single medication

FDA APPROVED INDICATIONS
All DPP-4 inhibitors are indicated to improve glycemic control in adults with type 2 diabetes mellitus

REFERENCES
Medication use in Pediatric/Young Adults:
1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation date: 09/26/2018
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

DPP-4 INHIBITOR - ONGLYZA

Generic	Brand	HICL	GPID	Comments
SAXAGLIPTIN	ONGLYZA	36471	27393, 27394	Non-formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following diagnoses and meet all diagnosis-specific criteria below :

A - DM2 in adults older than 25 years old
B - DM2 in pediatrics/young adults age 10 to 25 years

A. To treat type 2 diabetes in adults older than 25 years of age: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is within 1% or less from their designated goal
   2. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
   3. If on insulin, unable to adjust insulin regimen to achieve better control
   4. Patient has contraindications to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. maximum dose metformin, maximum dose sulfonylurea, maximum dose pioglitazone, Jardiance, and all possible combinations thereof
      b. sitagliptin (Zituvio)

      If initial criteria are met, approve at HICL x6 months.
      If initial criteria are not met, do not approve.

B. To treat type 2 diabetes in young adult/pediatric patients 10 years of age to less than 25 years of age: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is within 1% or less from their designated goal
   2. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
   3. Patient has contraindications to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. maximum dose metformin, maximum dose pioglitazone, Jardiance, and all possible combinations thereof
      b. sitagliptin (Zituvio)

      If initial criteria are met, approve at HICL x6 months.

If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
2. Most recent HgbA1c is at goal

If renewal criteria are met, approve at HICL x12 months.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: DM2 in Adults Older Than 25 Years Old, DM2 in Pediatrics/Young Adults Age 10 to 25 Years]

QUESTIONS BASED ON DIAGNOSIS SELECTED

DM2 in Adults Older Than 25 Years Old
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); glipizide, glimepiride, glyburide (1.25 mg. 2.5 mg, 5 mg) immediate-release tablets; pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

DM2 in Pediatrics/Young Adults Age 10 to 25 Years
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

Renewal Review questions
1. Current A1c lab (%):
2. Date of A1c lab (MMDDYY):
3. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

RATIONALE
- DPP-4 inhibitors [i.e., linagliptin (Tradjenta), alogliptin (Nesina), sitagliptin (Zituvio, Januvia), saxagliptin (Onglyza)] are not considered first- or second-line medications for the treatment of type

2 diabetes due to minimal A1c lowering (0.5% to 0.7%), lack of positive outcomes data (i.e., ASCVD, CKD, HF), undetermined long-term safety and high cost compared to other agents.
- SGLT-2 inhibitors (such as empagliflozin and canagliflozin) are preferred over DPP-4 inhibitors due to extra benefits in HF, chronic kidney disease, and ASCVD.
- Kaiser Permanente does not promote combination medications [i.e., Jentadueto (linagliptin/metformin)] and are excluded from coverage (not eligible for NF review) for several reasons:
  - lack of medical advantage
  - ease of dosage adjustment and discontinuation of a single medication
  - ease of identification and management of a side effect or an allergy of a single medication

FDA APPROVED INDICATIONS
All DPP-4 inhibitors are indicated to improve glycemic control in adults with type 2 diabetes mellitus

REFERENCES
Medication use in Pediatric/Young Adults:
1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation date: 09/26/2018
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

DPP-4 INHIBITOR - TRADJENTA

Generic	Brand	HICL	GPID	Comments
LINAGLIPTIN	TRADJENTA	37576	29890	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following diagnoses and meet all diagnosis-specific criteria below:

A - DM2 in adults older than 25 years old
B - DM2 in pediatrics/young adults age 10 to 25 years

A. To treat type 2 diabetes in adults older than 25 years of age: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is within 1% or less from their designated goal
   2. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
   3. If on insulin, unable to adjust insulin regimen to achieve better control
   4. Patient has contraindications to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. maximum dose metformin, maximum dose sulfonylurea, maximum dose pioglitazone, Jardiance, and all possible combinations thereof
      b. sitagliptin (Zituvio)

      If initial criteria are met, approve at HICL x6 months.
      If initial criteria are not met, do not approve.

B. To treat type 2 diabetes in young adult/pediatric patients 10 years of age to less than 25 years of age: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is within 1% or less from their designated goal
   2. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
   3. Patient has contraindications to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. maximum dose metformin, maximum dose pioglitazone, Jardiance, and all possible combinations thereof
      b. sitagliptin (Zituvio)

      If initial criteria are met, approve at HICL x6 months.

If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
2. Most recent HgbA1c is at goal

If renewal criteria are met, approve at HICL x12 months.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: DM2 in Adults Older Than 25 Years Old, DM2 in Pediatrics/Young Adults Age 10 to 25 Years]

QUESTIONS BASED ON DIAGNOSIS SELECTED

DM2 in Adults Older Than 25 Years Old
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); glipizide, glimepiride, glyburide (1.25 mg. 2.5 mg, 5 mg) immediate-release tablets; pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

DM2 in Pediatrics/Young Adults Age 10 to 25 Years
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

Renewal Review questions
1. Current A1c lab (%):
2. Date of A1c lab (MMDDYY):
3. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

RATIONALE
- DPP-4 inhibitors [i.e., linagliptin (Tradjenta), alogliptin (Nesina), sitagliptin (Zituvio, Januvia), saxagliptin (Onglyza)] are not considered first- or second-line medications for the treatment of type

2 diabetes due to minimal A1c lowering (0.5% to 0.7%), lack of positive outcomes data (i.e., ASCVD, CKD, HF), undetermined long-term safety and high cost compared to other agents.
- SGLT-2 inhibitors (such as empagliflozin and canagliflozin) are preferred over DPP-4 inhibitors due to extra benefits in HF, chronic kidney disease, and ASCVD.
- Kaiser Permanente does not promote combination medications [i.e., Jentadueto (linagliptin/metformin)] and are excluded from coverage (not eligible for NF review) for several reasons:
  - lack of medical advantage
  - ease of dosage adjustment and discontinuation of a single medication
  - ease of identification and management of a side effect or an allergy of a single medication

FDA APPROVED INDICATIONS
All DPP-4 inhibitors are indicated to improve glycemic control in adults with type 2 diabetes mellitus

REFERENCES
Medication use in Pediatric/Young Adults:
1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation date: 09/26/2018
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

DPP-4 INHIBITOR - ZITUVIO

Generic	Brand	HICL	GPID	Comments
SITAGLIPTIN	ZITUVIO	49275	54893, 54894, 54895	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following diagnoses and meet all diagnosis-specific criteria below:

A - DM2 in adults older than 25 years old
B - DM2 in pediatrics/young adults age 10 to 25 years

A. To treat type 2 diabetes in adults older than 25 years of age: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is within 1% or less from their designated goal
   2. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
   3. Patient has contraindications to, is currently using, or has failed maximum dose metformin, maximum dose sulfonylurea, maximum dose pioglitazone, Jardiance, and all possible combinations thereof, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception
   4. If on insulin, unable to adjust insulin regimen to achieve better control

      If initial criteria are met, approve at HICL x6 months.
      If initial criteria are not met, do not approve.

B. To treat type 2 diabetes in young adult/pediatric patients 10 years of age to less than 25 years of age: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is within 1% or less from their designated goal
   2. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
   3. Patient has contraindications to, is currently using, or has failed maximum dose metformin, maximum dose pioglitazone, Jardiance, and all possible combinations thereof, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

      If initial criteria are met, approve at HICL x6 months.
      If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Not currently using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)
2. Most recent HgbA1c is at goal

If renewal criteria are met, approve at HICL x12 months.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: DM2 in Adults Older Than 25 Years Old, DM2 in Pediatrics/Young Adults Age 10 to 25 Years]

QUESTIONS BASED ON DIAGNOSIS SELECTED

DM2 in Adults Older Than 25 Years Old
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); glipizide, glimepiride, glyburide (1.25 mg. 2.5 mg, 5 mg) immediate-release tablets; pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

DM2 in Pediatrics/Young Adults Age 10 to 25 Years
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

Renewal Review questions
1. Current A1c lab (%):
2. Date of A1c lab (MMDDYY):
3. Is the patient using a GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

RATIONALE
- DPP-4 inhibitors [i.e., linagliptin (Tradjenta), alogliptin (Nesina), sitagliptin (Zituvio, Januvia), saxagliptin (Onglyza)] are not considered first- or second-line medications for the treatment of type 2 diabetes due to minimal A1c lowering (0.5% to 0.7%), lack of positive outcomes data (i.e., ASCVD, CKD, HF), undetermined long-term safety and high cost compared to other agents.

- SGLT-2 inhibitors (such as empagliflozin and canagliflozin) are preferred over DPP-4 inhibitors due to extra benefits in HF, chronic kidney disease, and ASCVD.
- Kaiser Permanente does not promote combination medications [i.e., Jentadueto (linagliptin/metformin)] and are excluded from coverage (not eligible for NF review) for several reasons:
  - lack of medical advantage
  - ease of dosage adjustment and discontinuation of a single medication
  - ease of identification and management of a side effect or an allergy of a single medication

FDA APPROVED INDICATIONS
All DPP-4 inhibitors are indicated to improve glycemic control in adults with type 2 diabetes mellitus

REFERENCES
Medication use in Pediatric/Young Adults:
1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation date: 05/2024
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

DRY EYE DISEASE MEDICATIONS
MIEBO

Generic	Brand	HICL	GPID	Exception/Other
PERFLUOROHEXYLOCTANE/PF	MIEBO	45391	45636	Nonformulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all of the following:
1. Prescribed by an optometrist or ophthalmologist
2. Patient has a diagnosis of dry eye disease (DED)
3. Patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - over-the-counter (OTC) artificial tears
   - at least 3 consecutive months of therapy with cyclosporin ophthalmic drops
   - Xiidra
   - Tyrvaya

If initial criteria are met, approve indefinitely at GPID.
If initial criteria not met, do not approve.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (over-the-counter (OTC) artificial tears, at least 3 consecutive months of therapy with cyclosporin ophthalmic drops) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
To ensure appropriate utilization of Xiidra, Tyrvaya, and Miebo.

FDA APPROVED INDICATIONS
Treatment of the signs and symptoms of dry eye disease (DED)

REFERENCES
1. Xiidra (lifitegrast) [prescribing information]. Lexington, MA: Shire US Inc; December 2017.
2. Tyrvaya (varenicline) [prescribing information]. Princeton, NJ: Oyster Point Pharma; October 2021.

Creation date: 09/26/2018
Effective date: 10/2024
Reviewed date: 09/2024
Revised date: 09/2024

KAISER PERMANENTE

KAISER COLORADO HMO MR GUIDELINES

DRY EYE DISEASE MEDICATIONS
TYRVAYA

Generic	Brand	HICL	GPID	Exception/Other
VARENICLINE NASAL SPRAY	TYRVAYA	33766*	51384	Nonformulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all of the following:

1. Prescribed by an optometrist or ophthalmologist
2. Patient has a diagnosis of dry eye disease (DED)
3. Patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - over-the-counter (OTC) artificial tears
   - at least 3 consecutive months of therapy with cyclosporin ophthalmic drops
   - Xiidra

If initial criteria are met, approve indefinitely at GPID.
If initial criteria not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (over-the-counter (OTC) artificial tears, at least 3 consecutive months of therapy with cyclosporin ophthalmic drops) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

To ensure appropriate utilization of Xiidra, Tyrvaya, and Miebo.

FDA APPROVED INDICATIONS

Treatment of the signs and symptoms of dry eye disease (DED)

REFERENCES

1. Xiidra (lifitegrast) [prescribing information]. Lexington, MA: Shire US Inc; December 2017.
2. Tyrvaya (varenicline) [prescribing information]. Princeton, NJ: Oyster Point Pharma; October 2021.

*HICL includes oral varenicline (Chantix)

Creation date: 09/26/2018
Effective date: 10/2024
Reviewed date: 09/2024
Revised date: 09/2024

DRY EYE DISEASE MEDICATIONS
XIIDRA

Generic	Brand	HICL	GPID	Exception/Other
LIFITEGRAST	XIIDRA	43610	41847	Nonformulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all of the following:
1. Prescribed by an optometrist or ophthalmologist
2. Patient has a diagnosis of dry eye disease (DED)
3. Patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - over-the-counter (OTC) artificial tears
   - at least 3 consecutive months of therapy with cyclosporin ophthalmic drops

If initial criteria are met, approve indefinitely at GPID.
If initial criteria not met, do not approve.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (over-the-counter (OTC) artificial tears, at least 3 consecutive months of therapy with cyclosporin ophthalmic drops) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
To ensure appropriate utilization of Xiidra, Tyrvaya, and Miebo.

FDA APPROVED INDICATIONS
Treatment of the signs and symptoms of dry eye disease (DED)

REFERENCES
1. Xiidra (lifitegrast) [prescribing information]. Lexington, MA: Shire US Inc; December 2017.
2. Tyrvaya (varenicline) [prescribing information]. Princeton, NJ: Oyster Point Pharma; October 2021.

Creation date: 09/26/2018
Effective date: 10/2024
Reviewed date: 09/2024
Revised date: 09/2024

DUPILUMAB (DUPIXENT)

Generic	Brand	HICL	GPID	SIZE	Exception/Other
DUPILUMAB 200 MG/1.14 ML	DUPIXENT	44180	48785, 45522	1.14	F, Specialty Tier
DUPILUMAB 300 MG/2 ML	DUPIXENT	44180	43222, 48277	2	F, Specialty Tier

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA

1. Medication is prescribed by a dermatologist, allergist, pulmonologist, gastroenterologist, or ENT specialist
2. Patient is new to KPCO within the past 90 days, noted as stable on therapy, and has one of the following indications:
   a. Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)
   b. Asthma (Moderate/Severe)
   c. Chronic Obstructive Pulmonary Disease (COPD)
   d. Atopic Dermatitis (Moderate/Severe)
   e. Eosinophilic Esophagitis
   f. Prurigo Nodularis
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication

If above criteria are met, approve indefinitely at HICL, with the following quantity limits based on indication:

EoE: max 8 mL (4 syringes/pens) per 28 days [MDD 0.29].
All other above indications: max 4 mL (2 syringes/pens) per 28 days [MDD 0.15].

If above criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet General Criteria and the Diagnosis-Specific Criteria below:

A. GENERAL CRITERIA FOR ALL REQUESTS
B. Patient 12 years of age or older with CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS (CRSwNP)
C. ASTHMA (MODERATE/SEVERE)
D. CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)
E. Patient 6 years of age or younger with MODERATE/SEVERE ATOPIC DERMATITIS
F. Patient 7-17 years of age with MODERATE/SEVERE ATOPIC DERMATITIS
G. Patient 18 years of age or older with MODERATE/SEVERE ATOPIC DERMATITIS
H. EOSINOPHILIC ESOPHAGITIS
I. PRURIGO NODULARIS

A. GENERAL CRITERIA FOR ALL REQUESTS:
   1. Must be prescribed by a CPMG or an affiliated dermatologist, allergist, pulmonologist, gastroenterologist, or ENT specialist
   2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication

B. Patient 12 years of age or older with DIAGNOSIS OF CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS (CRSwNP): Must meet all the following:
   1. Patient has persistent rhinosinusitis symptoms (lasting longer than 12 weeks) with severe nasal obstruction and rhinorrhea or reduced sense of smell.

2. Patient has had sinus surgery.
3. Patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - At least one intranasal corticosteroid [e.g. fluticasone, mometasone, etc.]
   - At least one antileukotriene antagonists [e.g. montelukast, zafirlukast, zileuton]
   - Two or more courses of oral corticosteroids in the past year

If criteria are met, approve indefinitely at HICL, max 4mL (2 pens/syringes) per 28 days [MDD 0.15].
If criteria are not met, do not approve.

C. DIAGNOSIS OF MODERATE/SEVERE ASTHMA: Must meet all the following:
1. Uncontrolled asthma as evidenced by ANY one of the following:
   a. Two or more asthma exacerbations requiring systemic corticosteroids (at least 3 days each) in the past 12 months
   b. one asthma-related hospitalization in the past 12 months
   c. Asthma Control Test (ACT) consistently less than 20
2. Adherent (greater than 75% proportion of days covered) to optimized drug therapy (triple drug therapy with high-dose ICS-LABA plus LAMA) for the previous 6 months, OR has contraindications or intolerance to ICS/LABA/LAMA, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
3. Patient meets one of the following classifications:
   a. Patient has concurrent CRSwNP
   b. Patient does not have CRSwNP and does not have eosinophilic asthma
   c. Patient has eosinophilic asthma without CRSwNP and has failed therapy with Fasenra, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at HICL x1 fill for 14 days (do NOT code max day supply 14), [MDD: 0.29] max 4mL (2 pens/syringes) per 14 days (loading dose), then approve indefinitely at HICL, max 4mL (2 pens/syringes) per 28 days [MDD 0.15] (maintenance dose).
If criteria are not met, do not approve.

D. CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD): Must meet all the following:
   1. Patient has documentation of ONE of the following:
      i. At least 1 exacerbation requiring hospitalization in the past 12 months OR
      ii. At least 2 exacerbations treated with short-acting bronchodilators and oral corticosteroids, with or without antibiotics, in the past 12 months
   2. Adherent (greater than 75% proportion of days covered) to optimized drug therapy (triple drug therapy with high-dose ICS-LABA plus LAMA) taken WITH azithromycin 250-500mg three times per week OR roflumilast for at least the previous 12 months, OR has contraindications or intolerance to ICS/LABA/LAMA, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception
   3. Patient will continue to use triple maintenance (LAMA/LABA/ICS) therapy for COPD [unless intolerance or contraindication]

If initial criteria are met, approve x 1 year at HICL, max 4mL (2 pens/syringes) per 28 days [MDD 0.15]. If criteria are not met, do not approve.

E. Patient 6 years of age or younger with MODERATE/SEVERE ATOPIC DERMATITIS: Must meet all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Patient has experienced an inadequate response or intolerance to 2 topical therapies including topical corticosteroid, topical calcineurin inhibitor, or crisaborole (Eucrisa) 2% ointment [trials can be in the same drug class, one must be a topical steroid]

If criteria are met, approve at HICL indefinitely, max 4mL (2 pens/syringes) per 28 days [MDD 0.15]. If criteria are not met, do not approve.

F. Patient 7-17 years of age with MODERATE/SEVERE ATOPIC DERMATITIS: Must meet all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Patient has experienced an inadequate response or intolerance to a topical corticosteroid or topical calcineurin inhibitor.

2. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one**, or contraindication (see table 2) to at least **two** of the following therapies, or the patient is reported as having very high disease activity (i.e., greater than 50% BSA), or reported as being on a prior atopic dermatitis biologic or oral JAK inhibitor therapy within the past 4 months:
   - Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
   - Azathioprine
   - Cyclosporine
   - Methotrexate
   - Mycophenolate

If criteria are met, approve x1 fill at HICL for 14 days (do NOT code max day supply 14), [MDD: 0.29] max 4mL (2 pens/syringes) per 14 days (loading dose), then indefinitely at HICL, max 4mL (2 pens/syringes) per 28 days [MDD 0.15] (maintenance dose).
If criteria are not met, do not approve.

G. Patient 18 years of age or older with MODERATE/SEVERE ATOPIC DERMATITIS: Must meet all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Patient has experienced an inadequate response or intolerance to a topical corticosteroid or topical calcineurin inhibitor.
   2. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one**, or contraindication (see table 2) to at least **two** of the following pre-biologic therapies, or the patient is reported as being on a prior atopic dermatitis biologic or oral JAK inhibitor therapy within the past 4 months:
      - Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
      - Azathioprine
      - Cyclosporine
      - Methotrexate
      - Mycophenolate

If criteria are met, approve x1 fill at HICL for 14 days (do NOT code max day supply 14), [MDD: 0.29] max 4mL (2 pens/syringes) per 14 days (loading dose), then indefinitely at HICL, max 4mL (2 pens/syringes) per 28 days [MDD 0.15] (maintenance dose).
If criteria are not met, do not approve.

H. DIAGNOSIS OF EOSINOPHILIC ESOPHAGITIS
   1. Age 1 year and older and weighing at least 15 kg.
   2. Two or more episodes of dysphagia per week.
   3. Inadequate response after at least 8-week trial, or intolerance/contraindication to all the following therapies, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or

another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
- Twice daily PPI therapy
- Swallowed ICS (inhaled corticosteroid) therapy

If criteria are met, approve indefinitely at HICL, max 8mL (4 pens/syringes) per 28 days [MDD 0.29].
If criteria are not met, do not approve.

I. DIAGNSOSIS OF PRURIGO NODULARIS: Must meet age criteria and all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
1. Age 18 years of age or older.
2. Patient with inadequate response (after at least 3 months) or intolerance to ONE of the following:
   - Topical corticosteroid
   - Topical calcineurin inhibitor
   - Intralesional corticosteroid (at least 2 administrations)
3. Patient with inadequate response (after at least 3 months), intolerance, or contraindication to phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy.
4. Patient with inadequate response (after at least 2 months) or intolerance to at least TWO of the following: (can be within the same drug category)
   - Topical vitamin D analogue (calcipotriene, calcitriol)
   - Gabapentinoid: gabapentin or pregabalin
   - Antidepressant: tricyclic antidepressant, selective serotonin reuptake inhibitor (SSRI), or serotonin and norepinephrine reuptake inhibitor (SNRI)
   - Immunosuppressant: methotrexate, cyclosporine

If criteria are met, approve at HICL x1 fill for 14 days (do NOT code max day supply 14), [MDD: 0.29] max 4mL (2 pens/syringes) per 14 days (loading dose), then indefinitely at HICL, max 4mL (2 pens/syringes) per 28 days [MDD 0.15] (maintenance dose).
If criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following criteria based on diagnosis:

A. Chronic Obstructive Pulmonary Disease (COPD): Must meet all the following:
1. Patient is currently using dual (LAMA/LABA) or triple maintenance (LAMA/LABA/ICS) therapy +/- azithromycin for COPD, unless has an intolerance or contraindication
2. Patient has demonstrated clinical benefit by decreased symptoms and/or exacerbations

If met, approve x 1 year at HICL, max 4mL (2 pens/syringes) per 28 days [MDD 0.15].
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Is the patient using another biologic or advanced small molecule for the same indication?
2. Is the patient stable on therapy with dupilumab?
3. For patients noted stable on therapy, start date of therapy (MMDDYY):
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP); Asthma (Moderate/Severe); Chronic Obstructive Pulmonary Disease (COPD); Patient 6 years of age or younger with Atopic Dermatitis (Moderate/Severe); Patient 7-17 years of age with Atopic Dermatitis (Moderate/Severe); Patient 18 years of age or older with Atopic Dermatitis (Moderate/Severe); Eosinophilic Esophagitis; Prurigo Nodularis]

QUESTIONS BASED ON DIAGNOSIS SELECTED

CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS (CRSwNP)

1. Does the patient have persistent rhinosinusitis symptoms (lasting longer than 12 weeks) with severe nasal obstruction and rhinorrhea or reduced sense of smell?
2. Has the patient had sinus surgery?
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone, mometasone, etc.], antileukotriene antagonists [e.g., montelukast]) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
5. How many courses of oral corticosteroids has the patient taken for this indication in the past year?

MODERATE/SEVERE ASTHMA

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (triple drug therapy with high-dose ICS-LABA plus LAMA) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Has the patient experienced any of the following (check any/all boxes that apply):
    a. Two or more asthma exacerbations requiring systemic corticosteroids (at least 3 days each) in the past 12 months
    b. one asthma-related hospitalization in the past 12 months
    c. Asthma Control Test (ACT) consistently less than 20
4. Patient meets one of the following classifications (check any/all boxes that apply):
    a. Patient has concurrent CRSwNP
    b. Patient does not have CRSwNP and does not have eosinophilic asthma
    c. Patient has eosinophilic asthma without CRSwNP and has failed therapy with Fasenra

Patient 6 years of age or younger with MODERATE/SEVERE ATOPIC DERMATITIS

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

2. Is there reasoning why alternatives (topical corticosteroids, tacrolimus ointment) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Patient 7-17 years of age with MODERATE/SEVERE ATOPIC DERMATITIS

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (topical corticosteroids, tacrolimus ointment, phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy, azathioprine, cyclosporine, methotrexate, mycophenolate) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Percent body surface area (BSA) impacted:

Patient 18 years of age or older with MODERATE/SEVERE ATOPIC DERMATITIS

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (topical corticosteroids, tacrolimus ointment, phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy, azathioprine, cyclosporine, methotrexate, mycophenolate) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

EOSINOPHILIC ESOPHAGITIS

1. Current weight (in kg):
2. Date of current weight (MMDDYY):
3. Number of episodes of dysphasia per week:
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (twice daily PPI therapy, swallowed ICS therapy [budesonide respules (0.25 mg/2 ml, 0.5 mg/2 ml), Alvesco HFA (2 puffs swallowed), Asmanex HFA (2 puffs swallowed)]) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

PRURIGO NODULARIS

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (ex: topical corticosteroids, tacrolimus ointment, topical calcipotriene, intralesional corticosteroid, cyclosporine, methotrexate, SNRI, SSRI, TCA, gabapentin or pregabalin) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there a reasoning why alternatives (triple drug therapy with high-dose ICS-LABA plus LAMA, Azithromycin, etc.) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Has the patient experienced any of the following (check any/all boxes that apply):
   a. Two or more exacerbations requiring short-acting bronchodilators and systemic corticosteroids in the past 12 months
   b. A COPD exacerbation requiring hospitalization in the past 12 months

4. Will the patient continue to use triple maintenance (LAMA/LABA/ICS) therapy for COPD? If not, please provide reasoning why in the provider comment box or attach applicable chart notes.

Renewal Review Questions
CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)
1. Has the patient demonstrated clinical benefit by decreased symptoms and/or exacerbations?
2. Is the patient currently using dual (LAMA/LABA) or triple (LAMA/LABA/ICS) maintenance therapy?

RATIONALE
Per Health Plan.

1. Dupilumab has activity against a broad range of asthma phenotypes including atopic and eosinophilic phenotypes.

FDA APPROVED INDICATIONS
Asthma (Moderate to Severe)
Atopic Dermatitis (Moderate to Severe)
Chronic Rhinosinusitis with Nasal Polyposis
Prurigo Nodularis

REFERENCES
1. Dupixent [Prescribing Information]. Tarrytown, NY. Regeneron Pharmaceuticals, Inc., September 2024.

Table 1: High-dose ICS and High-dose ICS plus LABA combinations for Age 12 years or older

fluticasone/salmeterol DPI (Advair Diskus) 500/50 mcg, 1 inh twice daily
fluticasone/salmeterol MDI (Advair HFA) 230/21 mcg, 2 puffs twice daily
mometasone/formoterol MDI (Dulera) 200/5 mcg, 2 puffs twice daily
ciclesonide MDI (Alvesco) 160 mcg, 2 puffs twice daily
fluticasone MDI (Flovent HFA) 220 mcg, 2 puffs twice daily
Budesonide DPI (Pulmicort Flexhaler) 180 mcg, 4 inh twice daily
Mometasone MDI (Asmanex HFA) 200 mcg, 2 puffs twice daily
Mometasone DPI (Asmanex Twisthaler) 220 mcg, 2 inh twice daily

Table 2: Relative contraindications of various treatments

Treatment	
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses (ex: systemic lupus, porphyria).*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for dermatology indications.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities, active malignancy, and hypersensitivity.*
Azathioprine	*Pregnancy, breastfeeding, actively trying to conceive, liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities,* malignancy, *and hypersensitivity.*

Mycophenolate	*Hypersensitivity to mycophenolate, active malignancy, pregnancy, breastfeeding, women of childbearing age not using highly effective contraceptive methods. Mycophenolate requires REMS program for females of childbearing age.*

Creation Date: 4/2020
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

EDARAVONE (RADICAVA ORS)

Generic	Brand	HICL	GPID	Other
EDARAVONE (ORAL)	RADICAVA ORS ORAL SUSPENSION	44252	52318	Generic IV edaravone preferred

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Medication is prescribed by a CPMG or affiliated neurologist.
2. The patient has a diagnosis of clinical ALS and is 2 years or less from onset of first symptom.
3. Normal Respiratory Function defined as a Forced Vital Capacity (FVC) greater than or equal to 80% obtained within past two months.
4. The patient has an ALS Functional Rating Scale-Revised (ALSFRS-R) score of 2 points or better on each of the 12 items within past two months (e.g., speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, respiratory insufficiency).
5. The patient has a score of greater than 3 on ALSFRS-R for dyspnea, orthopnea, or respiratory insufficiency.
6. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. The patient is currently taking riluzole or has previously tried riluzole
   b. The patient is unable to use IV edaravone

If initial criteria are met, approve x 1 year at GPID.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following:
1. The patient is not dependent on invasive ventilation or tracheostomy

If met, approve x 1 year at GPID.
If not met, do not approve.

ePA Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: ALS]
2. Onset of first symptom (MMDDYY):
3. Has the patient completed ALS Functional Rating Scale-Revised (ALSFRS-R) in the past 2 months? If yes, must attach documentation showing the patient's score for each item (e.g., speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, respiratory insufficiency).
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (riluzole 50 mg tablets, IV edaravone) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Promote appropriate utilization of Radicava ORS based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS
Radicava ORS is an orally administered formulation of edaravone indicated for the treatment of amyotrophic lateral sclerosis (ALS).

DOSAGE AND ADMINISTRATION
The recommended dosage of Radicava ORS is an orally administered suspension of 105 mg (5 mL) given according to the same schedule as the infusion:

- An initial treatment cycle with daily dosing for 14 consecutive days, followed by a 14-day drug-free period.
- Subsequent treatment cycles with daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods
- Radicava ORS should be taken on an empty stomach in the morning after overnight fasting
    - Patients should not consume any food or drink (except water) for 1 hour after administration

ADDENDUM
The ALSFRS-R is a validated questionnaire-based scale designed to be a clinical rating tool to monitor the progression of patients in clinical practice as well as an outcome measure in clinical trials. The rate of progression of ALS patient population is typically linear, however it is not homogenous, therefore it is difficult to ascertain the general rate of progression for the patient population. The ALSFRS-R scale consists of 12 questions that evaluate the fine motor, gross motor, bulbar, and respiratory function of patients with ALS (speech, salivation, swallowing, handwriting, cutting food, dressing/hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, and respiratory insufficiency). There are four domains: bulbar, fine motor, gross motor and breathing. Each questionnaire item is scored from 0-4, with higher scores representing greater functional ability; the total possible score is 48 points.

A copy of the ALSFRS-R questionnaire can be accessed at: https://cytokinetics.com/wp-content/uploads/2015/10/2011ALS_MND_ASLFRS20.pdf

REFERENCES
- Radicava and Radicava ORS [prescribing information]. Jersey City, NJ: MT Pharma America, Inc.; May 2022.
- Cedarbaum J, Stambler N, Malt E et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. J Neurol Sci. 1999 Oct 31;169(1-2):13-21.
- Cedarbaum J, Mitsumoto H, Pestronk A, et al. The ALSFRS @ 20: Evolution of the ALSFRS-R, history, clinimetric properties and future directions [Poster]. Available at: https://cytokinetics.com/wp-content/uploads/2015/10/2011ALS_MND_ASLFRS20.pdf

Creation Date: 07/2022
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

ELAFIBRANOR (IQIRVO)

Generic	Brand	HICL	GPID	COMMENTS
ELAFIBRANOR	IQIRVO	49672		NF

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days.
2. Patient has a diagnosis of Primary Biliary Cholangitis (PBC) and is stable on therapy

If met, approve, max 1 per day x 1 year.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:

A. Primary Biliary Cholangitis (PBC) diagnosis:
1. Patient must be 18 years of age or older.
2. Medication must be prescribed by a Gastroenterology specialist.
3. Patient has had an incomplete response (alkaline phosphatase >1.67 ULN and /or an abnormal bilirubin) for at least 12 months to Ursodiol (dosed 13-15mg/kg/day) OR has an intolerance or contraindication to Ursodiol or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
4. Patient does not have decompensated cirrhosis
5. Patient does not have biliary obstruction
6. Not used in combination with obeticholic acid (Ocaliva) or another PPAR agonist (seladelpar)

If initial criteria are met, approve at HICL for 1 year [qty limit 30/month supply)
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of primary biliary cholangitis
2. Patient's alkaline phosphatase levels are less than 1.67-times the upper limit of normal OR have decreased by at least 15% from baseline while on treatment

If met, approve at HICL indefinitely, max 1 per day
If not met, do not approve.

ESCALATION CRITERIA: none

RATIONALE
PBC is a rare liver disease characterized by destruction and inflammation of the small bile ducts. The initial choice of drug therapy for PBC is Ursodiol (UDCA). UDCA has been shown to improve liver

biochemistry levels and improve transplant-free survival rates; however, it has not been shown to help fatigue or pruritus. In patients with PBC experiencing pruritus, the American Association of the Study of Liver Diseases (AASLD) guidelines recommend the use of cholestyramine and fibrates as initial therapies. With these therapies, up to 40% of patients may continue to have an inadequate response and need second line therapy, with a PPAR agonist, elafibranor (Iqirvo) or obetacholic acid (Ocaliva) and FXR agonist.

FDA APPROVED INDICATIONS
Primary Biliary Cirrhosis

REFERENCES:
Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Hepatology (Baltimore, Md.). 2019;69(1):394-419. doi:10.1002/hep.30145.

Elafibranor, an Agonist of the Peroxisome Proliferator-Activated Receptor-A And -Δ, Induces Resolution of Nonalcoholic Steatohepatitis Without Fibrosis Worsening. Ratziu V, Harrison SA, Francque S, et al. Gastroenterology. 2016;150(5):1147-1159.e5. doi:10.1053/j.gastro.2016.01.038.

Prescribing information QIRVO (elafibranor) tablets, for oral use Initial U.S. Approval: 2024

ePA Questions
1. Is the patient stable on therapy with elafibranor (Iqirvo)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Does the patient have decompensated cirrhosis?
4. Does the patient have biliary obstruction?
5. Will elafibranor (Iqirvo) be used in combination with Ocaliva or another PPAR agonist?
6. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
7. Is there reasoning why alternatives (ursodiol 250 mg, 500 mg tablets) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Creation Date: 5/2025
Effective Date: 06/2025
Reviewed Date: n/a
Revised Date: n/a

ORIAHNN

Generic	Brand	HICL	GPID	Exception/Other
ELAGOLIX/ ESTRADIOL /NORETHINDRONE (elagolix+E2/NETA)	ORIAHNN	46577	48158	

****Length of approval applies to Federal Group**

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following criteria:

1. Patient is a female at least 18 years of age
2. Medication is prescribed by an OB/GYN (with an appropriate referral, if required)
3. Patient is premenopausal with a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
4. Patient has tried and failed, has an intolerance to, or has a contraindication to each of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Combined Oral Contraceptive Pill (OCP) - Note: cannot take concurrently with Oriahnn
   b. Levonorgestrel-releasing Intrauterine device (LNG IUD), depot medroxyprogesterone, or Nora-BE
   c. GnRH (leuprolide)
5. Patient must not have previously completed 24 months of treatment with elagolix +E2/NETA (Oriahnn), relugolix + e2NETA (Myfembree), or elagolix monotherapy (Orilissa)
6. Patient must not be on an organic anion transporting polypeptide (OATP)1B1 inhibitor[b] (most common: cyclosporine, gemfibrozil; see comprehensive list in footnote)

   If initial criteria are met, then approve at GPID x 6 months [**Use for FEDERAL Group].
   If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following:

1. Patient has not been on elagolix+E2/NETA (Oriahnn) for 24 months or more
2. Patient meets one of the following:
   a. Patient is currently taking elagolix+E2/NETA (Oriahnn) and has a history of blood transfusion to treat heavy menstrual bleeding
   b. Patient has experienced a clinically significant improvement in fibroid-induced heavy menstrual bleeding, defined as at least 50% reduction in menstrual blood loss from baseline to the final month (6 months) of treatment with elagolix+E2/NETA (Oriahnn)

   If met, then approve at GPID for the number of months to meet the maximum of 24 total months of therapy. [**Use for Federal Group].
   If not met, do not approve.

RATIONALE- per OB/GYN

FDA APPROVED INDICATIONS Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women

REFERENCES

package insert

[a](including women >35 years of age who smoke, current or history of deep vein thrombosis or pulmonary embolism, vascular disease (eg, cerebrovascular disease, coronary artery disease, peripheral vascular disease), thrombogenic valvular or thrombogenic rhythm diseases of the heart (eg, subacute bacterial endocarditis with valvular disease, atrial fibrillation), inherited or acquired hypercoagulopathies, uncontrolled hypertension, or headaches with focal neurological symptoms or have migraine headaches with aura if >35 years of age.)

[b](atazanavir, clarithromycin, cobicistat, cyclosporine, daclatasvir, darolutamide, elbasvir, eltrombopag, eluxadoline, gemfibrozil, grazoprevir, ledipasvir, leflunomide, letermovir, lopinavir, simeprevir, teriflunomide, velpatasvir, voxilaprevir. Additional category X interactions are those with CYP3A4 metabolism (fusidic acid, idelalisib), and drugs reliant on PGP. The concentrations of these may be increased to toxic levels if administered with PGP inhibitor elagolix: pazopanib, IV topotecan, vincristine (liposomal).)

Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228.

Therapeutic management of uterine fibroid tumors: updated French guidelines.

NICE guideline [NG88] Heavy menstrual bleeding: assessment and management. National Institute for Health and Care Excellence. March 2020
https://www.nice.org.uk/guidance/ng88/chapter/Recommendations#management-of-hmb (Accessed on April 01, 2020).

Creation Date: 12/2020
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

ELAGOLIX SODIUM (ORILISSA)

Generic	Brand	HICL	GPID	Other
ELAGOLIX SODIUM 150MG	ORILISSA	45108	45026	
ELAGOLIX SODIUM 200MG	ORILISSA	45108	45028	

****Length of approval applies to Federal Group**

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA:

1. Patient is new to KPCO within the past 90 days and is stable on elagolix (Orilissa)
2. Patient has had at least 50% improvement of symptoms since starting treatment with elagolix (Orilissa)
3. Must meet the following based on indication:
   a. For endometriosis with dyspareunia: Patient has not yet completed 6 months of treatment (FDA-approved duration)

      If met, approve GPID 45028 x number of months to meet and not exceed 6 total months of therapy [**Use for FEDERAL Group]
      If not met, review by Initial Criteria

   b. For endometriosis: Patient has not yet completed 24 months of treatment (FDA-approved duration)

      If met, then approve GPID 45026 x1 fill, to allow time for evaluation by Ob/Gyn [**Use for Federal Group]
      If not met, review by Initial Criteria

INITIAL CRITERIA: Must meet all the following:

1. Patient is a female at least 18 years of age
2. Medication is prescribed by an obstetrician/gynecologist (with an appropriate referral, if required)
3. Patient has a surgically confirmed diagnosis of endometriosis with or without dyspareunia
4. Patient has tried and failed or has an absolute contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. At least one NSAID
   b. At least one estrogen-progestin combination contraceptives (pills, patch, or ring) taken in a continuous fashion (skipping placebo tablets)
   c. Depo-medroxyprogesterone acetate injection, norethindrone acetate oral, medroxyprogesterone acetate oral, levonorgestrel intrauterine device, or etonorgestrel implant
   d. GnRH agonist (nafarelin, leuprolide, goserelin or triptorelin) with add-back hormonal therapy (norethindrone [to counteract estrogen suppression effect of GnRH agonist])
5. Patient has had a BMD screening within the last 12 months
6. Patient cannot be currently on a strong organic anion transporting polypeptide 1b1 inhibitor (most common: cyclosporine, gemfibrozil, see comprehensive list in footnote)[4]

7. Provider attests to counselling patient on multiple forms of contraception and associated routine labs

If initial criteria are met, then approve per diagnosis: [**Use for FEDERAL Group]
- Endometriosis with dyspareunia: GPID 45028, 200mg twice daily for 6 months (FDA-approved duration).
- Endometriosis: GPID 45026, 150mg once daily for 12 months.

If initial criteria not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Patient has had at least 50% improvement of symptoms since starting treatment with elagolix (Orilissa)
2. Must meet the following based on indication:
   a. For endometriosis with dyspareunia:
      i. Patient has not yet completed 6 months of treatment (FDA-approved duration)
      ii. Patient has normal LFTs (checked while on therapy with elagolix)

      If renewal criteria are met, approve GPID 45028 x number of months to meet and not exceed 6 total months of therapy [**Use for FEDERAL Group].
      If renewal criteria not met, do not approve.

   b. For endometriosis:
      i. Patient has not yet completed 24 months of treatment (FDA-approved duration)
      ii. Patient has a BMD after 12 months of elagolix therapy that shows no more than 8% decrease in T-score in spine, femoral neck, and total hip
      iii. Patient has a current a negative pregnancy test and is willing to come back to confirm not pregnant with repeat urine pregnancy test in fourteen days, or had sterilization procedure
      iv. Patient has normal LFTs (checked while on therapy with elagolix)

      If renewal criteria are met, approve GPID 45026 for the number of months to meet the maximum of 24 total months of treatment (surgically proven endometriosis) or 6 total months of treatment (surgically proven endometriosis with primary symptom of dyspareunia). If no start date is submitted in review but other renewal criteria are met, approve x1 month only. [**Use for FEDERAL GROUP]

      If renewal criteria not met, do not approve.

RATIONALE
Ensure appropriate utilization and safety criteria are used for the management of requests for Orilissa (elagolix).
Insufficient data for use in breastfeeding.

FDA APPROVED INDICATIONS
Orilissa (elagolix) is a non-peptide, oral gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for management of moderate to severe pain associated with endometriosis. Through suppression of pituitary and ovarian hormone function, concentrations of LH, FSH, and estradiol are decreased during therapy, which reduces dysmenorrhea and nonmenstrual pelvic pain.

NOTES
1. Elagolix can cause increased HDL, LDL, total cholesterol or triglycerides.

2. Osteoporosis, a contraindication to using elagolix, is defined as a T score of -2.5 and below.
3. Osteopenia is defined as a T score of -1.0 to -2.5. Risk factors for fracture are weight < 157lbs, BMI < 21, history of fragility fracture after age 50, parental history of hip fracture, rheumatoid arthritis, corticosteroids (> 3 months at > 5mg), alcohol > 3 drinks/day, and current cigarette smoking. Risk factors requires supplementation with calcium and vitamin D.
4. OATP inhibitors may increase the serum concentration of elagolix: atazanavir, clarithromycin, cobicistat, cyclosporine, daclatasvir, darolutamide, elbasvir, eltrombopag, eluxadoline, gemfibrozil, grazoprevir, ledipasvir, leflunomide, letermovir, lopinavir, simeprevir, teriflunomide, velpatasvir, voxilaprevir. Additional category X interactions are those with CYP3A4 metabolism (fusidic acid, idelalisib), and drugs reliant on PGP. The concentrations of these may be increased to toxic levels if administered with PGP inhibitor elagolix: pazopanib, IV topotecan, vincristine (liposomal).

REFERENCES

1. Surrey E, Taylor HS, Giudice L, et al. Long-term outcomes of elagolix in women with endometriosis: results form two extension studies. Obstet Gynecol. 2018 Jul;132(1):147-160. doi: 10.1097/AOG.0000000000002675.
2. Taylor HS, Giudice LC, Lessey BA, et al. Treatment of endometriosis-associated pain with elagolix, an oral GnRH antagonist. N Engl J Med. 2017 Jul 6;377(1):28-40. doi: 10.1056/NEJMoa1700089. Epub 2017 May 19.
3. Ng J, Chwalisz K, Carter DC, Klein CE. Dose-dependent suppression of gonadotropins and ovarian hormones by elagolix in healthy premenopausal women. J Clin Endocrinol Metab. 2017 May 1;102(5):1683-1691. doi: 10.1210/jc.2016-3845.
4. Ben-Meir A, Sarajari S. Endometriosis. In: DeCherney AH, Nathan L, Laufer N, Roman AS. eds. CURRENT Diagnosis & Treatment: Obstetrics & Gynecology, 12e New York, NY: McGraw-Hill; . http://accessmedicine.mhmedical.com/content.aspx?bookid=2559&sectionid=206967961. Accessed November 12, 2019
5. Elagolix. Lexi-Drugs. [updated 2024 Oct 24; cited 2024 Nov 12] In Lexicomp Online [Internet]. Wolters Kluwer Clinical Drug Information, Inc. Hudson, Ohio. Available at: http://online.lexi.com/lco/action/home
6. ACOG Practice Bulletin No. 110: noncontraceptive uses of hormonal contraceptives. Obstet Gynecol. 2010 Jan;115(1):206-18.
7. Endometriosis: Treatment of pelvic pain. UpToDate [cited 2024 Nov 12] In UpToDate [Internet]. Wolters Kluwer Clinical Drug Information, Inc. Hudson, Ohio. Available at: http://www.uptodate.com/contents/search

Creation Date: 03/2020
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

ELEXACAFTOR/IVACAFTOR/TEZACAFTOR (TRIKAFTA)

Generic	Brand	HICL	GCN	Exception/Other
ELEXACAFTOR/IVACAFTOR/TEZACAFTOR	TRIKAFTA	46112		

GUIDELINES FOR USE

Requests for ELEXACAFTOR/IVACAFTOR/TEZACAFTOR will be approved if ALL the following are met:
1. Prescribed by a pulmonologist
2. Patient has a diagnosis of cystic fibrosis (CF) and
    a. has at least one *F508del* mutation in the CFTR gene
    OR
    b. has a mutation in the CFTR gene that is responsive based on *in vitro* data [Consult Trikafta website to check eligible mutations: https://www.trikafta.com/who-trikafta-is-for]
3. Patient is at least 2 years old

If above criteria are met, then approve indefinitely, max #3/day.
If above criteria are not met, do not approve.

ePA Questions

1. Does the patient have at least one *F508del* mutation in the CFTR gene? If yes, must attach supporting chart notes.
2. Does the patient have a mutation in the CFTR gene that is responsive based on *in vitro* data [Consult Trikafta website to check eligible mutations: https://www.trikafta.com/who-trikafta-is-for]? If yes, must list the patient's mutation in Provider Comment section below or attach applicable chart notes.

RATIONALE

Per Health Plan

REFERENCES

1. Kaiser Permanente Inter-regional Practice Recommendations 01/2020
2. Trikafta [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; 2021.
3. Trikafta website to check eligible mutations: https://www.trikafta.com/who-trikafta-is-for

Creation date: 07/2020
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

ELIGLUSTAT (CERDELGA)

Generic	Brand	HICL	GPID	Other
ELIGLUSTAT	CERDELGA	41346	36988	Specialty Non-formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

1. Must be prescribed by, or in consultation with a specialist in the area of the patient's diagnosis (e.g., endocrinologist, hematologist or geneticist).
2. Must be prescribed as monotherapy and is not given in combination with other SRT agents or enzyme replacement therapies [velaglucerase (Vpriv), imiglucerase (Cerezyme), or taliglucerase (Elelyso)].
3. Patient has a diagnosis of Gaucher Disease Type 1.
4. Patient must be age 18 or older.
5. Prior to any treatment for the intended diagnosis, patient has had at least ONE of the following clinical presentations:
   - Anemia (Hgb <13 g/dL in men, <12 g/dL in women)
   - Thrombocytopenia (platelet count <100,000/µL)
   - Hepatomegaly
   - Splenomegaly
   - Growth failure
   - Evidence of bone disease not due to other causes
6. Provider specifies, providing results detected by an FDA-cleared test that the patient is one of the following:
   - CYP2D6 extensive metabolizer (EM)
   - CYP2D6 intermediate metabolizer (IM)
   - CYP2D6 poor metabolizer (PM)
   - AND is NOT an ultra-rapid metabolizer (URM)
7. Cerdelga is not used concomitantly with any of the following:

CYP2D6 EM or IM	Moderate or strong CYP2D6 inhibitor (e.g., paroxetine, terbinafine) with a moderate or strong CYP3A inhibitor (e.g., ketoconazole)
CYP2D6 IM	Moderate or strong CYP3A inhibitor (e.g., ketoconazole, fluconazole)
CYP2D6 PM	Weak, moderate, or strong CYP3A inhibitor (e.g., ranitidine, ketoconazole, fluconazole)
CYP2D6 EM, IM, or PM	Strong CYP3A4 inducers (e.g., rifampin, phenytoin)

If initial criteria is met, approve x12 months at HICL as twice daily dosing (max 60 capsules per 30 days) for CYP2D6 extensive/intermediate metabolizer, OR once daily dosing (max 30 capsules per 30 days) for CYP2D6 poor metabolizer.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following disease specific criteria:

1. Gaucher Disease Type 1: Patient has demonstrated clinical symptom improvement or stability since starting on the drug, and no new contraindications to use, to at least one of the following:
   a. Hemoglobin level
   b. Platelet count

c. Liver volume
d. Spleen volume
e. Growth
f. Bone pain or crisis

If renewal criteria are met, approve x12 months at HICL as twice daily dosing (max 60 capsules per 30 days) for CYP2D6 extensive/intermediate metabolizer, OR once daily dosing (max 30 capsules per 30 days) for CYP2D6 poor metabolizer.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Will the requested medication be used in combination with other SRT agents or enzyme replacement therapies [velaglucerase (Vpriv), imiglucerase (Cerezyme), or taliglucerase (Elelyso)]? If yes, must provide explanation in Provider Comment section below or attach applicable chart notes.
2. Prior to any treatment for the intended diagnosis, has the patient had any of the following clinical presentations: [check boxes for all diagnoses listed in criteria: Anemia (Hgb <13 g/dL in men, <12 g/dL in women); Thrombocytopenia (platelet count <100,000/µL); Hepatomegaly; Splenomegaly; Growth failure; Evidence of bone disease not due to other causes]
3. Please indicate by checking the applicable box(es) to describe this patient, and attach results from an FDA-cleared test that showing: The patient is a: CYP2D6 extensive metabolizer (EM); CYP2D6 intermediate metabolizer (IM); CYP2D6 poor metabolizer (PM); ultra-rapid metabolizer (URM)

Renewal Review Questions
1. Please indicate by checking the applicable box(es) which clinical symptoms have improved since starting eliglustat (Cerdelga): [Hemoglobin level; Platelet count; Liver volume; Spleen volume; Growth; Bone pain or crisis]

RATIONALE
Cerdelga (eliglustat) has been shown to be non-inferior to enzyme replacement therapy (ERT) and is a first-line option for Gaucher Disease. Zavesca (miglustat) is a second-line alternative to ERT.

Per the 2018 consensus guidelines for Niemann-Pick Disease Type C (NPC), miglustat is the only disease modifying medication that may be used in the treatment of neurological manifestations of NPC. Miglustat may halt or attenuate disease progression in some patients. Miglustat is currently used off-label in treatment of NPC in the United States.

FDA APPROVED INDICATIONS
Cerdelga (eliglustat): Treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers, intermediate metabolizers, or poor metabolizers.

REFERENCES
1. Bennett LL, Fellner C. Pharmacotherapy of Gaucher Disease: Current and Future Options. *P T*. 2018;43(5):274-309.
2. Rosenbloom BE, Cox TM, Drelichman GI, et al. Encore - a randomized, controlled, open-label non-inferiority study comparing ELIGLUSTAT to imiglucerase in Gaucher disease type 1 patients stabilized on enzyme replacement therapy: 24-month results. *Blood*. 2014;124(21):1406-1406. doi:10.1182/blood.v124.21.1406.1406

3. Geberhiwot T, Moro A, Dardis A, et al. Consensus clinical management guidelines for Niemann-Pick disease type C. Orphanet J Rare Dis. 2018;13(1):50. Published 2018 Apr 6. doi:10.1186/s13023-018-0785-7

Creation Date: 07/2022
Effective Date: 10/2024
Reviewed Date: 09/2024
Revised Date: 09/2024

ELUXADOLINE

Generic	Brand	HICL	GPID	Exception/Other
ELUXADOLINE	VIBERZI	42445		Non-Formulary

GUIDELINES FOR COVERAGE

Must meet all the following:

1. Patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D)
2. The patient is 18 years of age or older
3. Therapy is prescribed by a gastroenterologist
4. The patient has tried and failed or has an intolerance or contraindication to all of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    - diphenoxylate and atropine (generic Lomotil) or OTC loperamide
    - at least one tricyclic antidepressant (e.g., amitriptyline, desipramine) [if patient is less than 65 years of age]
    - dicyclomine [if patient less than 65 years of age]
    - Xifaxan (NF, PA required)

   If criteria are met, approve indefinitely, max 2 per day.
   If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (diphenoxylate and atropine (generic Lomotil); OTC loperamide; dicyclomine; amitriptyline tablets, desipramine tablets, nortriptyline capsules) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

The 2021 American College of Gastroenterology (ACG) guidelines for the treatment of IBS list eluxadoline as a treatment option in its algorithm for IBS-D. Eluxadoline was approved based on two randomized, multicenter (MC), multinational, double-blind (DB), placebo controlled (PC) Phase 3 trials (IBS-3001 and IBS-3002) that evaluated the efficacy and safety of eluxadoline for IBS-D. The primary endpoint for both studies was the percentage of participants who were composite responders based on improvements from baseline in daily worst abdominal pain (WAP) and daily stool consistency scores for at least 50% of days with diary entry during 12 weeks of treatment. A statistically significantly higher proportion of patients treated with eluxadoline achieved the primary endpoint compared to PBO over a 12-week treatment period (23.9% and 28.9% on eluxadoline vs. 17.1% and 16.2% in the placebo group).
Based on the limited treatment effect over placebo, no head-to-head trials and high cost with less costly options available we recommend utilizing eluxadoline last line. Eluxadoline should be reserved last line for IBS-D symptoms that have not previously responded to over-the-counter loperamide, low-dose tricyclic antidepressants, or at least one course of rifaximin.

REFERENCES

Viberzi [Prescribing Information]. Madison, NJ: Allergan USA, Inc; June 2018.

Creation Date: 03/2023
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2024

EMTRICITABINE/TENOFOVIR (DESCOVY)

Generic	Brand	HICL	GPID	Exception/Other
EMTRICITABINE / TENOFOVIR ALAFENAMIDE	DESCOVY	43241	51964, 40953	Non-Formulary

GUIDELINES FOR COVERAGE

NOTE: All requests for Descovy are treated as urgent requests

INITIAL CRITERIA: Must meet one of the following:

1. Patient has a diagnosis of HIV infection
2. Patient has a CrCL or eGFR between 30 and 60 mL/min
3. Patient has a diagnosis of a metabolic bone disease, such as osteoporosis
4. Patient has suspected renal toxicity to emtricitabine/tenofovir disoproxil fumarate (Truvada), defined as worsening serum Cr, proteinuria or glucosuria that developed while taking emtricitabine/tenofovir disiproxil fumarate (Truvada)
5. Patient had an intolerance to emtricitabine/tenofovir disoproxil fumarate (Truvada), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If any of the above criteria are met, approve indefinitely at GPID level.
If no criteria are met, do not approve.

ePA Questions for Provider Outreach

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Truvada) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Does the patient have a diagnosis of metabolic bone disease, such as osteoporosis?
4. Current eGFR:
5. Date of Current eGFR (MMDDYY):

RATIONALE

To ensure appropriate use of Descovy

REFERENCES

Note: the adjudication systems are built to automatically send a $0 cost share if no other HIV drug is present, besides Truvada, in the claims history (assumed as PrEP) and will apply the applicable cost share for all other claims (assume treatment of HIV).

Creation date: 03/2022
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2024

ENSIFENTRINE (OHTUVAYRE)

Generic	Brand	HICL	SIZE	Exception/Other
ENSIFENTRINE	OHTUVAYRE	49726	2.5 ML	Non-Formulary, Specialty Tier

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

1. Patient must be 18 years of age or older
2. Medication must be prescribed by a Pulmonologist
3. Diagnosis of chronic obstructive pulmonary disease (COPD) with documented FEV1/FVC ratio < 0.7 post-bronchodilation
4. Current (within past 3 months) blood eosinophil level of 100 cells/microliter or greater (or absolute eosinophil level of 0.1 or greater)
5. Patient has documentation of ONE of the following:
   a. At least 1 exacerbation requiring hospitalization in the past 12 months OR
   b. At least 2 exacerbations treated with short-acting bronchodilators and oral corticosteroids, with or without antibiotics in the past 12 months
6. Patient has tried and failed or has an intolerance or a contraindication to at least one of the preferred therapies below, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - Triple inhaler therapy [high dose ICS-LABA-LAMA] + azithromycin 250-500 mg three times per week with adherence (greater than 75% proportion of days covered) for at least the previous 12 months
   - Triple inhaler therapy [high dose ICS-LABA-LAMA] + roflumilast* with adherence (greater than 75% proportion of days covered) for at least the previous 12 months (*may require a proactive non-formulary approval)
7. Patient will continue to use triple maintenance (LAMA/LABA/ICS) therapy for COPD [unless intolerance or contraindication]
8. Ohtuvayre will be used as maintenance treatment and NOT for relief of acute bronchospasm
9. Ohtuvayre must NOT be used in combination with roflumilast

If initial criteria are met, approve x1 year, max 2 ampules/day [5 mL/day].
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:

1. Patient is currently using triple maintenance (LAMA/LABA/ICS) therapy +/- azithromycin for COPD, unless has an intolerance or contraindication
2. Ohtuvayre will be used as maintenance treatment and NOT for relief of acute bronchospasm
3. Ohtuvayre must NOT be used in combination with roflumilast
4. Patient has demonstrated clinical benefit by decreased symptoms and/or exacerbations

If met, approve x1 year, max 2 ampules/day [5 mL/day].
If not met, do not approve.

ePA Questions
Initial Review Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there a reasoning why alternatives (triple drug therapy with high-dose ICS-LABA plus LAMA, Azithromycin, etc.) are not suitable? If yes, must list reasoning in the Provider Comment section below or attach applicable chart notes.
3. Has the patient experienced any of the following (check any/all boxes that apply):
   a. Two or more exacerbations requiring short-acting bronchodilators and systemic corticosteroids in the past 12 months
   b. One or more exacerbation(s) requiring hospitalization in the past 12 months
4. Current FEV1/FVC ratio, post-bronchodilation:
5. Date of FEV1/FVC ratio (MMDDYY):
6. Current (within the past 3 months) blood eosinophil level (cells/microliter):
7. Date of blood eosinophil level (MMDDYY):
8. Will Ohtuvayre be used as maintenance treatment and not for relief of acute bronchospasm?
9. Will Ohtuvayre be used in combination with roflumilast?

Renewal Review Questions
1. Has the patient demonstrated clinical benefit by decreased symptoms and/or exacerbations?
2. Is the patient currently using triple (LAMA/LABA/ICS) maintenance therapy?
3. Is Ohtuvayre being used as maintenance treatment and not for relief of acute bronchospasm?
4. Is Ohtuvayre being used in combination with roflumilast?

RATIONALE
*Ensifentrine has not been studied as an add-on to dual LAMA/LABA or triple ICS/LAMA/LABA inhaler, which is the standard of care for patients with moderate-to-severe COPD. For patients with recurrent exacerbations (e.g., at least two per year or one requiring hospitalization per year) despite optimized LAMA/LABA/ICS inhaled therapies, phosphodiesterase-4 (PDE-4) inhibitor roflumilast or chronic azithromycin should be considered as additional add-on treatment options per 2024 GOLD report. The optimal duration of therapy for add-on treatment is typically at least 12-months or longer based on clinical trials. Ensifentrine may be considered for patients with recurrent exacerbations after an adequate trial of GOLD treatment recommendations above.

FDA APPROVED INDICATIONS
OHTUVAYRE is a phosphodiesterase 3 (PDE3) inhibitor and phosphodiesterase 4 (PDE4) inhibitor indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.

The recommended dosage of OHTUVAYRE [inhalation suspension: 3 mg/2.5 mL] is 3 mg (one unit-dose ampule) twice daily, once in the morning and once in the evening, administered by oral inhalation using a standard jet nebulizer with a mouthpiece.

Creation Date: 11/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

EPINEPHRINE AUTO-INJECTOR NON-FORMULARY GUIDELINE

Generic	Brand	HICL	GCN	Exception/Other
EPINEPHRINE 0.3MG/0.3ML SOAJ	EPIPEN AUTH GENERIC		19862	Non-Formulary – Preferred
EPINEPHRINE 0.15MG/0.3ML SOAJ	EPIPEN JR AUTH GENERIC		19861	Non-Formulary - Preferred
EPINEPHRINE 0.3/0.3ML SOAJ	EPIPEN BRAND		19862	Non-Formulary - Least Preferred
EPINEPHRINE 0.15MG/0.3ML SOAJ	EPIPEN JR BRAND		19861	Non-Formulary – Least Preferred

Non-Formulary Criteria (NCQA reviewable): Must meet the following:

1. Patient is unable to utilize epinephrine 0.15mg/0.3mL or 0.3mg/0.3mL (Adrenaclick generic - 00115-1694-49 or Adrenaclick Jr generic 00115-1695-49) due to any of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Unable to use the device
   b. Institution (school, daycare, group home) requires other device (example retractable needle)

If met, approve indefinitely.
If not met, do not approve.

ePA Questions

1. Is there reasoning why generic epinephrine 0.15mg/0.3mL or 0.3mg/0.3mL is not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Per Health Plan.

- Epinephrine auto-injector (Adrenaclick and Adrenaclick Jr generic) is KPCO first-line formulary epinephrine auto-injector.
- The authorized generic for EpiPen or EpiPen Jr should be reserved as the preferred non-formulary option for patients unable to utilize generic Adrenaclick or Adrenaclick Jr to documented allergy, intolerance, or clinical failure.
- Brand EpiPen and EpiPen Jr should be reserved as the non-formulary option for patients unable to utilize epinephrine auto-injector (Adrenaclick and Adrenaclick Jr generic) or the authorized generic for EpiPen or EpiPen Jr.

FDA APPROVED INDICATIONS

See individual medications.

REFERENCES

00115-1694-49 is generic Adrenaclick (pref)
00115-1695-49 is generic Adrenaclick Jr (pref)
49502-0102-02 is authorized generic for EpiPen
49502-0101-02 is authorized generic for EpiPen Jr

49502-0500-02 is brand EpiPen
49502-0501-02 is brand EpiPen Jr

Creation date: 05/2021
Effective date: 04/2024
Reviewed date: 03/2024
Revised date: 09/2023

ERTUGLIFLOZIN (STEGLATRO)

Generic	Brand	HICL	GPID	Comments
ERTUGLIFLOZIN	STEGLATRO	44709		NF 3rd Preferred

GUIDELINES FOR COVERAGE
Must be used for one of the following indications and meet all related criteria as follows:

A. Adults 25 years of age or older with DM2
B. Pediatrics/Young Adults between 10 and 25 years of age with DM2

A. To treat adults 25 years of age or older with type 2 diabetes: Must meet all the following:
   1. Current (within the past 3 months) HgbA1c is above, but within 2% of their designated A1c goal
   2. Patient has an eGFR of at least 20 ml/min
   3. Patient has contraindications to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. maximum dose metformin IR and subsequently metformin ER
      b. empagliflozin (Jardiance)
      c. maximum dose sulfonylurea, maximum dose pioglitazone, and all possible combinations thereof unless the patient has one of the following:
         i. h/o bariatric surgery
         ii. BMI ≥ 35 (≥ 30 for Asian American/Pacific Islanders)
         iii. ≥ 5% increase in body weight after 6 months of starting diabetes medications associated with weight gain (i.e. sulfonylurea, insulin, pioglitazone)
         iv. patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day

If all criteria met, approve at HICL x 6 months, max 1 tablet per day.
If criteria are not met, do not approve.

B. To treat type 2 diabetes in young adult/pediatric patients between 10 and 25 years of age: Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Patient has contraindications to, is currently using, or has failed maximum doses of metformin IR and subsequently metformin ER
   2. Patient has an eGFR of at least 20 ml/min and has tried and failed, or has an intolerance or contraindication to empagliflozin (Jardiance)
   3. Patient has contraindications to, is currently using, or has failed maximum dose pioglitazone unless the patient has one of the following:

a. h/o bariatric surgery
b. BMI ≥ 95%ile for age and sex
c. ≥ 5% increase in body weight after 6 months of starting these medications
d. patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day

If all criteria met, approve at HICL x 6 months, max 1 tablet per day.
If criteria are not met, do not approve.

RENEWAL CRITERIA

1. HgbA1c is either at goal or has decreased by at least 0.5%.

If renewal criteria are met, approve indefinitely at HICL, max 1 tablet per day.
If renewal criteria are not met, do not approve.

RATIONALE

- KP National Diabetes Guidelines recommend using SGLT-2i for people with type 2 diabetes with clinical ASCVD who are already taking metformin to reduce the risk of: (1) cardiovascular events (myocardial infarction or stroke) or cardiovascular death, (2) progression of renal disease and/or (3) death from renal causes, and/or (4) heart failure hospitalizations. The American College of Cardiology (ACC) 2020 Expert Consensus Decision Pathway on Novel Therapies for Cardiovascular Risk Reduction in Patients with Type 2 Diabetes, which is also endorsed by the American Diabetes Association (ADA), recommends SGLT-2i as a first-line treatment in patients with type 2 diabetes and one or more of the following: ASCVD, HFrEF, HFpEF (empagliflozin only), diabetic kidney disease (DKD), or at high risk for ASCVD.
- Preferred order of agents:
  1) Empagliflozin (Jardiance), formulary without PA, is the preferred agent for ASCVD, CKD, and HF due to strength of clinical trial data, range of approved indications, and cost (1/2 tab regimen)
  2) Canagliflozin (Invokana), non-formulary with PA, is the 2nd preferred option for ASCVD, CKD and DM2 patients without compelling indications. due to broad range of indications and cost (1/2 tab regimen).
  3) Dapagliflozin (Farxiga), non-formulary with PA, is the 2nd preferred option for HF, and the 3rd preferred option for ASCVD, CKD and DM2 patients without compelling indications due to broad range of indications but at high cost.
  4) Ertugliflozin (Steglatro), non-formulary with PA, is least preferred due to high cost, paucity of positive clinical trial data, and lack of additional FDA-approved indications. Specifically, ertugliflozin has been studied in patients with type 2 diabetes and ASCVD and did not improve cardiovascular outcomes while all three other SGLT-2i have demonstrated such benefits in this population.
  5) Bexagliflozin (Brenzavvy): non-formulary with PA, is least preferred due to high cost and lack of additional FDA-approved indications.
  6) Sotagliflozin (Inpefa): non-formulary with PA, is 3rd preferred for HF given shorter history of postmarketing safety data compared to other SGLT2i's approved for HF as well as the need to titrate sotagliflozin dose for when others are fixed-dose regimens. Sotagliflozin (Inpefa) is least preferred for glycemic control due to lack of clinical trial data and FDA-approved indication as well as its high cost.
- Jardiance (empagliflozin) is the preferred sodium glucose co-transporter 2 inhibitor (SGLT-2i) at Kaiser Permanente Colorado (KPCO) and can be used effectively and safely with a GFR down to

20 mL/min. In addition, the dose of 12.5 mg (1/2 of 25mg tablet) is an effective dose for all patients regardless of GFR.

- Based on the available evidence, various organizations endorse SGLT-2is use down to lower GFR levels than indicated in product labels:
  - American College of Cardiology Expert Consensus now recommends empagliflozin in GFR ≥ 20 mL/min (2021).
  - National Kidney Foundation recommends SGLT-2is in GFR ≥ 20 mL/min as long as there are no contraindications (2023).
  - American Diabetes Association recognizes SGLT-2is benefits in patients with GFR ≥ 20 mL/min (2023).

FDA APPROVED INDICATIONS for SGLT2 Inhibitors

Empagliflozin (Jardiance)

1. Improve glycemic control in patients with DM2
2. Reduce the risk of CV death in pts with DM2 + CVD
3. Reduce risk of CVD death and HF hospitalizations in pts with HF
4. Reduce risk of sustained eGFR decline, ESRD, CV death and hospitalizations in adults with CKD at risk of progression

Canagliflozin (Invokana)

1. Improve glycemic control in patients with DM2
2. Reduce risk of MACE in pts with DM2 + CVD
3. Reduce the risk of ESRD, doubling of creatinine, CV death, or HF hospitalization in pts with DM2 + diabetic nephropathy

Dapagliflozin (Farxiga)

1. Improve glycemic control in patients with DM2
2. Reduce risk of HF hosp in pts with DM2 + CVD/multiple CV RFs
3. Reduce the risk of CV death and HF hosp in patients with HFrEF NYHA II-IV
4. Reduce risk of sustained eGFR decline, ESRD, CV death, and hospitalization for HF in adults with CKD at risk of progression

Ertugliflozin (Steglatro)

1. Improve glycemic control in patients with DM2

Bexagliflozin (Brenzavvy)

1. Improve glycemic control in patients with DM2

Sotagliflozin (Inpefa)

1. Reduce the risk of CV death and HF hosp in pts with heart failure
2. Reduce the risk of CV death and HF hosp in pts with DM2 + CKD + CV RF(s)

REFERENCES

Medication use in Pediatric/Young Adults:

1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012

3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation date: 09/26/18
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

ENBREL (ETANERCEPT)

Generic	Brand	HICL	GPID	SIZE	Other
ETANERCEPT	ENBREL 25MG/0.5ML SYRINGE	18830	98398	0.5	F
ETANERCEPT	ENBREL 25MG/0.5ML VIAL	18830	48417	0.5	NF
ETANERCEPT	ENBREL 50MG/ML SYRINGE	18830	23574	1	F
ETANERCEPT	ENBREL 50MG/ML MINI CARTRIDGE	18830	43924	1	NF
ETANERCEPT	ENBREL 50MG/ML PEN INJCTR	18830	23574	1	F

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on therapy.
2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
3. Patient has one of the following indications and medication is prescribed by the appropriate specialist as noted:
   a. Patient has a diagnosis of Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Ankylosing Spondylitis or subtype, Juvenile Psoriatic Arthritis, or Polyarticular Juvenile Idiopathic Arthritis (JIA) and requested medication is prescribed by a CPMG or affiliated rheumatologist.
   b. Patient has a diagnosis of psoriasis and requested medication is prescribed by a CPMG or affiliated dermatology specialist.

If met, approve indefinitely at HICL, max 8 vials/syringes per 28 days for 25 mg products or 4 pens/syringes/cartridges per 28 days for 50 mg products. [MDD 0.15]
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria:

A. Rheumatoid Arthritis
B. Psoriatic Arthritis (PsA)
C. Ankylosing Spondylitis
D. Psoriasis
E. Polyarticular Juvenile Idiopathic Arthritis (JIA)
F. Juvenile Psoriatic Arthritis

A. RHEUMATOID ARTHRITIS (RA): All the following must be met:
   1. Patient has a diagnosis of RA.
   2. Medication is prescribed by a rheumatologist.
   3. Patient is 18 years of age or older.
   4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   5. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

a. At least 2 of the following medications: methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
b. At least 1 TNF inhibitor (e.g., infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F])

If met, approve indefinitely at HICL, max 8 vials/syringes per 28 days for 25 mg products or 4 pens/syringes/cartridges per 28 days for 50 mg products. [MDD 0.15]
If criteria are not met, do not approve.

B. PSORIATIC ARTHRITIS (PsA): All the following must be met:
1. Patient has a diagnosis of PsA.
2. Medication is prescribed by a rheumatologist.
3. Patient is 2 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. At least 2 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, leflunomide, sulfasalazine
   b. At least 1 TNF inhibitor (e.g., infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F])

If met, approve indefinitely at HICL, max 8 vials/syringes per 28 days for 25 mg products or 4 pens/syringes/cartridges per 28 days for 50 mg products. [MDD 0.15]
If criteria are not met, do not approve.

C. ANKYLOSING SPONDYLITIS:
1. Patient has a diagnosis of ankylosing spondylitis or one of the following subtype diagnoses: spondyloarthritis (SpA), axial SpA, nonradiographic axial SpA, radiographic axial SpA, sacroiliitis, undifferentiated spondyloarthropathy, spondyloarthropathy, or enteropathic arthropathy.
2. Medication is prescribed by a rheumatologist.
3. Patient is 18 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

a. At least 1 TNF inhibitor (e.g., infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F])
b. At least 1 IL-17 inhibitor (e.g. secukinumab (Cosentyx) [F, PA])

If met, approve indefinitely at HICL, max 8 vials/syringes per 28 days for 25 mg products or 4 pens/syringes/cartridges per 28 days for 50 mg products. [MDD 0.15]
If criteria are not met, do not approve.

D. PSORIASIS: All the following must be met:
1. Patient has a diagnosis of moderate to severe psoriasis.
2. Medication is prescribed by a dermatologist.
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Patient has experienced an inadequate response, intolerance, or has a contraindication to a topical corticosteroid or topical calcineurin inhibitor (pimecrolimus, tacrolimus), or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate.
   b. Patient has experienced and inadequate response (after at least 2 months) or intolerance to at least **one** or contraindication to at least **two** of the following therapies, or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate: Acitretin, Cyclosporine, Methotrexate, Apremilast (Otezla), Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
   c. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one TNF inhibitor (adalimumab (Amjevita) - preferred [F], infliximab (Inflectra) - preferred [F])
   d. Patient has experienced an inadequate response, intolerance, or has a contraindication to an IL12-23 inhibitor (ustekinumab-kfce (Yesintek) - preferred [F, PA])
   e. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one IL-17 inhibitor (secukinumab (Cosentyx) - preferred [F])

If met, approve x 3 months (loading dose), MDD 0.29, to give max #8 vials/syringes/cartridges of 50 mg product or #16 vials/syringes of 25 mg product per 28 days. Then approve indefinitely at HICL, MDD 0.15, to give max #8 vials/syringes per 28 days for 25 mg products or #4 pens/syringes/cartridges per 28 days for 50 mg products.
If criteria are not met, do not approve.

E. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (JIA) or JUVENILE PSORIATIC ARTHRITIS: All the following must be met
1. Patient has a diagnosis of JIA.

2. Medication is prescribed by a rheumatologist.
3. Patient is 2 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient with failure, intolerance, or contraindication to at least 1 of the following medications, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Methotrexate
   b. Leflunomide
   c. Hydroxychloroquine
   d. Sulfasalazine

If met, approve indefinitely at HICL, max 8 vials/syringes per 28 days for 25 mg products or 4 pens/syringes/cartridges per 28 days for 50 mg products. [MDD 0.15]
If criteria are not met, do not approve.

ESCALATION CRITERIA/QTY LIMIT OVERRIDES: Patient must meet New Member or Initial Criteria prior to review of Quantities. Escalation criteria review only the quantities authorized upon PA approval.

Applicable only to patients with a diagnosis of Psoriasis:
1. Dermatology provider notes the patient is resuming therapy after a gap of 3 months or longer in treatment (to reload)

   If met, approve 3 months (loading dose), MDD 0.29, to give max #8 vials/syringes/cartridges of 50 mg product or #16 vials/syringes of 25 mg product per 28 days. Then approve indefinitely at HICL, MDD 0.15, to give max #8 vials/syringes per 28 days for 25 mg products or #4 pens/syringes/cartridges per 28 days for 50 mg products.
   If not met, deny and offer maximum 4 pens/syringes (for Enbrel 50 mg) or 8 vials/syringes (for Enbrel 25 mg) per 28 days per original approval.

ePA Questions
1. Is the patient stable on therapy with etanercept?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Will this medication be used in combination with a biologic or advanced small molecule for the same indication?
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Rheumatoid Arthritis (RA); Psoriatic Arthritis (PsA); Ankylosing Spondylitis or subtype; Psoriasis; Polyarticular Juvenile Idiopathic Arthritis (JIA) or Juvenile Psoriatic Arthritis]
   QUESTIONS BASED ON DIAGNOSIS SELECTED
   Rheumatoid Arthritis
   1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.

2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); infliximab) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Psoriatic Arthritis (PsA)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); infliximab) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Ankylosing Spondylitis or Subtype

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (infliximab) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Psoriasis

1. BSA impacted (%):
2. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (topical steroids; tacrolimus ointment; acitretin capsules (10 mg, 25 mg); cyclosporine capsules (25 mg, 100 mg); methotrexate tablets (2.5 mg) or injection (25 mg/mL); Otezla tablets; infliximab) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Polyarticular Juvenile Idiopathic Arthritis (JIA) or Juvenile Psoriatic Arthritis

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

References:

1. “Stable on therapy” means patient is tolerating well, appears to be effective and provider wishes to continue.

2. Juvenile Psoriatic Arthritis:
i. UpToDate: Psoriatic juvenile idiopathic arthritis: Management and prognosis. Accessed 4/7/25.
ii. Ringold S, Angeles-Han ST, Beukelman T, Lovell D, Cuello CA, Becker ML, Colbert RA, Feldman BM, Ferguson PJ, Gewanter H, Guzman J, Horonjeff J, Nigrovic PA, Ombrello MJ, Passo MH, Stoll ML, Rabinovich CE, Schneider R, Halyabar O, Hays K, Shah AA, Sullivan N, Szymanski AM, Turgunbaev M, Turner A, Reston J. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care Res (Hoboken). 2019 Jun;71(6):717-734. doi: 10.1002/acr.23870.

Treatment	Relative Contraindications for Psoriasis
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses (ex: systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for psoriasis.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities, active malignancy, and hypersensitivity*
Acitretin	*Women of child potential (cannot consider pregnancy up to 3 years after completion of treatment), pregnancy, lactation, severe hepatic or renal dysfunction, chronically abnormal elevated lipid values, and hypersensitivity*

Created: 01/2021
Effective: 06/2025
Reviewed: 05/2025
Revised: 05/2025

ESTRADIOL VAG INSERT (IMVEXXY)

Generic	Brand	HICL	GPID	Exception/Other
ESTRADIOL VAGINAL INSERT	IMVEXXY		44813, 44814	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient has benefit coverage for sexual dysfunction medications
2. Patient has tried and failed or has an intolerance or a contraindication to at least one of the following three KPCO-preferred products (listed in preferred order), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. estradiol vaginal cream
   b. estradiol vaginal tablet (Yuvafem) (nonformulary with PA restriction)
   c. estradiol vaginal ring (Estring) (nonformulary with PA restriction)

If all the above are met then approve x1 year at GPID level.
If all the above are not met, do not approve.

RENEWAL CRITERIA: Must meet the following:
1. Patient has benefit coverage for sexual dysfunction medications

If all the above are met then approve x1 year at GPID level.
If all the above are not met, do not approve.

ePA Questions
Initial Review Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication name, strength, date(s) of treatment, and reasoning for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there a reasoning why alternatives (such as estradiol vaginal cream or other vaginal estradiol products) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
To ensure appropriate utilization of nonformulary Imvexxy.
Imvexxy is categorized as Category 1 – Drugs to treat impotency.

FDA APPROVED INDICATIONS
IMVEXXY is an estrogen indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

REFERENCES
Imvexxy Package Insert

Creation date: 11/2021
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 09/2023

ETHACRYNIC ACID (EDECRIN)

Generic	Brand	HICL	GPID	Other
ETHACRYNIC ACID	EDECRIN	03659	34910	Non-Formulary

GUIDELINES FOR COVERAGE: Must meet one of the following:

1. Patient has tried and failed, or has an intolerance to or a contraindication to at least 1 of the preferred loop diuretics, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception: Furosemide, Torsemide, Bumetanide
2. Patient has experienced a severe drug reaction to a sulfonamide, including but not limited to: Stevens-Johnson Syndrome (SJS), Drug Reaction with Eosinophilia and System Symptoms (DRESS), Toxic Epidermal Necrolysis (TEN), or anaphylaxis

If either of the above are met, approve at GPID level indefinitely.
If neither criterion is met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (furosemide tablets, torsemide tablets, bumetanide tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Has the patient experienced any of the following reactions to a sulfonamide (check any/all that apply):
    a. Stevens-Johnson Syndrome (SJS)
    b. Drug Reaction with Eosinophilia and System Symptoms (DRESS)
    c. Toxic Epidermal Necrolysis (TEN)
    d. anaphylaxis

FDA APPROVED INDICATIONS

Management of edema associated with congestive heart failure, hepatic cirrhosis or renal disease; short-term management of ascites due to malignancy, idiopathic edema and lymphedema; short term management of hospitalized pediatric patients, other than infants, with congenital heart disease or nephrotic syndrome.

Creation Date: 4/22/2021
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

ETRASIMOD (VELSIPITY)

Generic	Brand	HICL	GPID	Exception/Other
ETRASIMOD	VELSIPITY	49267		Non-formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days.
2. Patient is 18 years of age or older.
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
4. Patient has a diagnosis of ulcerative colitis and is stable on therapy with etrasimod (Velsipity) prescribed by a gastroenterologist.

If met, approve indefinitely at HICL, max 1 tablet per day.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Patient must be 18 years of age or older.
2. Medication must be prescribed by a gastroenterology specialist.
3. Patient must have a diagnosis of moderately to severely active ulcerative colitis.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient has tried and failed, or has an intolerance or contraindication to all of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    - At least 1 TNF inhibitor (e.g. adalimumab (Amjevita) - preferred [F], infliximab (Inflectra) - preferred [F], or golimumab (Simponi) [NF, PA])
    - A JAK-inhibitor (e.g. tofacitinib (Xeljanz) – [F], upadacitinib (Rinvoq) [NF, PA])

If initial criteria are met, approve indefinitely at HICL, max 1 tablet per day.
If initial criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with etrasimod (Velsipity)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Will the patient be using this in combination with another biologic or advanced small molecule for the same indication?
4. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (Xeljanz 10 mg tablets – half tablet twice daily) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

RATIONALE
The December 2023 Kaiser Permanente Interregional Practice Recommendations for IBD encourages use of anti-TNFs (infliximab or adalimumab) first-line due to their established efficacy, safety, and affordability. Network meta-analyses have consistently demonstrated upadacitinib (JAK-inhibitor) as superior in ulcerative colitis. Therefore, it is reasonable to position etrasimod as a third-line option after anti-TNF and JAK-inhibitor based on efficacy and cost.

FDA APPROVED INDICATIONS
Moderately to severely active ulcerative colitis in adults

REFERENCES
KPCO Gastroenterology Clinical Pharmacy Services

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

EVOLOCUMAB (REPATHA)

Generic	Brand	HICL	GPID	Comments
EVOLOCUMAB	REPATHA SURECLICK, REPATHA SYRINGE	42378	38178, 39363	Nonformulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA:
1. Patient is new to KPCO within the past 90 days and stable on therapy.

If met, approve at HICL x1 year, max daily dose of 0.08 (2 syringes/pens per 28 days).
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of either homozygous familial hypercholesterolemia (HoFH), heterozygous familial hypercholesterolemia (HeFH), or atherosclerotic cardiovascular disease (ASCVD) with a clinical event^^*
2. Has a current LDL level drawn within the last 90 days of greater than or equal to one of the following:
   a) 55 mg/dL for ASCVD at very high risk defined as multiple ASCVD events^^ or 1 ASCVD event and 2 or more high risk conditions (age ≥ 65 years, familial hypercholesterolemia, diabetes, HTN, eGFR 15-59, current smoking)
   b) 70mg/dL for ASCVD not at very high risk
   c) 100 mg/dL for HeFH/HoFH
3. Patient must meet one of the following:
   a) have been taking atorvastatin 80mg or rosuvastatin 40mg daily or statin therapy at the maximally tolerated dose for at least 60 days prior to LDL lab;
   b) have an absolute contraindication to statin therapy (active, decompensated liver disease; nursing female, pregnancy, or plans to become pregnant;
   c) a hypersensitivity reaction;
   d) a documented history of CPK>10x ULN or rhabdomyolysis attributed to a statin and not explained by a drug interaction, fall, or prolonged immobility);
   e) or the patient is statin intolerant as defined by the National Lipid Association Statin Intolerance Panel**
4. Patient has been taking ezetimibe for at least 60 days prior to LDL lab, or the patient has a contraindication or intolerance to ezetimibe

If met, approve at HICL x1 year, max daily dose of 0.08 (2 syringes/pens per 28 days).
If not met, do not approve.

RENEWAL CRITERIA: Must meet ONE of the following:
1. Patient's LDL decreased by at least 20% after starting the PCSK9 inhibitor when compared to pre-PCSK9 inhibitor levels.
2. Patient's LDL is at goal.

If either criterion is met, approve at HICL indefinitely, max daily dose of 0.08 (2 syringes/pens per 28 days).
If neither criterion is met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient stable on evolocumab therapy?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: homozygous familial hypercholesterolemia (HoFH), heterozygous familial hypercholesterolemia (HeFH), or atherosclerotic cardiovascular disease (ASCVD) with a clinical event (must list the clinical event in Provider Comment section below or attach applicable chart notes.]
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (rosuvastatin tablets, atorvastatin tablets, lovastatin tablets, simvastatin tablets, pravastatin tablets; ezetimibe tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
6. Current LDL:
7. Date of LDL lab (MMDDYY):

Renewal Review Question
1. Current LDL:
2. Date of LDL lab (MMDDYY):
3. LDL Goal:

REFERENCES
*Requires documentation which may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and laboratory data.

^^**Includes**: MI, ACS, CAD with intervention (e.g., PCI, stent, CABG), ischemic non-cardioembolic stroke, PAD with intervention (e.g., stent, surgery); **Excludes**: High CAC score, AAA, CAD finding on diagnostic cath without MI/ACS/intervention, CAD equivalents (e.g. DM, CKD), primary prevention patients regardless of CV risk score

**Inability to tolerate at least 2 statins, with at least one started at the lowest starting daily dose

For primary prevention for a patient who has NOT been noted to have familial hypercholesterolemia, a PCSK9i would not be appropriate. If they have failed statins (even low dose 1-2 days per week) and ezetimibe, we could offer any formulary, unrestricted lipid-lowering therapy.

RATIONALE
Per Health Plan

Creation Date: 3/15/2017
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

EXTENDED-RELEASE STIMULANT QUANTITY LIMIT CRITERIA

Generic	Brand	HICL	GPID	Exception/Other
N/A	N/A	N/A	N/A	

GUIDELINES FOR QUANTITY LIMIT OVERRIDES

Must meet ONE of the following:

1. Dose is above FDA-labeled maximum, and medication is prescribed by a CPMG or affiliated behavioral health provider.
2. Patient requires different doses in am vs pm (i.e., Adderall XR 20mg qam and 30mg qpm).
3. Request is for BID dosing due to lack of efficacy (drug not lasting long enough) with daily dosing and the patient has tried and failed addition of an IR stimulant dose in pm.
4. Request is for a one-time approval for titration sig at the start of therapy.

If coverage criteria are met at criterion 1, 2, or 3, approve requested quantity x1 year.
If coverage criteria are met at criterion 4, approve requested quantity x1 fill only.
If no criteria are met, do not approve.

Drug	Strengths	CM/MP	Max FDA approved dose per Day	Qty Limit per 30 days
Dextroamphetamine/ amphetamine (Adderall XR) capsules	5, 10, 15, 20, 25, 30 mg	F	60 mg	60 caps
Dextroamphetamine/amphetamine (Mydayis) capsules	12.5, 25, 37.5, 50 mg	NF	50 mg	30 caps
Dextroamphetamine (Xelstrym) patch	4.5, 9, 13.5, 18 mg	NF	18 mg	30 patches
Amphetamine (Dyanavel XR) chewable tablet	5, 10, 15, 20 mg	NF	20 mg	30 tablets
Amphetamine (Dyanavel XR) suspension	2.5 mg/mL	NF	20 mg	240 mL
Amphetamine (Adzenys XR-ODT) tablet	3.1, 6.3, 9.4, 12.5, 15.7, 18.8 mg	NF	18.8 mg	30 tablets
Amphetamine (Adzenys ER) suspension	1.25 mg/mL	NF	18.8 mg	450 mL
Methylphenidate (Aptensio XR) extended-release capsules	10, 15, 20, 30, 40, 50, 60 mg	NF	60 mg	30 caps
Methylphenidate (Concerta) tablets	18, 26, 36, 54 mg	F	72 mg	60 tabs
Methylphenidate (Cotempla XR-ODT) oral disintegrating extended-release tablets	8.6, 17.3 25.9 mg	NF	51.8 mg	60 tabs
Methylphenidate (Metadate CD) capsules	10, 20, 30, 40, 50, 60 mg	F	60 mg	60 caps

Drug	Strengths	CM/MP	Max FDA approved dose per Day	Qty Limit per 30 days
Methylphenidate (Ritalin LA) capsules	10, 20, 30, 40 mg	NF	60 mg	60 caps
Methylphenidate (Daytrana) patch	10, 15, 20, 30 mg	NF	60 mg	30 patches
Methylphenidate (Quillivant XR) suspension	25 mg/5 mL	NF	60 mg	360 mL (1800 mg)
Methylphenidate (Quillichew ER) chewable tablet	20, 30, 40 mg	NF	60 mg	30 tabs
Methylphenidate (Jornay PM) extended-release capsules	20, 40, 60, 80, 100 mg	NF	100 mg	30 caps
Methylphenidate (Relexxii) extended-release tablets	18, 27, 36, 45, 54, 63, 72 mg	NF	72 mg	30 tabs
Lisdexamfetamine (Vyvanse) capsules	10, 20, 30, 40, 50, 60, 70 mg	NF	70 mg	30 caps
Lisdexamfetamine (Vyvanse) chewable tablets	10, 20, 30, 40, 50, 60 mg	NF	70 mg	30 tabs
Dexmethylphenidate (Focalin XR) capsules	5, 15, 20, 25, 30 mg	NF	40 mg	60 caps
Serdexmethylphenidate/dexmethylphenidate (Azstarys) capsules	26.1/ 5,2 mg, 39.2/ 7.8 mg, 52.3/ 10.4 mg	NF	52.3 mg/ 10.4 mg	30 caps

RATIONALE
Quantity limits help to reduce pill burden for patients, help reduce costs and since stimulants are controlled substances; it further helps to limit controlled substances in society.

FDA APPROVED INDICATIONS
Stimulants are FDA approved for treatment of attention-deficit/hyperactivity disorder (ADHD)

REFERENCES

Creation Date: 7/2020
Effective Date: 10/2024
Reviewed Date: 9/2024
Revised Date: 9/2024

FEBUXOSTAT (ULORIC) - STEP THERAPY

Generic	Brand	HICL	GPID	Exception/Other
FEBUXOSTAT	ULORIC	36106		Formulary (generic)

Step Therapy Criteria

1. Patient has failed or has a contraindication to allopurinol, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If met, approve at HICL indefinitely.
If not met, do not approve.

STEP THERAPY RULES:

- Coding is on generic febuxostat only. Brand Uloric is NF, unrestricted.
- Coding looks back at claims from the past 365 days.
- If there is a paid claim for allopurinol or febuxostat in the past 365 days, claims for generic febuxostat will pay without review.

RATIONALE

The 2020 ACR guidelines strongly recommend allopurinol over all other ULT as the preferred first-line agent for all patients, including in those with CKD stage >3.

REFERENCE

FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology guideline for the management of gout. Arthritis Care Res (Hoboken). 2020;72(6):744-760.

Creation date: 11/2020
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

FECAL MICROBIOTA (VOWST)

Generic	Brand	HICL	GCN	Exception/Other
FECAL MICROBIOTA, LIVE ORAL	VOWST	48888	54053	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient is 18 years of age or older.
2. Must be prescribed by a provider specializing in gastroenterology or infectious diseases.
3. Patient has a diagnosis of recurrent CDI with at least 3 total CDI episodes.
4. Patient will have completed standard of care treatment of CDI (i.e. vancomycin or fidaxomicin) with administration 2-4 days after completion.
5. Bowel cleanse with either 296 ml of magnesium citrate OR polyethylene glycol electrolyte solution (250ml) will occur on the day before the first dose of Vowst.
6. Patient has failed fecal microbiota transplant (FMT) or has a contraindication to colonoscopy/EGD required for FMT.

If initial criteria are met, approve x1 fill only, max 12 capsules (1 bottle).
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Patient had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of completing Vowst AND a positive stool test for C difficile.
2. Patient has not received more than 1 dose of Vowst.

If renewal criteria are met, approve x1 fill only, max 12 capsules (1 bottle).
If renewal criteria are not met, do not approve.

ePA Questions for Provider Outreach
Initial Review Questions
1. Number of *Clostridioides difficile* infections the patient has had:
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (i.e. fecal microbiota transplant (FMT)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
4. Completion date of most recent vancomycin or fidaxomicin treatment (MMDDYY):
5. Planned start date for Vowst treatment (MMDDYY):
6. Will the patient complete a bowel cleanse with either 296 ml of magnesium citrate OR polyethylene glycol electrolyte solution (250ml) on the day before the first dose of Vowst?

Renewal Review Questions
1. How many courses of Vowst has the patient received?
2. Has the patient experienced treatment failure, defined as the presence of CDI diarrhea within 8 weeks of completing Vowst AND a positive stool test for C difficile?

RATIONALE
While we expect utilization to be low, we want to ensure appropriate use of this high cost therapy with: (1) prescribing restricted to gastroenterology and infectious disease providers, (2) diagnosis of recurrent CDI with at least 3 total CDI episodes (in line with current guideline recommendations for use of FMT) (3) patient completing standard of care treatment for CDI prior to administration (since FML

oral is approved for prevention of recurrent CDI but not treatment), and (4) patient having trial and failure or intolerance to FMT OR has contraindication colonoscopy/EGD required for FMT (FML oral has not demonstrated any efficacy or safety advantage over non-FDA approved FMT. Given the limited efficacy data for FML oral, and its high-cost relative to non-FDA approved FMT, FML oral should be positioned after FMT when appropriate). In contrast, we do not propose to require a trial of bezlotoxumab prior to FML given limitations with timely infusion access.

FDA APPROVED INDICATIONS
Clostridioides difficile infection, prophylaxis: Prevention of recurrence of *C. difficile* infection (CDI) in patients ≥18 years of age following antibiotic treatment of recurrent CDI.
Limitations of use: Not indicated for treatment of CDI.

Creation Date: 3/2024
Effective Date: 4/2024
Reviewed Date:
Revised Date:

FENFLURAMINE (FINTEPLA)

Generic	Brand	HICL	GPID	Exception/Other
FENFLURAMINE ORAL SOLUTION	FINTEPLA	02116	48284	Nonformulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on fenfluramine (Fintepla)
2. Patient has a diagnosis of Lennox-Gastaut Syndrome or Dravet Syndrome and is being managed by a CPMG or affiliated neurologist or epileptologist

If New Member Criteria are met, approve indefinitely.
If New Member Criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria below:

A. Lennox-Gastaut syndrome (LGS)
B. Dravet syndrome (DS)

A. To treat Lennox-Gastaut Syndrome (LGS): All the following must be met:
   1. Medication is prescribed by a CPMG or affiliated neurologist or epileptologist.
   2. Patient is 2 years of age or older.
   3. The medication will be used as adjunctive therapy with at least one other anti-seizure drug.
   4. The patient is stable on fenfluramine (Fintepla), or the patient has failed a valproic acid derivative, and lamotrigine, and at least 2 of the following medications, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. clobazam
      b. topiramate
      c. rufinamide [nonformulary]
   5. Patient has failed or is concomitantly receiving Epidiolex [Nonformulary requires Prior Authorization].

      If initial criteria are met, approve indefinitely.
      If initial criteria are not met, do not approve.

B. To treat Dravet Syndrome (DS): All the following must be met:
   1. Medication is prescribed by a CPMG or affiliated neurologist or epileptologist.
   2. Patient is 2 years of age or older.
   3. The patient is stable on fenfluramine (Fintepla), or the patient has failed all the following medications, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the

patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
a. a valproic acid derivative
b. clobazam
c. Epidiolex [Nonformulary requires Prior Authorization]
d. Diacomit [Nonformulary requires Prior Authorization]

If initial criteria are met, approve indefinitely.
If initial criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with fenfluramine (Fintepla)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Lennox-Gastaut syndrome (LGS); Dravet syndrome (DS)]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Lennox-Gastaut syndrome (LGS)
1. Will the medication be used as adjunctive therapy with at least one other anti-seizure drug?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (divalproex sodium DR (12 hr) or ER (24 hr) tablets, divalproex sodium sprinkle caps (125 mg), valproic acid capsules (250 mg); lamotrigine IR, ER, or chewable tablets; clobazam tablets; topiramate IR tablets or sprinkle capsules (25 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Dravet syndrome (DS)
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (divalproex sodium DR (12 hr) or ER (24 hr) tablets, divalproex sodium sprinkle caps (125 mg), valproic acid capsules (250 mg); clobazam tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Ensure appropriate use consistent with FDA indication.

FDA APPROVED INDICATIONS
Treatment of seizures associated Dravet syndrome (DS) and Lennox-Gastaut Syndrome (LGS) in patients ≥2 years of age.

NOTES: As of December 2022, Fintepla is no longer a controlled substance.

REFERENCES
1. Fintepla [Package Insert], Emeryville, CA: Zogenix; 2023.

Creation date: 01/2021
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

FERRIC MALTOL (ACCRUFER) - PRIOR AUTHORIZATION GUIDELINE

Generic	Brand	HICL	GPID	Exception/Other
FERRIC MALTOL CAPSULES	ACCRUFER	44098	43028	Nonformulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of iron deficiency.
2. Medication is prescribed by a gastroenterologist, nephrologist, oncologist, or hematologist.
3. Must have hemoglobin less than 13 g/dL in men or less than 12 g/dL in women.
4. Must have ferritin less than 30 mcg/L.
5. Patient has tried and failed or has an intolerance or contraindication to intravenous iron dextran*, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve x 6 months, max 2 per day.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of iron deficiency.
2. Medication is prescribed by a gastroenterologist, nephrologist, oncologist, or hematologist.
3. Must have improvement in hemoglobin of at least 2.5 g/dL since starting ferric maltol capsules.
4. Must have ferritin less than 30 mcg/L.

If renewal criteria are met, approve x 6 months, max 2 per day.
If renewal criteria are not met, do not approve.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (ferrous sulfate, ferrous fumarate, ferrous gluconate, intravenous iron dextran) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current hemoglobin lab (g/dL):
4. Date of hemoglobin lab (MMDDYY):
5. Current ferritin lab (mcg/L):
6. Date of ferritin lab (MMDDYY):

RATIONALE
*IV iron dextran offers a different mechanism of action compared to oral iron preparations which require intestinal absorption. Hepcidin, a peptide involved in iron homeostasis in the intestines, has a dramatic role in absorption. This peptide is an acute phase reactant that downregulates iron absorption in the gut in both inflammatory states and with excess iron exposure in the gut. Therefore, failure of oral iron

formulation does not meet regulatory requirement for consideration, as absorption is often irrespective of the oral iron product.

- Phase 3 trials for oral ferric maltol enrolled patients who had failed prior oral ferrous formulations before enrollment. As a result, efficacy advantage over other oral iron supplements has not been established.
- Gastrointestinal side effects of ferric maltol were low but have not been directly compared to other oral iron supplements.

Creation Date: 07/2024
Effective Date: 10/2024
Reviewed Date: 09/2024
Revised Date: 09/2024

FEZOLINETANT

Generic	Brand	HICL	GPID	COMMENTS
FEZOLINETANT	VEOZAH	48921		

GUIDELINES FOR COVERAGE
Must meet all the following:
1. The patient has a diagnosis of moderate to severe menopausal vasomotor symptoms (VMS)
2. Documentation of at least 7 hot flashes per day
3. Patient < 65 years old
4. The patient has had an adequate trial* of or has a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Hormonal therapy (e.g., oral estradiol, transdermal patch [Climara, Dotti] with oral medroxyprogesterone or micronized progesterone [Prometrium] if needed).
    b. At least three preferred non-hormonal therapies (e.g., citalopram/escitalopram, venlafaxine/desvenlafaxine, paroxetine, gabapentin, clonidine).

*Adequate trial is defined as a trial at maximum tolerated dose for at least a 4-week duration.

If met, approve indefinitely at HICL with a quantity limit of #1 per day.
If not met, do not approve.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (estradiol tablets (0.5 mg, 1 mg, 2 mg); Climara patches, Dotti (generic Vivelle DOT) patches; medroxyprogesterone tablets, micronized progesterone capsules; citalopram tablets, escitalopram tablets, venlafaxine ER capsules, paroxetine IR tablets; gabapentin tablets or capsules; clonidine IR tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Number of hot flashes patient experiences per day: _____

RATIONALE
Per OB/Gyn
For further information, please refer to the Prescribing Information and/or Drug Monograph for Veozah. Veozah clinical trials were performed in women aged 40-65 years of age having an average of seven or more moderate-to-severe hot flashes per day.

FDA APPROVED INDICATIONS:
Treatment of moderate to severe vasomotor symptoms due to menopause.

REFERENCES
Veozah [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; May 2023.

Creation Date: 11/2023
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

FILGRASTIM

Brand	Generic	HICL	GPID	Comments
ZARXIO PREFILLED SYRINGE	FILGRASTIM-SNDZ	41814	38082, 38083	NF
NEUPOGEN VIAL	FILGRASTIM	06070	26001, 13206	NF - LATEX FREE
NEUPOGEN PREFILLED SYRINGE	FILGRASTIM	06070	13308, 13309	NF
NIVESTYM VIAL	FILGRASTIM-AAFI	45154	45098, 45099	Formulary (for HIX and PPO only); NF (all other plans) - LATEX FREE
NIVESTYM SYRINGE	FILGRASTIM-AAFI	45154	45103, 45104	Formulary (for HIX and PPO only); NF (all other plans) - LATEX FREE
RELEUKO PREFILLED SYRINGE	FILGRASTIM-AYOW	47848	51988, 51989	NF - PI does not include latex warning; manufacturer did not confirm

GUIDELINES FOR COVERAGE

1. Must have failed Granix [F] and Fulphila (pegfilgrastim-jmdb) [NF, PA] due to adverse drug reaction, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

If met, approve at HICL indefinitely.
If not met, do not approve.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Granix) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Adults: Granix [F] prefilled syringes and vials are the preferred short acting GCSF products for all patients. Fulphila (pegfilgrastim-jmbd) [NF, PA] is the second preferred GCSF product before all other short-acting GCSF products.

Pediatrics: Fulphila is the preferred GCSF product in pediatrics for the indication of febrile neutropenia prevention with chemotherapy. However, if short acting GCSF is requested by a provider, Granix is available.

Creation Date: 09/2021

Effective Date: 09/2024
Reviewed Date: 05/2024
Revised Date: 07/2024

FINERENONE (KERENDIA)

Generic	Brand	HICL	GCN	Exception/Other
FINERENONE	KERENDIA	47487		

GUIDELINES FOR COVERAGE

Must meet all the following:

1. Prescriber is a nephrologist
2. Patient has a diagnosis of Type 2 Diabetes
3. Patient has a diagnosis of chronic kidney disease defined as either:
   a. Urinary albumin-to-creatinine ration (UACR) of 30 to 300 mg/g and an estimated glomerular filtration rate (eGFR) of 25 to 60 mL/minute/1.73m2 and diabetic retinopathy
   b. UACR of 300 to 5,000 mg/g and an eGFR of 25-75 mL/minute/1.73m2
4. Patient is currently treated with a maximum tolerated dose of ACE inhibitor or ARB or has documented allergy, intolerance, or contraindication to both, the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
5. Patient has an allergy, intolerance, or contraindication to empagliflozin (Jardiance), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
6. Patient has a baseline serum potassium of 5 mEq/L or less
7. Patient does NOT have chronic heart failure with reduced ejection fraction of 40% or less

If criteria are met, approve indefinitely at HICL with a max of 1 tab/day.
If criteria are not met, do not approve.

Note: Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Jardiance, losartan tablets, lisinopril, benazepril, captopril) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Does the patient have chronic heart failure with reduced ejection fraction of 40% or less?
4. Urinary albumin-to-creatinine ration (UACR) lab [mg/g]:
5. Date of Urinary albumin-to-creatinine ration (UACR) lab [MMDDYY]:
6. Estimated glomerular filtration rate (eGFR) lab [mL/minute/1.73m2]:
7. Date of estimated glomerular filtration rate (eGFR) lab [MMDDYY]:

8. Serum potassium lab [mEq/L]:
9. Date of serum potassium lab [MMDDYY]:

RATIONALE
Ensure appropriate use consistent with FDA indication.

FDA APPROVED INDICATIONS
To reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction and hospitalization in adult patients with chronic kidney disease (CKD) associated with Type 2 Diabetes.

REFERENCES
1. Kerendia [Package Insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; 2021.

Creation Date: 09/2022
Effective Date: 10/2024
Reviewed Date: 09/2024
Revised Date: 09/2024

FLUTICASONE 44 MCG (FLOVENT)

Generic	Brand	HICL	GCN	Exception/Other
FLUTICASONE PROPIONATE 44 MCG	FLOVENT HFA	07873	53638	Formulary

GUIDELINES FOR COVERAGE

1. Patient is under 5 years of age.

If above criteria are met, approve until patient turns the age of 5.
If above criteria are not met, do not approve.

RATIONALE

1. Flovent HFA 44 mcg/inhalation inhaler should be reserved for patients < 5 years of age who require a low dose ICS
2. Patients 5 years of age and older on Flovent HFA 44 mcg/inhalation inhaler may be receiving suboptimal ICS dose or utilizing multiple inhalations to achieve therapeutic dose which is not cost-effective
3. Alvesco HFA is our preferred ICS inhaler for patients 5 years and older. Although FDA approved for age 12 years and older, use of Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference
4. If provider requests an FDA approved product for patient under 12 years of age, must trial/fail Asmanex HFA.

REFERENCES

Per Health Plan

Creation date: 10/2019
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2025

FOSTAMATINIB

Generic	Brand	HICL	GPID	Comments
FOSTAMATINIB 100MG	TAVALISSE 100MG	44895	44702	
FOSTAMATINIB 150MG	TAVALISSE 150MG	44895	44703	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Must be prescribed by a CPMG or affiliated Hematologist/Oncologist
2. Diagnosis of Idiopathic Thrombocytopenic Purpura (ITP)
3. Patient has tried and failed each of the following for the treatment of ITP, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or likely will cause an adverse reaction or harm; ii) based on supporting clinical documentation provided, the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and a received step therapy exception:
   a. at least one prior systemic corticosteroid
   b. rituximab
   c. IVIG
   d. romiplostim
   e. eltrombopag

If initial criteria are met, approve x6 months, max 2 tablets per day.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following criteria:
1. Prescriber must have evaluated for a response to fostamatinib after the patient completed at least 11 weeks of fostamatinib therapy
2. Patient's platelet count is increased above baseline to a level which has been sufficient to avoid clinically important bleeding

If renewal criteria are met, approve x1 year, max 2 tablets per day.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (corticosteroids, eltrombopag tablets (9 mg, 18 mg, 36 mg, 54 mg); rituximab) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Has the provider evaluated patient response to therapy after at least 11 weeks of treatment?
2. Is the patient’s platelet count increased above baseline to a level which has been sufficient to avoid clinically important bleeding?

RATIONALE
Multiple treatment options are available for management of ITP that may have a more tolerable side effect profile than fostamatinib.

FDA APPROVED INDICATIONS
Fostamatinib is a kinase inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

REFERENCES
Tavalisse prescribing information: https://tavalisse.com/downloads/pdf/Tavalisse-Full-Prescribing-Information.pdf

Creation Date: 5/2019
Effective Date: 6/2024
Reviewed Date: 5/2024
Revised Date: 5/2024

FREMANEZUMAB-VFRM (AJOVY) - STEP THERAPY

Generic	Brand	HICL	GPID	Exception/Other
FREMANEZUMAB-VFRM	AJOVY 225 MG/ML	45236	45306 47862	Formulary

Step Therapy Criteria
Must meet ONE of the criteria below (either 1 or 2), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed another drug in the same pharmacological class or with the same mechanism of action as the required drug and the drug was discontinued due to lack of efficacy, diminished effect, or adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. The requesting provider is a CPMG or affiliated network neurologist or headache specialist, with appropriate referral if needed.

2. The patient has tried and failed at least 2 migraine preventives from lookback list*.

Note: Step therapy to be bypassed if the requesting provider specialty defined in criterion 1 is met

If criteria are met, approve at HICL x indefinite
If criteria are not met, do not approve.

*Lookback List & Rules:
Must have a paid claim for two of the following in the past 365 days

- Antiseizure medications:
  - Divalproex sodium
  - Valproic acid
  - Topiramate
- Anti-hypertensives:
  - Atenolol
  - Metoprolol
  - Nadolol
  - Propranolol
  - Timolol
  - Candesartan
- Antidepressants:
  - Amitriptyline
  - Nortriptyline
  - Venlafaxine
  - Duloxetine
- CGRP directed:
  - Erenumab
  - Galcanezumab
  - Rimegepant
  - Atogepant
  - Eptinezumab

- Other:
    - OnabotulinumtoxinA (chronic migraine diagnosis only)

Grandfather edit will look back for itself and approves.

RATIONALE
Ajovy is KPCO's preferred CGRP directed medication for migraine prevention.
For step one: approving Ajovy for a Neurology prescriber at the PBM continues the current process for Neurologists.
For step two: requires trial of at least 2 migraine preventives with Level A or B evidence per current guidelines prior to trial of Ajovy for non-Neurologist prescribers.

Creation Date:01/2025
Effective Date: 06/2025
Reviewed Date:
Revised Date: 05/2025

FUMARIC ACID DERIVATIVES - BAFIERTAM

Generic	Brand	HICL	GCN	Exception/Other
MONOMETHYL FUMARATE	BAFIERTAM	46576	48156	Non-Formulary, specialty tier, least preferred

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. The requesting provider is a CPMG or affiliated network neurologist
2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include non-active Secondary-Progressive MS or Primary-Progressive MS)
3. The patient has tried and failed, or has an intolerance or allergy to dimethyl fumarate, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve at HICL x2 years, max 4 capsules per day.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: All the following must be met:
1. The requesting provider is a CPMG or affiliated network neurologist
2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include non-active Secondary-Progressive MS or Primary-Progressive MS)

If renewal criteria are met, approve at HICL x2 years, max 4 capsules per day.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Relapsing or active form of multiple sclerosis, Non-active Secondary-Progressive MS, Primary-Progressive MS]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (dimethyl fumarate tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Relapsing or active form of multiple sclerosis, Non-active Secondary-Progressive MS, Primary-Progressive MS]

Quantity and PA Approval Limits

Medication	Dosage Strength	Dosage Regimen	Typical Quantity dispensed	Duration of Approval
Vumerity	231 mg capsules	7-day titration: 231 mg BID	#14 capsules (for 7-day titration)	**Initial:** Approve x 90 days **Renewal:** 2 years
	231 mg capsules	Maintenance: 462 mg BID	#120 capsules	
Bafiertam	95 mg capsules	7-day titration: 95 mg BID	#14 capsules (for 7-day titration)	**Initial:** Approve x 90 days **Renewal:** 2 years
	95 mg capsules	Maintenance: 190 mg BID	#120 capsules	

Disease Modifying Therapies

Class	Generic name	Brand or alternative name	Formulation	Preferred or Non-preferred per IR KP guidelines *(Does NOT refer to formulary status)*
Synthetic Cytokines	Interferon-beta 1a	Avonex	IM injection	NP
	Interferon-beta 1a	Plegidy	SQ/IM injection	NP
	Interferon-beta 1a	Rebif	SQ injection	NP
	Interferon-beta 1b	Extavia	SQ injection	P
		Betaseron	SQ Injection	NP
Synthetic Myelin Basic Protein	Glatiramer acetate	Brand: Copaxone	SQ injection	NP
		Generic: Glatopa (Sandoz)	SQ injection	P
		Generic: Glatiramer acetate (Mylan)	SQ injection	NP
Reduced proliferation of activated T and B lymphocytes	Teriflunomide	Aubagio	Oral	NP
	Leflunomide** (pro-drug of teriflunomide)	Generic only (Brand: Arava)	Oral	NP
Stimulator of Nrf2 pathway (aka Fumaric Acid Derivatives)	Dimethyl fumarate (pro-drug of MMF)	Tecfidera	Oral	Generic – P Brand - NP
	Diroximel fumarate (pro-drug of MMF)	Vumerity (bioequivalent to Tecfidera)	Oral	NP
	Monomethyl fumarate (active metabolite)	Bafiertam	Oral	NP
S1P Receptor Modulator	Fingolimod	Gilenya	Oral	P
	Ozanimod	Zeposia	Oral	NP
	Ponesimod	Ponvory	Oral	NP
	Siponimod	Mayzent	Oral	NP
T and B cell Depleting Small Molecule	Cladribine	Mavenclad	Oral	NP
T and B cell Depleting Antibody	Alemtuzumab	Lemtrada	Infusion	NP
Lymphocyte Anti-migration Antibody	Natalizumab	Tysabri	Infusion	NP
B-cell Depleting Antibodies	Rituximab-abbs**	Biosimilar: Truxima,	Infusion	P
	Rituximab-pvvr**	Biosimilar: Ruxience	Infusion	NP
	Rituximab**	Brand: Rituxan	Infusion	NP

	Ocrelizumab	Ocrevus	Infusion	NP
	Ofatumumab	Kesimpta	SQ injection	NP

***Off-label disease modifying therapy for MS*

RATIONALE
Per Plan.

FDA APPROVED INDICATIONS
Treatment of patients with relapsing forms of multiple sclerosis

Creation date: 07/2020
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2024

FUMARIC ACID DERIVATIVES - VUMERITY

Generic	Brand	HICL	GCN	Exception/Other
DIROXIMEL FUMARATE	VUMERITY	46164	47209	Non-Formulary, specialty tier, preferred after dimethyl fumarate

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. The requesting provider is a CPMG or affiliated network neurologist
2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include non-active Secondary-Progressive MS or Primary-Progressive MS)
3. The patient has tried and failed, or has an intolerance or allergy to dimethyl fumarate, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve at HICL x2 years, max 4 capsules per day.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: All the following must be met:
1. The requesting provider is a CPMG or affiliated network neurologist
2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include non-active Secondary-Progressive MS or Primary-Progressive MS)

If renewal criteria are met, approve at HICL x2 years, max 4 capsules per day.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: relapsing or active form of multiple sclerosis, non-active Secondary-Progressive MS, Primary-Progressive MS]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (dimethyl fumarate tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Relapsing or active form of multiple sclerosis, Non-active Secondary-Progressive MS, Primary-Progressive MS]

Quantity and PA Approval Limits

Medication	Dosage Strength	Dosage Regimen	Typical Quantity dispensed	Duration of Approval
Vumerity	231 mg capsules	7-day titration: 231 mg BID	#14 capsules (for 7-day titration)	**Initial:** Approve x 90 days **Renewal:** 2 years
	231 mg capsules	Maintenance: 462 mg BID	#120 capsules	
Bafiertam	95 mg capsules	7-day titration: 95 mg BID	#14 capsules (for 7-day titration)	**Initial:** Approve x 90 days **Renewal:** 2 years
	95 mg capsules	Maintenance: 190 mg BID	#120 capsules	

Disease Modifying Therapies

Class	Generic name	Brand or alternative name	Formulation	Preferred or Non-preferred per IR KP guidelines *(Does NOT refer to formulary status)*
Synthetic Cytokines	Interferon-beta 1a	Avonex	IM injection	NP
	Interferon-beta 1a	Plegidy	SQ/IM injection	NP
	Interferon-beta 1a	Rebif	SQ injection	NP
	Interferon-beta 1b	Extavia	SQ injection	P
		Betaseron	SQ Injection	NP
Synthetic Myelin Basic Protein	Glatiramer acetate	Brand: Copaxone	SQ injection	NP
		Generic: Glatopa (Sandoz)	SQ injection	P
		Generic: Glatiramer acetate (Mylan)	SQ injection	NP
Reduced proliferation of activated T and B lymphocytes	Teriflunomide	Aubagio	Oral	NP
	Leflunomide** (pro-drug of teriflunomide)	Generic only (Brand: Arava)	Oral	NP
Stimulator of Nrf2 pathway (aka Fumaric Acid Derivatives)	Dimethyl fumarate (pro-drug of MMF)	Tecfidera	Oral	Generic – P Brand - NP
	Diroximel fumarate (pro-drug of MMF)	Vumerity (bioequivalent to Tecfidera)	Oral	NP
	Monomethyl fumarate (active metabolite)	Bafiertam	Oral	NP
S1P Receptor Modulator	Fingolimod	Gilenya	Oral	P
	Ozanimod	Zeposia	Oral	NP
	Ponesimod	Ponvory	Oral	NP
	Siponimod	Mayzent	Oral	NP
T and B cell Depleting Small Molecule	Cladribine	Mavenclad	Oral	NP
T and B cell Depleting Antibody	Alemtuzumab	Lemtrada	Infusion	NP
Lymphocyte Anti-migration Antibody	Natalizumab	Tysabri	Infusion	NP
B-cell Depleting Antibodies	Rituximab-abbs**	Biosimilar: Truxima,	Infusion	P
	Rituximab-pvvr**	Biosimilar: Ruxience	Infusion	NP
	Rituximab**	Brand: Rituxan	Infusion	NP

	Ocrelizumab	Ocrevus	Infusion	NP
	Ofatumumab	Kesimpta	SQ injection	NP

***Off-label disease modifying therapy for MS*

RATIONALE
Per Plan.

FDA APPROVED INDICATIONS
Treatment of patients with relapsing forms of multiple sclerosis

Creation date: 07/2020
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2024

GANAXOLONE

Generic	Brand	HICL	GPID	Exception/Other
GANAXOLONE	ZTALMY	47912	52095	

GUIDELINES FOR COVERAGE

Must meet all the following:
1. The patient has a diagnosis of seizures that are associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD).
2. The patient is 2 years of age or older

If yes, approve indefinitely at HICL, max #36 mL per day.
If no, do not approve.

ePA Questions
1. Does the patient have a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)]? If yes, please attaching supporting documentation.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ztalmy.

REFERENCES
Ztalmy [Prescribing Information]. Radnor, PA: Marinus Pharmaceuticals, Inc.; June 2022.

Creation date: 09/2022
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

GIP/GLP-1 AGONISTS
MOUNJARO

Generic	Brand	HICL	GPID	Comments	FDA Indication
TIRZEPATIDE	MOUNJARO		52333, 52334, 52335, 52336, 52337, 52338	Non-Formulary; Specialty tier	DM2 GIP/GLP-1 agonist

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following indications and meet indication-specific criteria as follows:

A. Adults 25 years of age or older with DM2 without ASCVD
B. Adults 25 years of age or older with DM2 with ASCVD
C. Pediatrics/Young Adults between 10 and 25 years of age with DM2
D. Excluded from coverage for the treatment of weight loss (with or without OSA), heart failure (with or without preserved ejection fraction), Metabolic Dysfunction-Associated Steatohepatitis (MASH), and any other indication, unless specified

A. To treat type 2 diabetes in patients without ASCVD: Must meet all the following:
1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
2. Patient is not taking another GLP-1 or GLP/GIP containing product
3. Current (within the past 3 months) HgbA1c is above but within 2% of patient's designated A1c goal unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Has contraindications to, is currently using, or has failed maximum dose metformin
   b. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months, or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor, or the patient has an intolerance to any SGLT-2 inhibitor
   c. Has contraindications to, is currently using, or has failed maximum dose sulfonylurea, maximum dose pioglitazone, and all possible combinations thereof unless the patient has one of the following:
      - h/o bariatric surgery
      - BMI ≥ 35 (≥ 30 for Asian American/Pacific Islanders)
      - ≥ 5% increase in body weight after 6 months of starting diabetes medications associated with weight gain (i.e., sulfonylurea, insulin, pioglitazone)
      - patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
   d. Patient has an intolerance, contraindication or failure (excludes convenience or needle phobia, whether or not related to injection frequency) to reach A1c goal (goal can be no less

than 7%) after a minimum 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day)

If initial criteria are met, approve at HICL x 6 months, max 1 box/4 pens/2 mL per 28 days [max daily dose of 0.08].
If initial criteria are not met, do not approve.

B. To treat type 2 diabetes in patients with ASCVD [acute coronary syndromes (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)]: Must meet all the following:

1. Patient is not taking another GLP-1 or GLP/GIP containing product.
2. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
3. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor, or the patient has an intolerance to any SGLT-2 inhibitor.
   b. Patient has an intolerance, contraindication or failure (excludes convenience or needle phobia, whether or not related to injection frequency) to reach A1c goal (goal can be no less than 7%) after a minimum 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day)

If initial criteria are met, approve at HICL indefinitely, max 1 box/4 pens/2 mL per 28 days [max daily dose of 0.08].
If initial criteria are not met, do not approve.

C. To treat type 2 diabetes in pediatric patients > 10 but <25 years of age. Must meet all the following:

1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
2. Patient is not taking another GLP-1 or GLP/GIP containing product.
3. Current (within the past 3 months) HgbA1c is above but within 2% of patient's designated A1c goal unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested

drug after undergoing step therapy or after having sought and received a step therapy exception:

a. Has contraindications to, is currently using, or has failed maximum dose metformin
b. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months, or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor or the patient has an intolerance to any SGLT-2 inhibitor
c. Patient has contraindications to, is currently using, or has failed maximum dose of pioglitazone unless the patient has one of the following:
   - h/o bariatric surgery
   - BMI ≥ 95%ile for age and sex
   - ≥ 5% increase in body weight after 6 months of starting these medications
   - patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
d. Patient has an intolerance, contraindication or failure to (excludes convenience or needle phobia, whether or not related to injection frequency) reach A1c goal (goal can be no less than 7%) after a minimum 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day)

If initial criteria are met, approve at HICL x 6 months, max 1 box/4 pens/2 mL per 28 days [max daily dose of 0.08].
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:

1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
2. Patient is not taking another GLP-1 or GLP/GIP containing product
3. HgbA1c is either at goal or has decreased by at least 1% or more from baseline prior to starting GLP-1 therapy unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day.

If renewal criteria are met, approve indefinitely at HICL, max 1 box/4 pens/2 mL per 28 days [max daily dose of 0.08].
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
Diagnosis associated with this request:
[Check boxes for all diagnoses listed in criteria]: Adults 25 years of age or older with DM2 without ASCVD; Adults 25 years of age or older with DM2 with ASCVD; Pediatrics/Young Adults between 10 and 25 years of age with DM2

QUESTIONS BASED ON DIAGNOSIS SELECTED
Adults 25 years of age or older with DM2 without ASCVD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); glipizide, glimepiride, glyburide (1.25 mg, 2.5 mg, 5 mg) immediate-release tablets; pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to

Lantus), Humulin N, Humulin R), or others are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current (within the past 3 months) A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Current (within the past 4 weeks) BMI (kg/m²):
6. Date of current BMI (MMDDYY):
7. Does the patient have history of bariatric surgery?
8. Is the patient taking a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
9. Is the patient using another GLP-1 or GLP/GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)?

Adults 25 years of age or older with DM2 with ASCVD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (such as Jardiance tablets or others) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient taking a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
4. Is the patient using another GLP-1 or GLP/GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)?

Pediatrics/Young Adults between 10 and 25 years of age with DM2

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current (within the past 3 months) A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Current (within the past 4 weeks) BMI (kg/m²):
6. Date of current BMI (MMDDYY):
7. Does the patient have history of bariatric surgery?
8. Is the patient taking a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
9. Is the patient using another GLP-1 or GLP/GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)?

Renewal Review questions

1. Current (within the past 3 months) A1c lab (%):
2. Date of A1c lab (MMDDYY):
3. Is the patient taking a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
4. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

RATIONALE

- Generic liraglutide (Victoza) is the KP preferred GLP-1RA for all indications, except to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and

either obesity or overweight, based on its long-term clinical experience, wide market use and preferential cost.

- GLP-1RAs are not to be used in combination with DPP-4 inhibitors since these 2 drug classes have not been studied together, represent therapeutic duplication based on the mechanism of action, and have no additive benefits.
- The 2024 KP National Diabetes Guidelines recommend Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RA) for people with type 2 diabetes on metformin monotherapy, with clinical ASCVD who cannot take SGLT-2 inhibitors (SGLT2is) (i.e., empagliflozin), to reduce the risk of cardiovascular events (myocardial infarction or stroke) or cardiovascular death. SGLT-2is and GLP-1RAs, including tirzepatide, have strong evidence in diabetes. Tirzepatide has no CV data.

FDA APPROVED INDICATIONS
Tirzepatide (Mounjaro) is indicated to improve glycemic control in patients with type 2 diabetes.

REFERENCES
Per Health Plan

Medication use in Pediatric/Young Adults:

1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012.
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP-4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP-4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation Date: 11/16/2016
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

GIP/GLP-1 AGONISTS
ZEPBOUND

Generic	Brand	HICL	GPID	Comments	FDA Indication
TIRZEPATIDE	ZEPBOUND		54991, 54992, 54993, 54994, 54988, 54989, 56105, 56102	Non-Formulary; Specialty tier	Weight loss GIP/GLP-1 agonist

GUIDELINES FOR COVERAGE
INITIAL CRITERIA: Must have one of the following indications and meet indication-specific criteria as follows:

A. Patients 12 years of age or older for weight loss
B. Moderate to severe obstructive sleep apnea (OSA) in adults with obesity
C. Excluded from coverage for the treatment of diabetes (with or without ASCVD and/or CKD), Metabolic Dysfunction-Associated Steatohepatitis (MASH), and any other indication, unless specified

A. Patients 12 years of age or older for weight loss
1. Medication is being used for weight loss in patients 12 years of age or older.
2. Patient must have benefit plan with coverage for weight loss medications.
3. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
4. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
5. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check)
6. Patient must have an initial body mass index (BMI) of greater than or equal to 30 kg/m2, OR an initial BMI of greater than or equal to 27 kg/m2 AND at least one weight-related comorbid condition, such as hypertension, dyslipidemia, type 2 diabetes.
7. Provider attests to patient being on a reduced calorie diet and has increased physical activity.
8. Patient has documented intolerance, contraindication*, or failure (^excludes convenience or needle phobia, whether or not related to injection frequency) to lose and maintain at least 5% body weight after a trial (defined below) to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception [listed below in preferential order]:
    - phentermine or diethylpropion: on a therapeutic dose of phentermine 37.5 mg per day or diethylpropion 75 mg per day for at least 3 months
    - Qsymia: on a therapeutic dose of phentermine 15 mg/topiramate 92 mg per day for at least 3 months
    - Contrave: on a therapeutic dose of naltrexone 32 mg/bupropion 360 mg per day for at least 3 months
    - Generic liraglutide (Victoza)^: on a therapeutic dose of liraglutide 3 mg per day for at least 3 months

If initial criteria are met, approve x 6 months at HICL, max 1 box/4 pens/2mL per 28 days [max daily dose of 0.08].
If initial criteria are not met, do not approve.

B. Moderate to severe obstructive sleep apnea (OSA) in adults with obesity

1. Prescribed by or in consultation with a Sleep Medicine provider.
2. Patient is ≥ 18 years of age
3. Patient does not have a diagnosis of diabetes.
4. Patient has a diagnosis of moderate-to-severe OSA confirmed on a recent (within 12 months) ambulatory or in-lab polysomnogram demonstrating an apnea/hypopnea index (AHI) ≥ 15 events per hour.
5. Patient has positive airway pressure (PAP) treatment failure, defined as an inability to achieve AHI < 15 events per hour with PAP use, or an inability to use PAP therapy for greater than 4 hours for 70% of nights in a 30-day period.
6. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
7. Patient must have an initial body mass index (BMI) of greater than or equal to 30 kg/m2, calculated using the current weight (as defined in initial criteria #5).
8. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
9. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
10. Provider attests to patient being on a reduced calorie diet and has increased physical activity.
11. Patient has documented intolerance, contraindication*, or failure (^excludes convenience or needle phobia, whether or not related to injection frequency) to lose and maintain at least 5% body weight after a trial (defined as below) to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception [listed below in preferential order]:
    - Qsymia: on a therapeutic dose of phentermine 15 mg/topiramate 92 mg per day for at least 3 months
    - Generic liraglutide (Victoza)^: on a therapeutic dose of liraglutide 3 mg per day for at least 3 months

If initial criteria are met, approve x 6 months at HICL, max 1 box/4 pens/2mL per 28 days [max daily dose of 0.08].
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following criteria based on diagnosis:

A. Patients 12 years of age or older for weight loss
B. Moderate to severe obstructive sleep apnea (OSA) in adults with obesity

A. Patients 12 years of age or older for weight loss

1. Not currently using a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).

2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
3. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
4. Patient must have achieved and maintained at least a 5% weight loss from baseline (objectively measured with in-office weight checks).

If renewal criteria are met, approve x 1 year at HICL, max 1 box/4 pens/2mL per 28 days [max daily dose of 0.08].
If renewal criteria are not met, do not approve.

B. Moderate to severe obstructive sleep apnea (OSA) in adults with obesity

1. Patient experienced a decrease from the baseline apnea/hypopnea index (AHI) (specifically, the baseline AHI used to meet initial criteria #3)
2. Not currently using a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
3. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
4. Patient is on a minimum target dose of 10 mg once weekly.

If renewal criteria are met, approve x 1 year at HICL, max 1 box/4 pens/2mL per 28 days [max daily dose of 0.08].
If renewal criteria are not met, do not approve.

*Contraindications to stimulants (phentermine, diethylpropion, Qsymia) include: pregnancy/breast feeding, hyperthyroidism, closed angle glaucoma, uncontrolled HTN, tachycardia, uncontrolled anxiety, recent (14 days) use of MAOI, substance abuse history, hx of cardiovascular disease (arrhythmias, CAD, CVA, systolic CHF), ADHD/ADD meds
Contraindications to Qsymia (pregnancy/ breast feeding, closed angle glaucoma, hyperthyroidism, recent (14 days) use of MAO, CVD, HTN, tachycardia, uncontrolled anxiety, h/o substance abuse, heavy alcohol use, nephrolithiasis, metabolic acidosis)
Contraindications to Contrave (pregnancy/ breast feeding, recent (14 days) use of MAOI, uncontrolled HTN, seizure disorders, anorexia nervosa or bulimia, or undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs, use of other bupropion-containing products, chronic opioid use)

ePA Questions
Initial Review Questions
Diagnosis associated with this request:
[Check boxes for all diagnoses listed in criteria]: Patients 12 years of age or older for weight loss; Moderate to severe obstructive sleep apnea (OSA) in adults with obesity
QUESTIONS BASED ON DIAGNOSIS SELECTED
Patients 12 years of age or older for weight loss

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (such as phentermine 37.5 mg tablets, diethylpropion tablets, Qsymia, Contrave, Liraglutide (generic Victoza)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current (within the past 4 weeks) BMI (kg/m²):
4. Date of current BMI (MMDDYY):
5. Does the patient have any weight-related comorbidities? Please check any/all boxes that apply:

- Hypertension
- Dyslipidemia
- Type 2 diabetes

6. Is the patient taking a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
7. Is the patient using another GLP-1 or GLP/GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)?
8. Does the provider attest to the patient being on a reduced calorie diet with increased physical activity?

Moderate to severe Obstructive Sleep Apnea (OSA) in adults with obesity

1. Has the patient failed other treatments for this indication? If yes, must list prior treatment(s) trialed, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Does the patient have a diagnosis of diabetes?
3. Has the patient had a recent (within 12 months) ambulatory or in-lab polysomnogram?
4. Provide the apnea-hypopnea index (AHI) events per hour from the patient's most recent polysomnogram:
5. Date of most recent polysomnogram (MMDDYY):
6. Is the patient taking a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
7. Is the patient using another GLP-1 or GLP/GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)?
8. Does the provider attest to patient being on a reduced calorie diet and with increased physical activity?
9. Does the patient have a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check)?
10. Current (within the past 4 weeks) BMI (kg/m^2):
11. Date of current BMI (MMDDYY):

Renewal Review Questions
Diagnosis associated with this request:
[check boxes for all diagnoses listed in criteria]: Patients 12 years of age or older for weight loss; Moderate to severe obstructive sleep apnea (OSA) in adults with obesity
QUESTIONS BASED ON DIAGNOSIS SELECTED
Patients 12 years of age or older for weight loss

1. Current (within the past 4 weeks) BMI (kg/m^2):
2. Date of current BMI (MMDDYY):
3. Is the patient taking a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
4. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

Moderate to severe obstructive sleep apnea (OSA) in adults with obesity

1. Is the patient taking a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
2. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?
3. Most recent apnea-hypopnea index (AHI) events per hour:
4. Date of most recent AHI value (MMDDYY):

RATIONALE

- Generic liraglutide (Victoza) is the KP preferred GLP-1RA for all indications, except to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight, based on its long-term clinical experience, wide market use and preferential cost.
- GLP-1Ras are not are not to be used in combination with DPP-4 inhibitors since these 2 drug classes have not been studied together, represent therapeutic duplication based on the mechanism of action, and have no additive benefits.
- The 2024 KP National Overweight and Obesity Guidelines recommend pharmacotherapy for patients who have a history of being unable to successfully lose weight and maintain body weight loss and have a BMI ≥ 30 kg/m2 or a BMI ≥ 27 kg/m2 with an obesity associated comorbidity, as an adjunct to lifestyle modification. Patients must participate in a comprehensive lifestyle program since pharmacotherapy is most effective when used as an adjunct to such a program. The guidelines also recommend offering continued use of medication for weight maintenance for those patients who have achieved an initial weight loss goal of at least 5% of initial body weight and have not experienced serious or intolerable side effects. Trials of oral weight loss medications and liraglutide are required since they can produce the guideline-recommended 5% weight loss. Victoza contains the same active drug, liraglutide, as Saxenda but in a lower strength. Victoza is FDA approved for the treatment of type 2 diabetes but also has been shown in clinical trials to result in weight loss and thus is commonly used off label for weight management in patients with and without type 2 diabetes. Since generic liraglutide (Victoza) delivers doses in 0.6 mg intervals up to 1.8 mg, the patients requiring a weight loss dose of 2.4 mg and 3 mg will have to do two separate injections in a day.
- PAP remains the mainstay for OSA treatment. However, studies consistently demonstrate that weight loss significantly improves OSA control, with reductions in both the severity of symptoms and related comorbidities. Specifically, in individuals with OSA who are obese, weight loss interventions—ranging from lifestyle changes to pharmacotherapy and surgical options—are critical components of comprehensive care. While weight loss medications such as liraglutide and phentermine/topiramate (Qsymia) are primarily indicated for obesity management, there is clinical evidence supporting their role in improving OSA outcomes. Both drugs have been studied in clinical trials for their potential benefit in OSA patients, with findings indicating positive effects on OSA severity. A meta-analysis of 27 studies involving weight reduction interventions—such as pharmacotherapy, bariatric surgery, and lifestyle modifications—found that a 20% reduction in body mass index (BMI) was associated with a 57% reduction in OSA severity, as measured by the apnea-hypopnea index (AHI). Thus, while the evidence specifically linking pharmacotherapy to clinically meaningful outcomes in OSA—such as mortality and cardiovascular events—is limited, the weight loss achieved through medications like liraglutide and phentermine/topiramate has been shown to significantly improve OSA severity. These medications provide an important option for patients who are unable to achieve sufficient weight loss through lifestyle interventions alone, offering a more accessible and effective pathway to managing OSA in the context of obesity. Since generic liraglutide (Victoza) delivers doses in 0.6 mg intervals up to 1.8 mg, the patients requiring a weight loss dose of 2.4 mg and 3 mg will have to do two separate injections in a day.

FDA APPROVED INDICATIONS

Tirzepatide (Zepbound) is indicated as adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:

Adult patients with an initial body mass index (BMI) of

- 30 kg/m2 or greater (obese)*, or
- 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)

Tirzepatide (Zepbound) is also indicated for moderate to severe obstructive sleep apnea (OSA) and obesity in combination with a reduced-calorie diet and increased physical activity for adults.

REFERENCES
Per Health Plan

Medication use in Pediatric/Young Adults:
1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012.
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP-4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP-4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation Date: 11/16/2016
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

GIVINOSTAT (DUVYZAT) ORAL SUSPENSION

Generic	Brand	HICL	GPID	Comments
GIVINOSTAT	DUVYZAT ORAL SUSP	49667	55857	Non-Formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days.
2. Patient has a diagnosis of Duchenne muscular dystrophy (DMD) and is stable on therapy

If met, approve x1 year at HICL.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Patient is male.
2. Patient is 6 years of age or older.
3. Medication is prescribed by a neurologist.
4. DMD diagnosis confirmed by genetic testing.
5. DMD characteristic clinical signs or symptoms are present (e.g., proximal muscle weakness, Gowers' maneuver, elevated serum creatinine kinase level).
6. Patient is ambulatory
7. Patient is not currently taking or plans to discontinue other DMD therapies (excluding steroid regimen) prior to starting givinostat. [DMD therapies include exon-skipping therapies (e.g., casimersen, eteplirsen, golodirsen, and vitolarsen).]
8. Patient has not received gene therapy for DMD (e.g., delandistrogene moxeparvovec).
9. Patient is on a stable systemic steroid regimen (e.g., glucocorticoid, deflazacort, or vamorolone), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve x 1 year at HICL.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Patient is ambulatory.
2. Patient is not currently receiving other DMD therapies (excluding steroid regimen). [DMD therapies include exon-skipping therapies (e.g., casimersen, eteplirsen, golodirsen, and vitolarsen).]
3. Patient has not received gene therapy for DMD (e.g., delandistrogene moxeparvovec).

If met, approve x 1 year at HICL.
If not met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient stable on therapy with the requested medication?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Does the patient have DMD diagnosis confirmed by genetic testing? If yes, please attach applicable chart notes/genetic testing results.
4. Is the patient ambulatory?
5. Is the patient taking/Will the patient be starting any of the following DMD therapies: [check boxes: casimersen, eteplirsen, golodirsen, and vitolarsen]
6. Has the patient received gene therapy for DMD (e.g., delandistrogene moxeparvovec)?
7. Is the patient on a stable systemic steroid regimen? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
8. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Is the patient ambulatory?
2. Is the patient taking/Will the patient be starting any of the following DMD therapies? [check boxes: casimersen, eteplirsen, golodirsen, and vitolarsen]
3. Has the patient received gene therapy for DMD (e.g., delandistrogene moxeparvovec)?

RATIONALE
Givinostat (Duvyzat) is a histone deacetylase inhibitor and is thought to increase transcription and translation of myogenic factors, thereby promoting muscle fiber regeneration. Givinostat is the first nonsteroidal medication approved for DMD for all DMD gene mutations.

Approval of givinostat was based on one trial in ambulatory patients with DMD that found patients treated with givinostat had significantly less decline in the time it took to climb four stairs (4-stair climb) compared to patients treated with placebo (mean decline of 1.25 seconds versus 3.03 seconds, respectively), however, the change in the North Star Ambulatory assessment (NSAA) was nominally significant but not statistically significant between the two treatment groups. Given the limited clinical trial data and lack of long-term safety data, exceedingly judicious prescribing and monitoring of therapy are warranted.

There is no evidence to support treatment using combination of givinostat with gene therapy (e.g., delandistrogene moxeparvovec) or exon skipping therapies (e.g., casimersen, eteplirsen, golodirsen, and vitolarsen).

FDA APPROVED INDICATIONS
Duchenne muscular dystrophy (DMD) in patients 6 years of age and older

REFERENCES
1. Duvyzat [package insert]. Concord, MA: ITF Therapeutics, LLC; 2024.
2. Arif M. Results from Italfarmaco's EPIDYS trial. Action Duchenne. Published July 4, 2022. Accessed March 29, 2024. https://www.actionduchenne.org/results-from-italfarmacos-epidys-trial/.
3. Mercuri E, Vilchez JJ, Boespflug-Tanguy O, et al. Safety and efficacy of givinostat in boys with Duchenne muscular dystrophy (EPIDYS): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Neurol. 2024;23(4):393-403.

Creation Date: 09/2024
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

GLASDEGIB (DAURISMO)

Generic	Brand	HICL	GPID	Comments
GLASDEGIB	DAURISMO 25MG, 100MG TABLET	45502	45798, 45797	Non-preferred for AML Non-Formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA:
Patient is new to KPCO in the past 90 days and stable on therapy.

If new member criteria are met, approve indefinitely.
If new member criteria are not met, proceed to Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Medication is prescribed by a CPMG or affiliated Oncologist
2. Patient has the FDA-labeled indication for use: newly diagnosed with AML, medication will be used in combination with low-dose cytarabine, and either the patient is 75 years or older or the patient has comorbidities that preclude the use of an intensive induction chemotherapy
3. Patient is unable to use an AML regimen that includes venetoclax; or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria above are met, then approve indefinitely.
If initial criteria above are not met, do not approve.

ePA Questions
1. Will the medication be used in combination with low-dose cytarabine?
2. Does the patient have comorbidities that preclude the use of an intensive induction chemotherapy? If yes, must explain in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use an AML regimen that includes venetoclax? If yes, must explain in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per KPCO treatment guidelines
Glasdegib combination therapy would be nonpreferred compared to venetoclax combination therapies in newly diagnosed AML for majority of cases, unless patient has a contraindication or ineligibility to venetoclax combination therapies.

FDA APPROVED INDICATIONS
DAURISMO™(glasdegib) is a hedgehog pathway inhibitor indicated for the treatment of newly diagnosed acute myeloid leukemia, in combination with low-dose cytarabine, in adults 75 years of age or older or who have comorbidities that preclude use of intensive induction chemotherapy.

Creation Date: 3/8/2019
Effective Date: 04/2025

Reviewed Date: 03/2025
Revised Date: 03/2025

MAVYRET (GLECAPREVIR/PIBRENTASVIR)

Generic	Brand	HICL	GCN	Exception/Other
GLECAPREVIR/PIBRENTASVIR	MAVYRET	44453		Non-Formulary

GUIDELINES FOR COVERAGE
Must meet all general criteria, have one of the following diagnoses, and meet diagnosis-specific criteria below:

A. General criteria for all requests
B. Diagnosis of Hepatitis C virus (HCV)+ transplant recipient
C. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis, treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)
D. Diagnosis of chronic Hepatitis C virus (HCV) with compensated cirrhosis, treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)
E. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past sofosbuvir-based and elbasvir/grazoprevir treatment failure
F. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past glecaprevir/pibrentasvir treatment failure
G. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with multiple past direct-acting antiviral (DAA) treatment failure
H. Diagnosis of pediatric chronic Hepatitis C virus (HCV) and weight < 45 kg

A. General criteria for all requests: Must meet all the following:
1. Patient is at least 3 years old and currently supervised by a gastroenterologist, infectious disease specialist, provider specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model.
2. Patient does not have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
3. Patient is not currently taking any medications that have a clinically significant interaction with the Hepatitis C medication ordered.*

B. The patient is receiving or has received an HCV+ transplant: Must meet all the following:
1. Patient has intolerance or contraindication to sofosbuvir/velpatasvir.
2. Request must be for 100-40 mg strength.

If criteria are met, approve x12 weeks at GPID. Must "Override Force Flag" in the "Override Restriction" field to allow dispense by the Mayo pharmacy in Arizona (post-transplant), and add a formulary override.
If criteria are not met, do not approve.

Note: Only if patient is out of state at Mayo Clinic and immediate post-HCV+ liver transplant may you place a force override to allow the Hep C drug to be dispensed by a non-KP pharmacy.

C. **The patient has diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis, treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)**: Must meet all the following:
1. Patient has a detectable HCV RNA level.
2. Patient does not have a suspected acute HCV exposure in the last 6 months.

3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
4. Patient has intolerance or contraindication to sofosbuvir/velpatasvir.
5. Request must be for 100-40 mg strength.

   If met, approve x8 weeks at GPID.
   If criteria are not met, do not approve.

D. **The patient has diagnosis of chronic Hepatitis C virus (HCV) with compensated cirrhosis, treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)**: Must meet all the following:
   1. Patient has a detectable HCV RNA level.
   2. Patient does not have a suspected acute HCV exposure in the last 6 months.
   3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
   4. Patient has intolerance or contraindication to sofosbuvir/velpatasvir OR patient has genotype 3 and is positive for NS5A RAS Y93H and has intolerance/contraindication to ribavirin.
   5. Request must be for 100-40 mg strength.
   6. Provider attests patient is not HIV co-infected.

      If met and provider attests patient is not HIV co-infected, approve x8 weeks at GPID.
      If met and provider attests patient is HIV co-infected, approve x12 weeks at GPID.
      If not met, do not approve.

E. **The patient has diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past sofosbuvir-based and elbasvir/grazoprevir treatment failure**: Must meet all the following:
   1. Patient has a detectable HCV RNA level. The detectable HCV RNA level must be from at least 12 weeks after completion of the previous treatment.
   2. Patient does not have a suspected acute HCV exposure in the last 6 months.
   3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
   4. Patient has intolerance or contraindication to sofosbuvir/velpatasvir/voxilaprevir.
   5. Patient does not have genotype 3 infection with sofosbuvir/NS5A inhibitor experience.
   6. Patient has not failed NS3/4 protease inhibitor inclusive combination direct acting antiviral (DAA) regimen.
   7. Request must be for 100-40 mg strength.

      If met, approve x16 weeks at GPID.
      If not met, do not approve.

F. **The patient has diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past glecaprevir/pibrentasvir treatment failure**: Must meet all the following:

1. Patient has a detectable HCV RNA level. The detectable HCV RNA level must be from at least 12 weeks after completion of the previous treatment.
2. Patient does not have a suspected acute HCV exposure in the last 6 months.
3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
4. Patient has intolerance or contraindication to sofosbuvir/velpatasvir/voxilaprevir.
5. Provider attests glecaprevir/pibrentasvir will be used in combination with sofosbuvir and ribavirin.
6. Request must be for 100-40 mg strength.

   If met, approve x16 weeks at GPID.
   If criteria are not met, do not approve.

G. **Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with multiple past direct-acting antiviral (DAA) treatment failure**: Must meet all the following:
   1. Patient has a detectable HCV RNA level. The detectable HCV RNA level must be from at least 12 weeks after completion of the previous treatment.
   2. Patient does not have a suspected acute HCV exposure in the last 6 months.
   3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
   4. Patient has failed 2+ previous DAA treatments, including sofosbuvir/velpatasvir/voxilaprevir.
   5. Provider attests glecaprevir/pibrentasvir will be used in combination with sofosbuvir and ribavirin.
   6. Request must be for 100-40 mg strength.

      If met, approve x24 weeks at GPID.
      If criteria are not met, do not approve.

H. **The patient has diagnosis of pediatric chronic Hepatitis C virus (HCV) and weighs < 45 kg**: Must meet all the following:
   1. Patient has a detectable HCV RNA level.
   2. Patient does not have a suspected acute HCV exposure in the last 6 months.
   3. Patient is treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir).
   4. Patient has intolerance or contraindication to sofosbuvir/velpatasvir.

      If met, approve x8 weeks at HICL.
      If not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Does the patient have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions?

3. Is the patient taking any medications that have a clinically significant interaction with the Hepatitis C medication ordered?
4. Diagnosis/Indication associated with this request: [check boxes for all diagnoses listed in criteria: Hepatitis C virus (HCV)+ transplant recipient; Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis, treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir); Diagnosis of chronic Hepatitis C virus (HCV) with compensated cirrhosis, treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir); Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past sofosbuvir-based and elbasvir/grazoprevir treatment failure; Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past glecaprevir/pibrentasvir treatment failure; Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with multiple past direct-acting antiviral (DAA) treatment failure; Diagnosis of pediatric chronic Hepatitis C virus (HCV) and weight < 45 kg]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis, treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.

Diagnosis of chronic Hepatitis C virus (HCV) with compensated cirrhosis, treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Is the patient HIV+?
5. HCV genotype:
6. Is the patient positive for NS5A RAS Y93H with an intolerance/contraindication to ribavirin?
7. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.

Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past sofosbuvir-based and elbasvir/grazoprevir treatment failure

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. HCV genotype:
4. Does the patient have a suspected acute HCV exposure in the last 6 months?
5. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.

Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past glecaprevir/pibrentasvir treatment failure

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
5. Yes/No: The provider confirms glecaprevir/pibrentasvir will be used in combination with sofosbuvir and ribavirin.

Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with multiple past direct-acting antiviral (DAA) treatment failure

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
5. Yes/No: The provider confirms glecaprevir/pibrentasvir will be used in combination with sofosbuvir and ribavirin.

Diagnosis of pediatric chronic Hepatitis C virus (HCV) and weight < 45 kg

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Is the patient treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)?

RATIONALE

*Clinically significant is defined as an interaction that is moderate to severe and cannot be mitigated easily

Note: There are no renewal criteria as reviews using above criteria apply for a one-time treatment regimen.

FDA APPROVED INDICATIONS

Hepatitis C

REFERENCES

AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C
Kaiser Permanente Inter-Regional Consensus Hepatitis C Treatment Recommendations

Creation date: 05/2024
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: n/a

GLP-1 AGONISTS
TRULICITY

Generic	Brand	HICL	GPID	Comments	FDA Indication
DULAGLUTIDE	TRULICITY	41421		Non-Formulary	DM2

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following indications and meet indication-specific criteria as follows:

A. Adults 25 years of age or older with DM2 without ASCVD
B. Adults 25 years of age or older with DM2 with ASCVD
C. Pediatrics/Young Adults between 10 and 25 years of age with DM2
D. Excluded from coverage for the treatment of weight loss (with or without OSA), heart failure (with or without preserved ejection fraction), Metabolic Dysfunction-Associated Steatohepatitis (MASH), and any other indication, unless specified

A. To treat type 2 diabetes in patients without ASCVD:
1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
3. Current (within the past 3 months) HgbA1c is above but within 2% of patient's designated A1c goal unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Has contraindications to, is currently using, or has failed maximum dose metformin
    b. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months, or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor, or the patient has an intolerance to any SGLT-2 inhibitor
    c. Has contraindications to, is currently using, or has failed maximum dose sulfonylurea, maximum dose pioglitazone, and all possible combinations thereof unless the patient has one of the following:
        - h/o bariatric surgery
        - BMI ≥ 35 (≥ 30 for Asian American/Pacific Islanders)
        - ≥ 5% increase in body weight after 6 months of starting diabetes medications associated with weight gain (i.e., sulfonylurea, insulin, pioglitazone)
        - patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
    d. Patient has an intolerance, contraindication or failure (excludes convenience or needle phobia, whether or not related to injection frequency) to reach A1c goal (goal can be no less than 7%) after a 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day)

If initial criteria are met, approve at HICL x 6 months, max daily dose of 0.08 (1 box/4 pens/2mL per 28 days).
If initial criteria are not met, do not approve.

B. To treat type 2 diabetes in patients with ASCVD [acute coronary syndromes (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)]: Must meet all the following:

1. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
2. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
3. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor, or the patient has an intolerance to any SGLT-2 inhibitor.
    b. Patient has an intolerance, contraindication or failure (excludes convenience or needle phobia, whether or not related to injection frequency) to reach A1c goal (goal can be no less than 7%) after a 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day)

If initial criteria are met, approve at HICL indefinitely, max 1 box/4 pens/2mL per 30 days [max daily dose of 0.08].
If initial criteria are not met, do not approve.

C. To treat type 2 diabetes in pediatric patients > 10 but <25 years of age.

1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
3. Current (within the past 3 months) HgbA1c is above but within 2% of patient's designated A1c goal unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Has contraindications to, is currently using, or has failed maximum dose metformin

b. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months, or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor or the patient has an intolerance to any SGLT-2 inhibitor
c. Patient has contraindications to, is currently using, or has failed maximum dose of pioglitazone unless the patient has one of the following:
   - h/o bariatric surgery
   - BMI ≥ 95%ile for age and sex
   - ≥ 5% increase in body weight after 6 months of starting these medications
   - patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
d. Patient has an intolerance, contraindication or failure (excludes convenience or needle phobia, whether or not related to injection frequency) to reach A1c goal (goal can be no less than 7%) after a 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day)

If initial criteria are met, approve at HICL x 6 months, max daily dose of 0.08 (1 box/4 pens/2mL per 28 days).
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
2. HgbA1c is either at goal or has decreased by at least 1% or more from baseline prior to starting GLP-1 therapy unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day.
3. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.

If renewal criteria are met, approve indefinitely at HICL, max 1 box/4 pens/2 mL per 28 days [max daily dose of 0.08].
If renewal criteria are not met, do not approve.

RATIONALE
- Generic liraglutide (Victoza) is the KP preferred GLP-1RA for all indications, except to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight, based on its long-term clinical experience, wide market use and preferential cost.
- GLP-1RAs are not to be used in combination with DPP-4 inhibitors since these 2 drug classes have not been studied together, represent therapeutic duplication based on the mechanism of action, and have no additive benefits.
- The 2024 KP National Diabetes Guidelines recommend Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RA) for people with type 2 diabetes on metformin monotherapy, with clinical ASCVD who cannot take SGLT-2 inhibitors (SGLT2is) (i.e., empagliflozin), to reduce the risk of cardiovascular events (myocardial infarction or stroke) or cardiovascular death. SGLT-2is and GLP-1RAs, including dulaglutide, have strong evidence in diabetes and CV protection.

FDA APPROVED INDICATIONS
- To improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus.
- To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

REFERENCES

Per Health Plan

Medication use in Pediatric/Young Adults:

1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012.
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP-4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP-4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation Date: 11/16/2016
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

GLP-1 AGONISTS
BYETTA

Generic	Brand	HICL	GPID	Comments	FDA Indication
EXENATIDE IR	BYETTA	32893		Non-Formulary	DM2

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following indications and meet indication-specific criteria as follows:

A. Adults 25 years of age or older with DM2 without ASCVD
B. Adults 25 years of age or older with DM2 with ASCVD
C. Pediatrics/Young Adults between 10 and 25 years of age with DM2
D. Excluded from coverage for the treatment of weight loss (with or without OSA), heart failure (with or without preserved ejection fraction), Metabolic Dysfunction-Associated Steatohepatitis (MASH), and any other indication, unless specified

A. To treat type 2 diabetes in patients without ASCVD: Must meet all the following:
1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
3. Current (within the past 3 months) HgbA1c is above but within 2% of patient's designated A1c goal unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Has contraindications to, is currently using, or has failed maximum dose metformin
   b. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months, or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor, or the patient has an intolerance to any SGLT-2 inhibitor
   c. Has contraindications to, is currently using, or has failed maximum dose sulfonylurea, maximum dose pioglitazone, and all possible combinations thereof unless the patient has one of the following:
      - h/o bariatric surgery
      - BMI ≥ 35 (≥ 30 for Asian American/Pacific Islanders)
      - ≥ 5% increase in body weight after 6 months of starting diabetes medications associated with weight gain (i.e., sulfonylurea, insulin, pioglitazone)
      - patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
   d. Patient has an intolerance, contraindication or failure to reach A1c goal (goal can be no less than 7%) after a minimum 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day)

If initial criteria are met, approve at HICL x 6 months, max daily dose of 0.09 (1 box/1 pen/2.4mL per 28 days).
If initial criteria are not met, do not approve.

B. To treat type 2 diabetes in patients with ASCVD [acute coronary syndromes (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)]: Must meet all the following:

1. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
2. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
3. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor, or the patient has an intolerance to any SGLT-2 inhibitor.
   b. Patient has an intolerance, contraindication or failure to reach A1c goal (goal can be no less than 7%) after a minimum 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day).

If initial criteria are met, approve at HICL indefinitely, max daily dose of 0.09 (1 box/1 pen/2.4mL per 28 days).
If initial criteria are not met, do not approve.

C. To treat type 2 diabetes in pediatric patients > 10 but <25 years of age. Must meet all the following:

1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
3. Current (within the past 3 months) HgbA1c is above but within 2% of patient's designated A1c goal unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Has contraindications to, is currently using, or has failed maximum dose metformin

b. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months, or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor or the patient has an intolerance to any SGLT-2 inhibitor
c. Patient has contraindications to, is currently using, or has failed maximum dose of pioglitazone unless the patient has one of the following:
   - h/o bariatric surgery
   - BMI ≥ 95%ile for age and sex
   - ≥ 5% increase in body weight after 6 months of starting these medications
   - patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
d. Patient has an intolerance, contraindication or failure to reach A1c goal (goal can be no less than 7%) after a minimum 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day).

If initial criteria are met, approve at HICL x 6 months, max daily dose of 0.09 (1 box/1 pen/2.4mL per 28 days).
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
2. HgbA1c is either at goal or has decreased by at least 1% or more from baseline prior to starting GLP-1 therapy unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day.
3. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.

If renewal criteria are met, approve indefinitely at HICL, with a max 1 box/1 pen/2.4 mL per 28 days [max daily dose of 0.09].
If renewal criteria are not met, do not approve.

RATIONALE
- Generic liraglutide (Victoza) is the KP preferred GLP-1RA for all indications, except to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight, based on its long-term clinical experience, wide market use and preferential cost.
- GLP-1RAs are not to be used in combination with DPP-4 inhibitors since these 2 drug classes have not been studied together, represent therapeutic duplication based on the mechanism of action, and have no additive benefits.
- The 2024 KP National Diabetes Guidelines recommend Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RA) for people with type 2 diabetes on metformin monotherapy, with clinical ASCVD who cannot take SGLT-2 inhibitors (SGLT2is) (i.e., empagliflozin), to reduce the risk of cardiovascular events (myocardial infarction or stroke) or cardiovascular death. SGLT-2is and several GLP-1RAs, including liraglutide, have strong evidence in diabetes and CV protection. Exenatide does not have CV data.

FDA APPROVED INDICATIONS
Exenatide (Byetta) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

REFERENCES
Per Health Plan

Medication use in Pediatric/Young Adults:
1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012.
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP-4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP-4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation Date: 11/16/2016
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

GLP-1 AGONISTS
SAXENDA

Generic	Brand	HICL	GPID	Comments	FDA Indication
LIRAGLUTIDE	SAXENDA		37637	Non-Formulary; Specialty tier	Weight loss

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
A. Patients 12 years of age or older for weight loss
B. Excluded from coverage for the treatment of diabetes (with or without ASCVD and/or CKD), obstructive sleep apnea (OSA) with obesity, heart failure (with or without preserved ejection fraction), Metabolic Dysfunction-Associated Steatohepatitis (MASH), and any other indication, unless specified

A. Patients 12 years of age or older for weight loss
1. Medication is being used for weight loss in a patient 12 years of age or older.
2. Patient must have a benefit plan with coverage for weight loss medications.
3. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
4. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
5. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check)
6. Patient must have an initial body mass index (BMI) of greater than or equal to 30 kg/m2, OR an initial BMI of greater than or equal to 27 kg/m2 AND at least one weight-related comorbid condition, such as hypertension, dyslipidemia, type 2 diabetes.
7. Provider attests to patient being on a reduced calorie diet and has increased physical activity.
8. Patient has documented intolerance, contraindication*, or failure (^excludes convenience or needle phobia, whether or not related to injection frequency) to lose and maintain at least 5% body weight after a trial (defined as below) to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception [listed below in preferential order]:
    - phentermine or diethylpropion: on a therapeutic dose of phentermine 37.5 mg per day or diethylpropion 75 mg per day for at least 3 months
    - Qsymia: on a therapeutic dose of phentermine 15 mg/topiramate 92 mg per day for at least 3 months
    - Contrave: on a therapeutic dose of naltrexone 32 mg/bupropion 360 mg per day for at least 3 months
    - Generic liraglutide (Victoza)^: on a therapeutic dose of liraglutide 3 mg per day for at least 3 months

If initial criteria are met, approve x 6 months at HICL, max 1 box/1 pen/15mL per 30 days [max daily dose of 0.5].
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Not currently using a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
3. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
4. Patient must have achieved and maintained at least a 5% weight loss from baseline (objectively measured with in-office weight checks).

If renewal criteria are met, approve x 1 year at HICL, with a max 1 box/1 pen/15mL per 30 days [max daily dose of 0.5].
If renewal criteria are not met, do not approve.

*Contraindications to stimulants (phentermine, diethylpropion, Qsymia) include: pregnancy/breast feeding, hyperthyroidism, closed angle glaucoma, uncontrolled HTN, tachycardia, uncontrolled anxiety, recent (14 days) use of MAOI, substance abuse history, hx of cardiovascular disease (arrhythmias, CAD, CVA, systolic CHF), ADHD/ADD meds

ePA Questions
Initial Review Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (phentermine 37.5 mg tablets, diethylpropion tablets, Qsymia, Contrave, or others are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current (within the past 4 weeks) BMI (kg/m²):
4. Date of current BMI (MMDDYY):
5. Does the patient have any weight-related comorbidities? Please check any/all boxes that apply:
   - Hypertension
   - Dyslipidemia
   - Type 2 diabetes
6. Is the patient taking a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
7. Is the patient using another GLP-1 or GLP/GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)?
8. Does the provider attest to the patient being on a reduced calorie diet with increased physical activity?

Renewal Review questions
1. Current (within the past 4 weeks) BMI (kg/m^2):
2. Date of current BMI (MMDDYY):
3. Is the patient taking a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
4. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

RATIONALE
- Generic liraglutide (Victoza) is the KP preferred GLP-1RA for all indications, except to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and

either obesity or overweight, based on its long-term clinical experience, wide market use and preferential cost.
- GLP-1RAs are not to be used in combination with DPP-4 inhibitors since these 2 drug classes have not been studied together, represent therapeutic duplication based on the mechanism of action, and have no additive benefits.
- The 2024 KP National Overweight and Obesity Guidelines recommend pharmacotherapy for patients who have a history of being unable to successfully lose weight and maintain body weight loss and have a BMI ≥ 30 kg/m2 or a BMI ≥ 27 kg/m2 with an obesity associated comorbidity, as an adjunct to lifestyle modification. Patients must participate in a comprehensive lifestyle program since pharmacotherapy is most effective when used as an adjunct to such a program. The guidelines also recommend offering continued use of medication for weight maintenance for those patients who have achieved an initial weight loss goal of at least 5% of initial body weight and have not experienced serious or intolerable side effects. Trial of oral weight loss medications is required since they can produce the guideline-recommended 5% weight loss.

FDA APPROVED INDICATIONS
Liraglutide (Saxenda) is indicated as adjuncts to a reduced-calorie diet and increased physical activity for chronic weight management in:
Adult patients with an initial body mass index (BMI) of
- 30 kg/m2 or greater (obese), or
- 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)

Pediatric patients aged 12 years and older with:
- body weight above 60 kg and
- an initial BMI corresponding to 30 kg/m2 or greater for adults (obese) by international cut-offs.

REFERENCES
Per Health Plan

Medication use in Pediatric/Young Adults:
1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012.
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP-4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP-4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation Date: 11/16/2016
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

GLP-1 AGONISTS
VICTOZA

Generic	Brand	GPID	Comments	Indication
LIRAGLUTIDE	VICTOZA	26189	1st line GLP-1 (except for h/o MI + overweight/obesity indication) Formulary (generic)	DM2 (Off-label use for weight loss, OSA and diabetic CKD permitted per PA criteria)

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Patient has one of the following diagnoses and meets all diagnosis specific criteria as follows:

A. DM2 without ASCVD: Patient is new to KPCO in the past 90 days and is currently using a GLP1 agonist for the management of DM2 without ASCVD and meets the following:
    1. Patient has lab history showing A1c above 7% prior to GLP1 therapy
    2. Current clinical presentation falls into one of the following categories:
        a. A1c is at or below goal
        b. A1c is above goal but the patient has failed at least two other diabetes medications (including metformin, unless contraindicated).

B. DM2 with ASCVD [acute coronary syndromes (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)]: Patient is new to KPCO in the past 90 days and is currently using a GLP1 agonist for the management of DM2 with ASCVD. :

If met, approve indefinitely at GPID, max 1 box/3 pens/9 mL per 28 days [max daily dose of 0.33].
If New Member Criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following indications and meet indication-specific criteria as follows:

A. Adults 25 years of age or older with DM2 without ASCVD
B. Adults 25 years of age or older with DM2 with ASCVD
C. Pediatrics/Young Adults between 10 and 25 years of age with DM2
D. Patients 12 years of age or older for weight loss
E. Moderate to severe obstructive sleep apnea (OSA) in adults with obesity
F. To reduce the risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and chronic kidney disease (CKD)

A. To treat type 2 diabetes in patients without ASCVD: Must meet all the following,
1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
3. Current (within the past 3 months) HgbA1c is above but within 2% of patient's designated A1c goal unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are)

contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

a. Has contraindications to, is currently using, or has failed maximum dose metformin
b. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months, or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor, or the patient has an intolerance to any SGLT-2 inhibitor
c. Has contraindications to, is currently using, or has failed maximum dose sulfonylurea, maximum dose pioglitazone, and all possible combinations thereof unless the patient has one of the following:
    - h/o bariatric surgery
    - BMI ≥ 35 (≥ 30 for Asian American/Pacific Islanders)
    - ≥ 5% increase in body weight after 6 months of starting diabetes medications associated with weight gain (i.e., sulfonylurea, insulin, pioglitazone)
    - patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day

If initial criteria are met, approve x indefinite at GPID, max 1 box/3 pens/9 mL per 30 days [max daily dose of 0.3].
If initial criteria are not met, do not approve.

B. To treat type 2 diabetes in patients with ASCVD [acute coronary syndromes (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)]: Must meet all the following:

1. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
2. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
3. has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor, or the patient has an intolerance to any SGLT-2 inhibitor; or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

   If initial criteria are met, approve x indefinite at GPID, max 1 box/3 pens/9 mL per 30 days [max daily dose of 0.3].
   If initial criteria are not met, do not approve.

C. **To treat type 2 diabetes in pediatric patients > 10 but <25 years of age. Must meet all the following:**

1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
3. Current (within the past 3 months) HgbA1c is above but within 2% of patient's designated A1c goal unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Has contraindications to, is currently using, or has failed maximum dose metformin
    b. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months, or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor or the patient has an intolerance to any SGLT-2 inhibitor
    c. Patient has contraindications to, is currently using, or has failed maximum dose of pioglitazone unless the patient has one of the following:
        - h/o bariatric surgery
        - BMI ≥ 95%ile for age and sex
        - ≥ 5% increase in body weight after 6 months of starting these medications
        - patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day

If initial criteria are met, approve x indefinite at GPID, max 1 box/3 pens/9 mL per 30 days [max daily dose of 0.3].
If initial criteria are not met, do not approve.

D. **For weight loss in patients 12 years of age or older: Must meet all the following:**
1. Patient must have benefit plan with coverage for weight loss medications.
2. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
3. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
4. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
5. Patient must have an initial body mass index (BMI) of greater than or equal to 30 kg/m2, OR an initial BMI of greater than or equal to 27 kg/m2 AND at least one weight-related comorbid condition, such as hypertension, dyslipidemia, type 2 diabetes.
6. Provider attests to patient being on a reduced calorie diet and has increased physical activity.
7. Patient has documented intolerance, contraindication*, or failure to lose and maintain at least 5% body weight after a trial (defined as below) to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv)

the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception [listed below in preferential order]:

- phentermine or diethylpropion: on a therapeutic dose of phentermine 37.5 mg per day or diethylpropion 75 mg per day for at least 3 months
- Qsymia: on a therapeutic dose of phentermine 15 mg/topiramate 92 mg per day for at least 3 months
- Contrave: on a therapeutic dose of naltrexone 32 mg/bupropion 360 mg per day for at least 3 months

If initial criteria are met, approve x indefinite at GPID, max 2 box/6 pens/18 mL per 30 days [max daily dose of 0.6].

If initial criteria are not met, do not approve.

E. **Moderate to severe obstructive sleep apnea (OSA) in adults with obesity**

1. Prescribed by or in consultation with a Sleep Medicine provider.
2. Patient is ≥ 18 years of age
3. Patient does not have a diagnosis of diabetes.
4. Patient has a diagnosis of moderate-to-severe OSA confirmed on a recent (within 12 months) ambulatory or in-lab polysomnogram demonstrating an apnea/hypopnea index (AHI) ≥ 15 events per hour.
5. Patient has positive airway pressure (PAP) treatment failure, defined as an inability to achieve AHI < 15 events per hour with PAP use, or an inability to use PAP therapy for greater than 4 hours for 70% of nights in a 30-day period
6. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
7. Patient must have an initial body mass index (BMI) of greater than or equal to 30 kg/m2, calculated using the current weight (as defined in initial criteria #5).
8. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
9. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
10. Provider attests to patient being on a reduced calorie diet and has increased physical activity.
11. Patient has documented intolerance, contraindication*, or failure to lose and maintain at least 5% body weight after a trial (as defined below) to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    - Qsymia: on a therapeutic dose of phentermine 15 mg/topiramate 92 mg per day for at least 3 months

If initial criteria are met, approve x indefinite at GPID, max 2 box/6 pens/18 mL per 30 days [max daily dose of 0.6].
If initial criteria are not met, do not approve.

F. **To reduce the risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and chronic kidney disease (CKD):**
   1. Patient is at least 18 years of age
   2. Patient has a diagnosis of type 2 diabetes
   3. Current (within the past 3 months) HgbA1c is ≤ 10%
   4. Patient has high-risk CKD defined as ONE of the following (within the past 3 months):
      a. eGFR ≥ 50 to ≤ 75 ml/min/1.73m2 + UACR > 300 mg/g
      b. eGFR ≥ 25 to < 50 ml/min/1.73m2 + UACR > 100 mg/g
   5. Patient does not have any of the following conditions:
      a. Congenital or hereditary kidney disease (including autoimmune kidney disease or polycystic disease)
      b. NYHA Class IV heart failure (HF)
   6. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
   7. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
   8. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Patient is currently treated with a maximum tolerated dose of ACE inhibitor or ARB or has documented allergy, intolerance, or contraindication to both.
      b. Patient is currently treated with empagliflozin (Jardiance), dapagliflozin (Farxiga) or canagliflozin (Invokana) for at least 6 months with proteinuria [defined as UACR > 100 mg/g for patients with an eGFR ≥ 25 to < 50 mL/min OR UACR > 300 mg/g for patients with an eGFR of ≥ 50 to ≤ 75 mL/min (eGFR and UACR measured after taking one of the above SGLT-2i medications for at least 6 months)] or has documented allergy, intolerance, or contraindication.

   If initial criteria are met, approve x indefinite at GPID, max 1 box/3 pens/9 mL per 30 days [max daily dose of 0.3].
   If initial criteria are not met, do not approve.

*Contraindications to stimulants (phentermine, diethylpropion, Qsymia) include: pregnancy/breast feeding, hyperthyroidism, closed angle glaucoma, uncontrolled HTN, tachycardia, uncontrolled anxiety, recent (14 days) use of MAOI, substance abuse history, hx of cardiovascular disease (arrhythmias, CAD, CVA, systolic CHF), ADHD/ADD meds

ePA Questions
Initial Review Questions
1. **Diagnosis associated with this request:**
   [Check boxes for all diagnoses listed in criteria]: Adults 25 years of age or older with DM2 without ASCVD; Adults 25 years of age or older with DM2 with ASCVD; Pediatrics/Young Adults between 10 and 25 years of age with DM2; Patients 12 years of age or older for weight loss;

Disorder of cardiovascular system; To reduce risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and chronic kidney disease (CKD); Moderate to severe obstructive sleep apnea (OSA) in adults with obesity

QUESTIONS BASED ON DIAGNOSIS SELECTED

Adults 25 years of age or older with DM2 without ASCVD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); glipizide, glimepiride, glyburide (1.25 mg, 2.5 mg, 5 mg) immediate-release tablets; pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current (within the past 3 months) A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Current (within the past 4 weeks) BMI (kg/m²):
6. Date of current BMI (MMDDYY):
7. Does the patient have history of bariatric surgery?
8. Is the patient taking a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
9. Is the patient using another GLP-1 or GLP/GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)?

Adults 25 years of age or older with DM2 with ASCVD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (such as Jardiance tablets or others) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient taking a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
4. Is the patient using another GLP-1 or GLP/GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)?

Pediatrics/Young Adults between 10 and 25 years of age with DM2

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current (within the past 3 months) A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Current (within the past 4 weeks) BMI (kg/m²):
6. Date of current BMI (MMDDYY):
7. Does the patient have history of bariatric surgery?
8. Is the patient taking a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
9. Is the patient using another GLP-1 or GLP/GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)?

Patients 12 years of age or older for weight loss

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (phentermine 37.5 mg tablets, diethylpropion tablets, Qsymia, or Contrave) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current (within the past 4 weeks) BMI (kg/m²):
4. Date of current BMI (MMDDYY):
5. Does the patient have any weight-related comorbidities? Please check any/all boxes that apply:
   - Hypertension
   - Dyslipidemia
   - Type 2 diabetes
6. Is the patient taking a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
7. Is the patient using another GLP-1 or GLP/GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)?
8. Does the provider attest to the patient being on a reduced calorie diet with increased physical activity?

To reduce the risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and chronic kidney disease (CKD)

1. Does the patient have a diagnosis of type 2 diabetes?
2. Does the patient have history of congenital or hereditary kidney disease (including autoimmune kidney disease or polycystic disease)?
3. Does the patient have NYHA Class IV heart failure?
4. Is the patient taking another GLP-1 or GLP/GIP containing product?
5. Is the patient currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
6. Is the patient currently treated with a maximum tolerated dose of ACE inhibitor or ARB; or has documented allergy, intolerance or contraindication to both?
7. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
8. Is there reasoning why alternatives (such as lisinopril, benazepril, losartan, Jardiance, etc.) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
9. Current (within the past 3 months) A1c lab (%):
10. Date of A1c lab (MMDDYY):
11. Current (within the past 3 months) eGFR:
12. Date of eGFR (MMDDYY):
13. Current (within the past 3 months) urine albumin-to-creatinine ratio (UACR):
14. Date of urine albumin-to-creatinine ratio/UACR (MMDDYY):

Moderate to severe Obstructive Sleep Apnea (OSA) in adults with obesity

1. Has the patient failed other treatments for this indication? If yes, must list prior treatment(s) trialed, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Does the patient have a diagnosis of diabetes?
3. Has the patient had a recent (within 12 months) ambulatory or in-lab polysomnogram?
4. Provide the apnea-hypopnea index (AHI) events per hour from the patient's most recent polysomnogram:

5. Date of polysomnogram (MMDDYY):
6. Is the patient taking a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
7. Is the patient using another GLP-1 or GLP/GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide, dulaglutide, tirzepatide)?
8. Does the provider attest to patient being on a reduced calorie diet and with increased physical activity?
9. Does the patient have a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check)?
10. Current (within the past 4 weeks) BMI (kg/m^2):
11. Date of current BMI (MMDDYY):

RATIONALE

- Generic liraglutide (Victoza) is the KP preferred GLP-1RA for all indications, except to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight, based on its long-term clinical experience, wide market use and preferential cost.
- GLP-1RAs are not to be used in combination with DPP-4 inhibitors since these 2 drug classes have not been studied together, represent therapeutic duplication based on the mechanism of action, and have no additive benefits.
- The 2024 KP National Diabetes Guidelines recommend Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RA) for people with type 2 diabetes on metformin monotherapy, with clinical ASCVD who cannot take SGLT-2 inhibitors (SGLT2is) (i.e., empagliflozin), to reduce the risk of cardiovascular events (myocardial infarction or stroke) or cardiovascular death. SGLT-2is and GLP-1RAs, including liraglutide and semaglutide, have strong evidence in diabetes and CV protection.
- The 2024 KP National Overweight and Obesity Guidelines recommend pharmacotherapy for patients who have a history of being unable to successfully lose weight and maintain body weight loss and have a BMI ≥ 30 kg/m2 or a BMI ≥ 27 kg/m2 with an obesity associated comorbidity, as an adjunct to lifestyle modification. Patients must participate in a comprehensive lifestyle program since pharmacotherapy is most effective when used as an adjunct to such a program. The guidelines also recommend offering continued use of medication for weight maintenance for those patients who have achieved an initial weight loss goal of at least 5% of initial body weight and have not experienced serious or intolerable side effects. Trials of oral weight loss medications and liraglutide are required since they can produce the guideline-recommended 5% weight loss. Victoza contains the same active drug, liraglutide, as Saxenda but in a lower strength. Victoza is FDA approved for the treatment of type 2 diabetes but also has been shown in clinical trials to result in weight loss and thus is commonly used off label for weight management in patients with and without type 2 diabetes. Since generic liraglutide (Victoza) delivers doses in 0.6 mg intervals up to 1.8 mg, the patients requiring a weight loss dose of 2.4 mg and 3 mg will have to do two separate injections in a day.
- PAP remains the mainstay for OSA treatment. However, studies consistently demonstrate that weight loss significantly improves OSA control, with reductions in both the severity of symptoms and related comorbidities. Specifically, in individuals with OSA who are obese, weight loss interventions—ranging from lifestyle changes to pharmacotherapy and surgical options—are critical components of comprehensive care. While weight loss medications such as liraglutide and phentermine/topiramate (Qsymia) are primarily indicated for obesity management, there is clinical evidence supporting their role in improving OSA outcomes. Both drugs have been studied in clinical trials for their potential benefit in OSA patients, with findings indicating positive effects on OSA

severity. A meta-analysis of 27 studies involving weight reduction interventions—such as pharmacotherapy, bariatric surgery, and lifestyle modifications—found that a 20% reduction in body mass index (BMI) was associated with a 57% reduction in OSA severity, as measured by the apnea-hypopnea index (AHI). Thus, while the evidence specifically linking pharmacotherapy to clinically meaningful outcomes in OSA—such as mortality and cardiovascular events—is limited, the weight loss achieved through medications like liraglutide and phentermine/topiramate has been shown to significantly improve OSA severity. These medications provide an important option for patients who are unable to achieve sufficient weight loss through lifestyle interventions alone, offering a more accessible and effective pathway to managing OSA in the context of obesity. Since generic liraglutide (Victoza) delivers doses in 0.6 mg intervals up to 1.8 mg, the patients requiring a weight loss dose of 2.4 mg and 3 mg will have to do two separate injections in a day.

- For people with T2D and CKD, the goal is to reduce urinary albumin to creatinine ratio. ACE/ARB and SGLT2i are recommended for CKD prior to GLP-1RAs based on abundance of data, FDA indications, and guideline-supported use. Semaglutide (Ozempic) is the first in class to receive the FDA indication to reduce the risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and CKD. While liraglutide does not have this indication, it has been studied in patients with DM2 and CKD. Based on the secondary outcomes from a phase III trial, liraglutide significantly reduced combined renal end point (new onset macroalbuminuria, doubling of Scr, ESRD, or renal-related death) as compared to placebo. The post hoc analysis of the same trial showed that the use of liraglutide in CKD was safe, with no difference between patients with and without CKD. Similarly to semaglutide, liraglutide does not require renal dosing adjustments down to CKD stage 5 (eGFR<15). Use of Liraglutide for this condition is an accepted off-label use supported by AHFS.

FDA APPROVED INDICATIONS

Liraglutide (Victoza) is indicated as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus.
Liraglutide (Victoza) is indicated to reduce the risk of cardiovascular events including cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke in adults with type 2 diabetes and cardiovascular disease.

REFERENCES

Per Health Plan

Medication use in Pediatric/Young Adults:

1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012.
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP-4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP-4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation Date: 11/16/2016

Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

GLP-1 AGONISTS
OZEMPIC

Generic	Brand	HICL	GPID	Comments	FDA Indication
SEMAGLUTIDE INJECTION	OZEMPIC		53536, 48208, 52125	Formulary (brand)	DM2 +/- ASCVD or CKD May use off-label for weight loss and h/o MI + obesity per PA criteria

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Patient has one of the following diagnoses and meets all diagnosis specific criteria as follows:

A. DM2 without ASCVD: Patient is new to KPCO in the past 90 days and is currently using a GLP1 agonist for the management of DM2 without ASCVD and meets the following:
   1. Patient has lab history showing A1c above 7% prior to GLP1 therapy
   2. Current clinical presentation falls into one of the following categories:
      a. A1c is at or below goal with use of a higher dosed injectable GLP1 agonist product: Ozempic 1 mg or 2 mg once weekly, Trulicity 3 mg or 4.5 mg once weekly, or Mounjaro ≥ 5 mg once weekly
      b. A1c is above goal but the patient has failed at least two other diabetes medications (including metformin, unless contraindicated).

If met, override restriction only at HICL indefinitely, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If New Member Criteria are not met, review by Initial Criteria.

B. DM2 with ASCVD: Patient is new to KPCO in the past 90 days and is currently using a GLP1 agonist for the management of DM2 with ASCVD [acute coronary syndromes (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)] and meets ONE of the following:
   1. On Ozempic 1 mg or 2 mg once weekly, Trulicity 3 mg or 4.5 mg once weekly or Mounjaro ≥ 5 mg once weekly, regardless of A1c
   2. On Ozempic 0.25 mg or 0.5 mg once weekly, Trulicity 0.75 mg or 1.5 mg once weekly, Mounjaro 2.5 mg once weekly or any dose of Rybelsus AND A1c is above goal.

If met, override restriction only at HICL indefinitely, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If New Member Criteria are not met, review by Initial Criteria.

C. History of myocardial infarction (MI) plus overweight/obese: Patient is new to KPCO in the past 90 days, has history of MI, currently has (or had) a BMI of 27 or greater, and is currently using a GLP-1 agonist for the prevention of heart attack.

If met, override restriction only at HICL x6 months, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If New Member Criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following indications and meet indication-specific criteria as follows:

A. Adults 25 years of age or older with DM2 without ASCVD
B. Adults 25 years of age or older with DM2 with ASCVD
C. Pediatrics/Young Adults between 10 and 25 years of age with DM2
D. Patients 12 years of age or older for weight loss
E. Disorder of cardiovascular system; Prophylaxis - Obesity, or overweight (To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight)
F. Adults 18 years of age or older with DM2 and CKD [To reduce the risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and chronic kidney disease]
G. Excluded from coverage for the treatment of obstructive sleep apnea (OSA) with obesity, heart failure (with or without preserved ejection fraction), and any other indication, unless specified

A. To treat type 2 diabetes in patients without ASCVD: Must meet all the following:
1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
3. Current (within the past 3 months) HgbA1c is above but within 2% of patient's A1c goal (goal can be no less than 7%), unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day.
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Has contraindications to, is currently using, or has failed maximum dose metformin
    b. Patient has failed to reach A1C goals (goal can be no less than 7%) with any SGLT-2 inhibitor for 3 months, or has a contraindication (including but not limited to UTI, mycotic infections) or intolerance to any SGLT-2 inhibitor
    c. Has contraindications to, is currently using, or has failed maximum dose sulfonylurea, maximum dose pioglitazone, and all possible combinations thereof unless the patient has one of the following:
        - h/o bariatric surgery
        - BMI ≥ 35 (≥ 30 for Asian American/Pacific Islanders)
        - ≥ 5% increase in body weight after 6 months of starting diabetes medications associated with weight gain (i.e., sulfonylurea, insulin, pioglitazone)
        - patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
    d. Patient has an intolerance, contraindication or failure (excludes convenience or needle phobia, whether or not related to injection frequency) to reach A1c goal (goal can be no less than 7%) after a minimum 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day)

If initial criteria are met, override restriction only at HICL x 6 months, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If initial criteria are not met, do not approve.

B. To treat type 2 diabetes in patients with ASCVD [acute coronary syndromes (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)]: Must meet all the following:

1. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
2. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
3. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Patient has failed to reach A1C goals (goal can be no less than 7%) with any SGLT-2 inhibitor for 3 months or has a contraindication (including but not limited to UTI, mycotic infections) or intolerance to any SGLT-2 inhibitor.
    b. Patient has an intolerance, contraindication or failure (excludes convenience or needle phobia, whether or not related to injection frequency) to reach A1c goal (goal can be no less than 7%) after a minimum 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day)

If initial criteria are met, override restriction only at HICL indefinitely, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If initial criteria are not met, do not approve.

C. To treat type 2 diabetes in pediatric patients > 10 but <25 years of age: Must meet all the following:

1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
3. Current (within the past 3 months) HgbA1c is above but within 2% of patient's A1c goal (goal can be no less than 7%), unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day.
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Has contraindications to, is currently using, or has failed maximum dose metformin

b. Patient has failed to reach A1C goals (goal can be no less than 7%) with any SGLT-2 inhibitor for 3 months, or has a contraindication (including but not limited to UTI, mycotic infections) or intolerance to any SGLT-2 inhibitor
c. Patient has contraindications to, is currently using, or has failed maximum dose of pioglitazone unless the patient has one of the following:
   - h/o bariatric surgery
   - BMI ≥ 95%ile for age and sex
   - ≥ 5% increase in body weight after 6 months of starting this medication
   - patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
d. Patient has an intolerance, contraindication or failure (excludes convenience or needle phobia, whether or not related to injection frequency) to reach A1c goal (goal can be no less than 7%) after a minimum 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day)

If initial criteria are met, override restriction only at HICL x 6 months, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If initial criteria are not met, do not approve.

D. For weight loss in patients 12 years of age or older: Must meet all the following:
1. Patient must have benefit plan with coverage for weight loss medications.
2. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
3. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
4. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check)
5. Patient must have an initial body mass index (BMI) of greater than or equal to 30 kg/m2, OR an initial BMI of greater than or equal to 27 kg/m2 AND at least one weight-related comorbid condition, such as hypertension, dyslipidemia, type 2 diabetes.
6. Provider attests to patient being on a reduced calorie diet and has increased physical activity.
7. Patient has documented intolerance, contraindication*, or failure (^excludes convenience or needle phobia, whether or not related to injection frequency) to lose and maintain at least 5% body weight after a trial (defined as below) to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception [listed below in preferential order]:
   - phentermine or diethylpropion: on a therapeutic dose of phentermine 37.5 mg per day or diethylpropion 75 mg per day for at least 3 months
   - Qsymia: on a therapeutic dose of phentermine 15 mg/topiramate 92 mg per day for at least 3 months
   - Contrave: on a therapeutic dose of naltrexone 32 mg/bupropion 360 mg per day for at least 3 months
   - Generic liraglutide (Victoza)^: on a therapeutic dose of liraglutide 3 mg per day for at least 3 months

If initial criteria are met, override restriction only x 6 months at HICL, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If initial criteria are not met, do not approve.

E. To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight: Must meet all the following:

1. Patient does not have diabetes or NYHA Class IV heart failure (HF).
2. Patient is between 55 and 74 years of age.
3. Patient has a history of MI.
4. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
5. Patient has a BMI of 27 kg/m^2 or greater.
6. Provider attests to patient being on a reduced calorie diet and has increased physical activity.
7. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
8. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
9. Patient is receiving or has an intolerance/contraindication to the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - Antiplatelet therapy (aspirin and/or P2Y12 inhibitor)
   - Lipid-lowering therapy (statin and/or ezetimibe and/or PCSK9 inhibitor)

If initial criteria are met, override restriction only x 6 months at HICL, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If initial criteria are not met, do not approve.

F. To reduce the risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and chronic kidney disease (CKD):

1. Patient is at least 18 years of age
2. Patient has a diagnosis of type 2 diabetes
3. Current (within the past 3 months) HgbA1c is ≤ 10%
4. Patient has high-risk CKD defined as ONE of the following (within the past 3 months):
   a. eGFR ≥ 50 to ≤ 75 ml/min/1.73m2 + UACR > 300 mg/g
   b. eGFR ≥ 25 to < 50 ml/min/1.73m2 + UACR > 100 mg/g
5. Patient does not have any of the following conditions:
   a. Congenital or hereditary kidney disease (including autoimmune kidney disease or polycystic disease)
   b. NYHA Class IV heart failure (HF)
6. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
7. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
8. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are)

contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

a. Patient is currently treated with a maximum tolerated dose of ACE inhibitor or ARB or has documented allergy, intolerance, or contraindication.
b. Patient is currently treated with empagliflozin (Jardiance), dapagliflozin (Farxiga) or canagliflozin (Invokana) for at least 6 months with proteinuria [defined as UACR > 100 mg/g for patients with an eGFR ≥ 25 to < 50 mL/min OR UACR > 300 mg/g for patients with an eGFR of ≥ 50 to ≤ 75 mL/min (eGFR and UACR measured after taking one of the above SGLT-2i medications for at least 6 months)] or has documented allergy, intolerance, or contraindication.
c. Patient is currently treated with liraglutide (Victoza) and unable to reach A1c goal (goal can be no less than 7%) after a minimum 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day) AND/OR at least 6 months with proteinuria [defined as UACR > 100 mg/g for patients with an eGFR ≥ 25 to < 50 mL/min OR UACR > 300 mg/g for patients with an eGFR of ≥ 50 to ≤ 75 mL/min (eGFR and UACR measured after taking liraglutide for at least 6 months)] or has documented allergy, intolerance, or contraindication (excludes convenience or needle phobia, whether or not related to injection frequency).

If initial criteria are met, override restriction only x 6 months at HICL, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following criteria based on diagnosis:

A. DM2 without ASCVD
B. Patients 12 years of age or older for weight loss
C. Disorder of cardiovascular system; Prophylaxis - Obesity, or overweight (To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight)
D. DM2 with CKD [To reduce the risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and chronic kidney disease]

A. To treat type 2 diabetes in patients without ASCVD: Must meet all the following:
1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
2. HgbA1c is either at goal or has decreased by at least 1% or more from baseline prior to starting GLP-1 therapy unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day.
3. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.

If renewal criteria are met, override restriction only indefinitely at HICL, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If renewal criteria are not met, do not approve.

B. For weight loss in patients 12 years of age or older: Must meet all the following:
1. Not currently using a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
2. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
3. Patient must have achieved and maintained at least a 5% weight loss from baseline (objectively measured with in-office weight checks).
4. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.

If renewal criteria are met, override restriction only x 1 year at HICL, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If renewal criteria are not met, do not approve.

C. To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight: Must meet all the following:
1. Patient has not developed NYHA Class IV heart failure (HF).
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.

If renewal criteria are met, override restriction only x 1 year at HICL, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If renewal criteria are not met, do not approve.

D. To reduce the risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and chronic kidney disease (CKD)
1. Patient has not developed <u>any</u> of the following conditions:
   a. Congenital or hereditary kidney disease (including autoimmune kidney disease or polycystic disease)
   b. NYHA Class IV heart failure (HF)
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
3. Not currently using a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).

If renewal criteria are met, override restriction only x 1 year at HICL, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If renewal criteria are not met, do not approve.

*Contraindications to stimulants (phentermine, diethylpropion, Qsymia) include: pregnancy/breast feeding, hyperthyroidism, closed angle glaucoma, uncontrolled HTN, tachycardia, uncontrolled anxiety, recent (14 days) use of MAOI, substance abuse history, hx of cardiovascular disease (arrhythmias, CAD, CVA, systolic CHF), ADHD/ADD meds

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Adults 25 years of age or older with DM2 without ASCVD; Adults 25 years of age or older with DM2 with ASCVD; Pediatrics/Young Adults between 10 and 25 years of age with DM2; Patients 12 years of age or older for weight loss; Disorder of cardiovascular system; Prophylaxis - Obesity, or overweight (To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight); To reduce risk of kidney disease

worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and chronic kidney disease (CKD)

QUESTIONS BASED ON DIAGNOSIS SELECTED

Adults 25 years of age or older with DM2 without ASCVD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); glipizide, glimepiride, glyburide (1.25 mg. 2.5 mg, 5 mg) immediate-release tablets; pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current (within the past 3 months) A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Current (within the past 4 weeks) BMI (kg/m^2):
6. Date of current BMI (MMDDYY):
7. Does the patient have history of bariatric surgery?
8. Is the patient taking a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
9. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

Adults 25 years of age or older with DM2 with ASCVD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Jardiance tablets, generic Victoza, or others) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient taking a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
4. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

Pediatrics/Young Adults between 10 and 25 years of age with DM2

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metformin IR (500 mg, 850 mg, 1000 mg) or ER (500 mg, 750 mg); pioglitazone tablets; Jardiance tablets; vials of glargine-yfgn (interchangeable biosimilar to Lantus), Humulin N, Humulin R)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current (within the past 3 months) A1c lab (%):
4. Date of A1c lab (MMDDYY):
5. Current (within the past 4 weeks) BMI (kg/m^2):
6. Date of current BMI (MMDDYY):
7. Does the patient have history of bariatric surgery?
8. Is the patient taking a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
9. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

Patients 12 years of age or older for weight loss

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (phentermine 37.5 mg tablets, diethylpropion tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current (within the past 4 weeks) BMI (kg/m^2):
4. Date of current BMI (MMDDYY):
5. Does the patient have any weight-related comorbidities? Please check any/all boxes that apply:
    - Hypertension
    - Dyslipidemia
    - Type 2 diabetes
6. Is the patient taking a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
7. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?
8. Does the provider attest to the patient being on a reduced calorie diet with increased physical activity?

Disorder of cardiovascular system; Prophylaxis - Obesity, or overweight

1. Current (within the past 4 weeks) BMI (kg/m^2):
2. Date of current BMI (MMDDYY):
3. Does the patient have diabetes?
4. Does the patient have NYHA Class IV heart failure (HF)?
5. Does the patient have history of myocardial infarction?
6. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?
7. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
8. Is there reasoning why alternatives (aspirin, clopidogrel, prasugrel, ticagrelor, statin, ezetimibe) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
9. Does the provider attest to the patient being on a reduced calorie diet with increased physical activity?

To reduce the risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and chronic kidney disease (CKD)

1. Does the patient have a diagnosis of type 2 diabetes?
2. Does the patient have history of congenital or hereditary kidney disease (including autoimmune kidney disease or polycystic disease)?
3. Does the patient have NYHA Class IV heart failure?
4. Is the patient taking another GLP-1 or GLP/GIP containing product?
5. Is the patient currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
6. Is the patient currently treated with a maximum tolerated dose of ACE inhibitor or ARB; or has documented allergy, intolerance or contraindication to both?
7. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

8. Is there reasoning why alternatives (such as lisinopril, benazepril, losartan, Jardiance, etc.) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
9. Current (within the past 3 months) A1c lab (%):
10. Date of A1c lab (MMDDYY):
11. Current (within the past 3 months) eGFR:
12. Date of eGFR (MMDDYY):
13. Current (within the past 3 months) urine albumin-to-creatinine ratio (UACR):
14. Date of urine albumin-to-creatinine ratio/UACR (MMDDYY):

Renewal Review questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: To treat type 2 diabetes in patients without ASCVD; Patients 12 years of age or older for weight loss; Disorder of cardiovascular system; Prophylaxis - Obesity, or overweight; To reduce risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and chronic kidney disease (CKD)

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   To treat type 2 diabetes in patients without ASCVD
   1. Current (within the past 3 months) A1c lab (%):
   2. Date of A1c lab (MMDDYY):
   3. Is the patient taking a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
   4. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

   Patients 12 years of age or older for weight loss
   1. Current (within the past 4 weeks) BMI (kg/m^2):
   2. Date of current BMI (MMDDYY):
   3. Is the patient taking a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
   4. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

   Disorder of cardiovascular system; Prophylaxis - Obesity, or overweight
   1. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?
   2. Does the patient have NYHA Class IV heart failure (HF)?

   To reduce risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and chronic kidney disease (CKD)
   1. Has the patient developed any of the following conditions: Congenital kidney disease, hereditary kidney disease, or NYHA Class IV heart failure (HF)?
   2. Is the patient taking another GLP-1 or GLP/GIP containing product?
   3. Is the patient taking a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?

RATIONALE

- Generic liraglutide (Victoza) is the KP preferred GLP-1RA for all indications, except to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight, based on its long-term clinical experience, wide market use and preferential cost.

- GLP-1RAs are not to be used in combination with DPP-4 inhibitors since these 2 drug classes have not been studied together, represent therapeutic duplication based on the mechanism of action, and have no additive benefits.
- The 2024 KP National Diabetes Guidelines recommend Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RA) for people with type 2 diabetes on metformin monotherapy, with clinical ASCVD who cannot take SGLT-2 inhibitors (SGLT2is) (i.e., empagliflozin), to reduce the risk of cardiovascular events (myocardial infarction or stroke) or cardiovascular death. SGLT-2is and GLP-1RAs, including liraglutide and semaglutide, have strong evidence in diabetes and CV protection.
- The 2024 KP National Overweight and Obesity Guidelines recommend pharmacotherapy for patients who have a history of being unable to successfully lose weight and maintain body weight loss and have a BMI ≥ 30 kg/m2 or a BMI ≥ 27 kg/m2 with an obesity associated comorbidity, as an adjunct to lifestyle modification. Patients must participate in a comprehensive lifestyle program since pharmacotherapy is most effective when used as an adjunct to such a program. The guidelines also recommend offering continued use of medication for weight maintenance for those patients who have achieved an initial weight loss goal of at least 5% of initial body weight and have not experienced serious or intolerable side effects. Trials of oral weight loss medications and liraglutide are required since they can produce the guideline-recommended 5% weight loss. Victoza contains the same active drug, liraglutide, as Saxenda but in a lower strength. Victoza is FDA approved for the treatment of type 2 diabetes but also has been shown in clinical trials to result in weight loss and thus is commonly used off label for weight management in patients with and without type 2 diabetes. Since generic liraglutide (Victoza) delivers doses in 0.6 mg intervals up to 1.8 mg, the patients requiring a weight loss dose of 2.4 mg and 3 mg will have to do two separate injections in a day.
- For people with T2D and CKD, the goal is to reduce urinary albumin to creatinine ratio. ACE/ARB and SGLT2i are recommended for CKD prior to GLP-1RAs based on abundance of data, FDA indications, and guideline-supported use. Semaglutide (Ozempic) is the first in class to receive the FDA indication to reduce the risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with DM2 and CKD. While liraglutide does not have this indication, it has been studied in patients with DM2 and CKD. Based on the secondary outcomes from a phase III trial, liraglutide significantly reduced combined renal end point (new onset macroalbuminuria, doubling of Scr, ESRD, or renal-related death) as compared to placebo. The post hoc analysis of the same trial showed that the use of liraglutide in CKD was safe, with no difference between patients with and without CKD. Similarly to semaglutide, liraglutide does not require renal dosing adjustments down to CKD stage 5 (eGFR<15).

FDA APPROVED INDICATIONS

Semaglutide (Ozempic) is approved:

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.
- to reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.

REFERENCES

Per Health Plan

Medication use in Pediatric/Young Adults:

1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012.
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP-4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP-4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation Date: 11/16/2016
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

GLP-1 AGONISTS
WEGOVY

Generic	Brand	HICL	GPID	Comments	FDA Indication
SEMAGLUTIDE INJECTION	WEGOVY		49748, 49749, 49752, 49753, 49754	Non-Formulary; Specialty tier	Weight loss, h/o MI + obesity

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following indications and meet indication-specific criteria as follows:

A. Patients 12 years of age or older for weight loss
B. Disorder of cardiovascular system; Prophylaxis - Obesity, or overweight (To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight)
C. Excluded from coverage for the treatment of diabetes (with or without ASCVD and/or CKD), obstructive sleep apnea (OSA) with obesity, heart failure (with or without preserved ejection fraction), and any other indication, unless specified

A. For weight loss in patients 12 years of age and older: Must meet all the following:
1. Medication is being used for weight loss in patient 12 years of age or older.
2. Patient must have benefit plan with coverage for weight loss medications.
3. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
4. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
5. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
6. Patient must have an initial body mass index (BMI) of greater than or equal to 30 kg/m2, OR an initial BMI of greater than or equal to 27 kg/m2 AND at least one weight-related comorbid condition, such as hypertension, dyslipidemia, type 2 diabetes.
7. Provider attests to patient being on a reduced calorie diet and has increased physical activity.
8. Patient has documented intolerance, contraindication*, or failure (^excludes convenience or needle phobia, whether or not related to injection frequency) to lose and maintain at least 5% body weight after a trial (defined as below) to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception [listed below in preferential order]:
    - phentermine or diethylpropion: on a therapeutic dose of phentermine 37.5 mg per day or diethylpropion 75 mg per day for at least 3 months
    - Qsymia: on a therapeutic dose of phentermine 15 mg/topiramate 92 mg per day for at least 3 months
    - Contrave: on a therapeutic dose of naltrexone 32 mg/bupropion 360 mg per day for at least 3 months

- Generic liraglutide (Victoza)^: on a therapeutic dose of liraglutide 3 mg per day for at least 3 months

If initial criteria are met, approve x 6 months at HICL, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If initial criteria are not met, do not approve.

B. To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight: Must meet all the following [listed below in preferential order]:

1. Patient does not have diabetes or NYHA Class IV heart failure (HF).
2. Patient aged 55 to 74 years of age.
3. Patient has a history of MI.
4. Patient has a BMI of 27 kg/m^2 or greater.
5. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
6. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
7. Provider attests to patient being on a reduced calorie diet and has increased physical activity.
8. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
9. Patient is receiving or has an intolerance/contraindication to all of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - Antiplatelet therapy (aspirin and/or P2Y12 inhibitor)
   - Lipid-lowering therapy (statin and/or ezetimibe and/or PCSK9 inhibitor)
   - Ozempic (semaglutide)

If initial criteria are met, approve x 6 months at HICL, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following criteria based on diagnosis:

A. Patients 12 years of age or older for weight loss
B. Disorder of cardiovascular system; Prophylaxis - Obesity, or overweight (To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight)

A. For weight loss in patients 12 years of age and older: Must meet all the following:

1. Not currently using a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
2. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check)

3. Patient must have achieved and maintained at least a 5% weight loss from baseline (objectively measured with in-office weight checks).
4. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.

If renewal criteria are met, approve x 1 year at HICL, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If renewal criteria are not met, do not approve.

B. To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight: Must meet all the following:
1. Patient has not developed NYHA Class IV heart failure (HF).
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.

If renewal criteria are met, approve x 1 year at HICL, max 1 box/1 pen/3mL per 28 days [max daily dose of 0.11].
If renewal criteria are not met, do not approve.

*Contraindications to stimulants (phentermine, diethylpropion, Qsymia) include: pregnancy/breast feeding, hyperthyroidism, closed angle glaucoma, uncontrolled HTN, tachycardia, uncontrolled anxiety, recent (14 days) use of MAOI, substance abuse history, hx of cardiovascular disease (arrhythmias, CAD, CVA, systolic CHF), ADHD/ADD meds

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Patients 12 years of age or older for weight loss; Disorder of cardiovascular system; Prophylaxis - Obesity, or overweight (To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight)]

QUESTIONS BASED ON DIAGNOSIS SELECTED
Patients 12 years of age or older for weight loss
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (such as phentermine 37.5 mg tablets, diethylpropion tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current (within the past 4 weeks) BMI (kg/m^2):
4. Date of current BMI (MMDDYY):
5. Does the patient have any weight-related comorbidities? Please check any/all boxes that apply:
    - Hypertension
    - Dyslipidemia
    - Type 2 diabetes
6. Is the patient taking a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
7. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?
8. Does the provider attest to the patient being on a reduced calorie diet with increased physical activity?

Disorder of cardiovascular system; Prophylaxis - Obesity, or overweight (To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight)

1. Current (within the past 4 weeks) BMI (kg/m^2):
2. Date of current BMI (MMDDYY):
3. Does the patient have diabetes?
4. Does the patient have NYHA Class IV heart failure (HF)?
5. Does the patient have history of myocardial infarction?
6. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?
7. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
8. Is there reasoning why alternatives (aspirin, clopidogrel, prasugrel, ticagrelor, statin, ezetimibe) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
9. Does the provider attest to the patient being on a reduced calorie diet with increased physical activity?

Renewal Review questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Patients 12 years of age or older for weight loss; Disorder of cardiovascular system; Prophylaxis - Obesity, or overweight (To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight)]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Patients 12 years of age or older for weight loss

1. Current (within the past 4 weeks) BMI (kg/m^2):
2. Date of current BMI (MMDDYY):
3. Is the patient taking a DPP-4 (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)?
4. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

Disorder of cardiovascular system; Prophylaxis - Obesity, or overweight (To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight)

1. Is the patient using another GLP-1 +/- GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?
2. Does the patient have NYHA Class IV heart failure (HF)?

RATIONALE

- Generic liraglutide (Victoza) is the KP preferred GLP-1RA for all indications, except to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight, based on its long-term clinical experience, wide market use and preferential cost.
- GLP-1RAs are not to be used in combination with DPP-4 inhibitors since these 2 drug classes have not been studied together, represent therapeutic duplication based on the mechanism of action, and have no additive benefits.
- The 2024 KP National Overweight and Obesity Guidelines recommend pharmacotherapy for patients who have a history of being unable to successfully lose weight and maintain body weight loss and have a BMI ≥ 30 kg/m2 or a BMI ≥ 27 kg/m2 with an obesity associated comorbidity, as an adjunct to lifestyle modification. Patients must participate in a comprehensive lifestyle program

since pharmacotherapy is most effective when used as an adjunct to such a program. The guidelines also recommend offering continued use of medication for weight maintenance for those patients who have achieved an initial weight loss goal of at least 5% of initial body weight and have not experienced serious or intolerable side effects. Trial of oral weight loss medications is required since they can produce the guideline-recommended 5% weight loss. Victoza contains the same active drug, liraglutide, as Saxenda but in a lower strength. Victoza is FDA approved for the treatment of type 2 diabetes but also has been shown in clinical trials to result in weight loss and thus is commonly used off label for weight management in patients with and without type 2 diabetes. Since generic liraglutide (Victoza) delivers doses in 0.6 mg intervals up to 1.8 mg, the patients requiring a weight loss dose of 2.4 mg and 3 mg will have to do two separate injections in a day.

- The 2024 KP National Evidence Review document provides consensus recommendations for the appropriate use of semaglutide for the secondary prevention of cardiovascular (CV) events in adult patients overweight or obese without diabetes. While the FDA approval for the semaglutide (Wegovy) indication was based on the SELECT trial, the FDA-approved indication is much broader than the studied population. KPCO PA criteria is in alignment with KP National recommendations based on an analysis of the SELECT trial, including national preference for Ozempic over Wegovy.

FDA APPROVED INDICATIONS

Semaglutide (Wegovy) is indicated as adjuncts to a reduced-calorie diet and increased physical activity for chronic weight management in:

Adult patients with an initial body mass index (BMI) of

- 30 kg/m2 or greater (obese)*, or
- 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)

Pediatric patients aged 12 years and older with:

- body weight above 60 kg and
- an initial BMI corresponding to 30 kg/m2 or greater for adults (obese) by international cut-offs.

Semaglutide (Wegovy) is indicated to reduce the risk of major adverse cardiovascular events in patients with established cardiovascular disease with either obesity or overweight.

REFERENCES

Per Health Plan

Medication use in Pediatric/Young Adults:

1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012.
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP-4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP-4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation Date: 11/16/2016
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

GLP-1 AGONISTS
RYBELSUS

Generic	Brand	HICL	GPID	Comments	FDA Indication
SEMAGLUTIDE ORAL	RYBELSUS		46964, 46965, 46966	Non-Formulary; Max daily dose is 1 tab/day	DM2

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following indications and meet indication-specific criteria as follows:

A. Adults 25 years of age or older with DM2 without ASCVD
B. Adults 25 years of age or older with DM2 with ASCVD
C. Pediatrics/Young Adults between 10 and 25 years of age with DM2
D. Excluded from coverage for the treatment of weight loss (with or without OSA), heart failure (with or without preserved ejection fraction), Metabolic Dysfunction-Associated Steatohepatitis (MASH), and any other indication, unless specified

A. To treat type 2 diabetes in patients without ASCVD: Must meet all the following:
1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
3. Current (within the past 3 months) HgbA1c is above but within 2% of patient's designated A1c goal unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Has contraindications to, is currently using, or has failed maximum dose metformin
    b. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months, or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor, or the patient has an intolerance to any SGLT-2 inhibitor
    c. Has contraindications to, is currently using, or has failed maximum dose sulfonylurea, maximum dose pioglitazone, and all possible combinations thereof unless the patient has one of the following:
        - h/o bariatric surgery
        - BMI ≥ 35 (≥ 30 for Asian American/Pacific Islanders)
        - ≥ 5% increase in body weight after 6 months of starting diabetes medications associated with weight gain (i.e., sulfonylurea, insulin, pioglitazone)
        - patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
    d. Patient has an intolerance, contraindication or failure (excludes convenience or needle phobia, whether or not related to injection frequency) to reach A1c goal (goal can be no

less than 7%) after a minimum 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day)

If initial criteria met, approve at HICL x 6 months, max 1 tablet/day.
If initial criteria are not met, do not approve.

B. To treat type 2 diabetes in patients with ASCVD [acute coronary syndromes (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)]: Must meet all the following:

1. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
2. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
3. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor, or the patient has an intolerance to any SGLT-2 inhibitor.
    b. Patient has an intolerance, contraindication or failure (excludes convenience or needle phobia, whether or not related to injection frequency) to reach A1c goal (goal can be no less than 7%) after a minimum 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day)

If initial criteria are met, approve at HICL indefinitely, max 1 tablet/day.
If initial criteria are not met, do not approve.

C. To treat type 2 diabetes in pediatric patients > 10 but <25 years of age. Must meet all the following:

1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
2. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.
3. Current (within the past 3 months) HgbA1c is above but within 2% of patient's designated A1c goal unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

a. Has contraindications to, is currently using, or has failed maximum dose metformin
b. Patient has tried and failed to reach A1C goals with any SGLT-2 inhibitor for 3 months, or has a contraindication (including but not limited to UTI, mycotic infections) to any SGLT-2 inhibitor or the patient has an intolerance to any SGLT-2 inhibitor
c. Patient has contraindications to, is currently using, or has failed maximum dose of pioglitazone unless the patient has one of the following:
   - h/o bariatric surgery
   - BMI ≥ 95%ile for age and sex
   - ≥ 5% increase in body weight after 6 months of starting these medications
   - patient is either on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day
d. Patient has an intolerance, contraindication or failure (excludes convenience or needle phobia, whether or not related to injection frequency) to reach A1c goal (goal can be no less than 7%) after a minimum 3-month trial of maximum tolerated dose of liraglutide (1.8 mg/day)

If initial criteria are met, approve at HICL x 6 months (44675), max 1 tablet/day.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Not currently using a DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin).
2. HgbA1c is either at goal or has decreased by at least 1% or more from baseline prior to starting GLP-1 therapy unless the patient is on basal insulin at a dose of ≥ 0.5 units/kg/day or basal/bolus regimen at a dose ≥ 1.5 units/kg/day.
3. Patient is not taking another GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.

If renewal criteria are met, approve indefinitely at HICL, max 1 tablet/day.
If renewal criteria are not met, do not approve.

RATIONALE
- Generic liraglutide (Victoza) is the KP preferred GLP-1RA for all indications, except to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight, based on its long-term clinical experience, wide market use and preferential cost.
- GLP-1RAs are not to be used in combination with DPP-4 inhibitors since these 2 drug classes have not been studied together, represent therapeutic duplication based on the mechanism of action, and have no additive benefits.
- The 2024 KP National Diabetes Guidelines recommend Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RA) for people with type 2 diabetes on metformin monotherapy, with clinical ASCVD who cannot take SGLT-2 inhibitors (SGLT2is) (i.e., empagliflozin), to reduce the risk of cardiovascular events (myocardial infarction or stroke) or cardiovascular death. SGLT-2is and GLP-1RAs, including liraglutide, have strong evidence in diabetes and CV protection. Oral semaglutide does not have CV data.

FDA APPROVED INDICATIONS
Semaglutide (Rybelsus) is approved for glycemic control in adults with type 2 diabetes mellitus.

REFERENCES
Per Health Plan

Medication use in Pediatric/Young Adults:
1. Tamborlane WV, Barrientos-Pérez M., Fainberg U et al. Liraglutide in children and adolescents with type 2 diabetes. NEJM. 381;7. Aug. 2019.
2. Zeitler P, Hirst K, Pyle L et al. A clinical trial to maintain glycemic control in youth with type 2 diabetes. NEJM. 366;24: June 2012.
3. Nadeau KJ, Hannon TS, Edelstein SL, et al. Impact of insulin and metformin versus metformin alone on b-cell function in youth with impaired glucose tolerance or recently diagnosed type 2 diabetes. Diabetes Care 2018;41:1717–1725.
4. An email (MM Kelsey, 2020, personal communication and power point included March 3) LM2 TD2 Medical Management July 2019 at Children's Hospital Colorado validates use of off-label use of SGLT-2s, DPP-4 inhibitors, GLP-1 Agonists, and pioglitazone.
5. Children's Hospital use of off-label SGLT-2 inhibitors, DPP-4 inhibitors, pioglitazone use and GLP-1 agonists and lack of preference of one agent over another in a specific class were confirmed during a phone interview (M Alonzo, PharmD 2020, personal communication, 20 November).

Creation Date: 11/16/2016
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

GUSELKUMAB (TREMFYA)

Generic	Brand	HICL	GPID	Exception/Other
GUSELKUMAB	TREMFYA 100 MG/ML SYRINGE	44418	43612	Nonformulary
GUSELKUMAB	TREMFYA 100 MG/ML AUTO INJCT	44418	46024	Nonformulary
GUSELKUMAB	TREMFYA 200 MG/2 ML SYRINGE	44418	56228	Nonformulary
GUSELKUMAB	TREMFYA 200 MG/2 ML AUTO INJCT	44418		Nonformulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on therapy.
2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
3. Patient has one of the following indications and medication is prescribed by the appropriate specialist as noted:
   a. Patient has a diagnosis of psoriatic arthritis (PsA) and requested medication is prescribed by a CPMG or affiliated rheumatologist or dermatologist.
   b. Patient has a diagnosis of psoriasis and requested medication is prescribed by a CPMG or affiliated dermatologist.
   c. Patient has a diagnosis of Crohn's Disease, ulcerative colitis, or inflammatory bowel disease-unclassified (IBD-U) and requested medication is prescribed by a CPMG or affiliated gastroenterologist.

If met, approve indefinitely, with the following quantity limits based on indication:
- PsA or Psoriasis: 1 pen/syringe per 56 days [max qty: 1, min ds: 56]
- Crohn's Disease, ulcerative colitis, or inflammatory bowel disease-unclassified (IBD-U): 1 pen/syringe per 28 days [max qty: 1, min ds: 28]

If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria:

A. Psoriatic Arthritis (PsA)
B. Psoriasis
C. Crohn's Disease
D. Ulcerative colitis, or inflammatory bowel disease-unclassified (IBD-U)

A. Psoriatic Arthritis: All the following must be met:
   1. Patient has a diagnosis of psoriatic arthritis.
   2. Medication is prescribed by a rheumatologist or dermatologist.
   3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   4. Patient has experienced an inadequate response, intolerance, or has a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is

stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
a. At least 2 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, leflunomide, sulfasalazine
b. At least 1 TNF inhibitor (e.g., adalimumab-atto (Amjevita)-preferred [F], infliximab-dyyb (Inflectra)-preferred [F])
c. At least 1 IL-17 inhibitor (e.g. secukinumab (Cosentyx) [F, PA])
d. IL-12/23 inhibitor (ustekinumab-kfce (Yesintek)-preferred [F]) unless patient has documented high disease activity.

If criteria are met, approve at HICL, x1 month (loading dose) max 1 pen/syringe per 28 days [max qty: 1, min ds: 28], then 1 pen/syringe per 56 days (maintenance dose) indefinitely [max qty: 1, min ds: 56].
If criteria are not met, do not approve.

B. Psoriasis: All the following must be met:
1. Patient has a diagnosis of moderate to severe psoriasis.
2. Medication is prescribed by a dermatologist .
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Patient has experienced an inadequate response, intolerance, or has a contraindication to a topical corticosteroid or topical calcineurin inhibitor (pimecrolimus, tacrolimus), or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate
   b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one** or contraindication to at least **two** of the following therapies, or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate: Acitretin, Cyclosporine, Methotrexate, Apremilast (Otezla), Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
   c. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one TNF inhibitor (adalimumab (Amjevita) - preferred [F], infliximab (Inflectra) - preferred [F])
   d. Patient has experienced an inadequate response, intolerance, or has a contraindication to an IL12-23 inhibitor (ustekinumab-kfce (Yesintek) - preferred [F, PA])
   e. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one IL-17 inhibitor (secukinumab (Cosentyx) - preferred [F, PA])

If criteria are met, approve at HICL, x1 month (loading dose) max 1 pen/syringe per 28 days [max qty: 1, min ds: 28], then 1 pen/syringe per 56 days (maintenance dose) indefinitely [max qty: 1, min ds: 56].
If criteria are not met, do not approve.

C. Crohn's Disease: Must meet the following #1-4 OR #1-3 and 5:
   1. Patient has a diagnosis of Crohn's Disease.
   2. Medication is prescribed by a gastroenterologist.
   3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication
   4. Has received, or is scheduled to receive, 3 IV induction doses that were authorized by the prior authorization or utilization management teams.
   5. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least 1 TNF inhibitor (ex: infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred, or certolizumab [NF, PA]), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

   If criteria are met, approve indefinitely at HICL, max 1 pen/syringe per 28 days [max qty: 1, min ds: 28]. If member is newly starting treatment and SQ induction dose is requested (400 mg on Weeks 0, 4, and 8), refer to preferred intravenous (IV) guselkumab CAMS PA criteria for induction doses.
   If criteria are not met, do not approve.

D. Ulcerative colitis or inflammatory bowel disease-unclassified (IBD-U): Must meet the following #1-4 OR #1-3 and 5:
   1. Patient has a diagnosis of ulcerative colitis or inflammatory bowel disease-unclassified (IBD-U)
   2. Medication is prescribed by a gastroenterologist.
   3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   4. Has received, or is scheduled to receive, 3 IV induction doses that were authorized by the prior authorization or utilization management teams.
   5. Patient has experienced an inadequate response, intolerance, or has a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      - at least 1 anti-TNF (ex: infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F]] or certolizumab [NF, PA])
      - at least 1 JAKi (ex: tofacitinib [F] or upadacitinib [NF, PA])
      - IL-12/23 inhibitor (ustekinumab-kfce (Yesintek)-preferred [F])

If criteria are met, approve indefinitely at HICL, max 1 pen/syringe per 28 days [max qty: 1, min ds: 28]
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Is the patient stable on therapy with guselkumab?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Psoriatic Arthritis (PsA), Psoriasis, Crohn's Disease, Ulcerative Colitis or Inflammatory Bowel Disease Unclassified (IBD-U)]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Psoriatic Arthritis (PsA)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg), adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

Psoriasis

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (tacrolimus ointment, acitretin capsules (10 mg, 25 mg), cyclosporine capsules (25 mg, 100 mg), methotrexate tablets (2.5 mg) or injection (25 mg/mL), Otezla tablets, Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy, adalimumab-atto (Amjevita)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?
4. Current BSA (%):
5. Date of BSA assessment (MMDDYY):
6. Does the patient have psoriasis affecting critical areas (such as genitals or face)?

Crohn's Disease

1. Has the patient received, or is the patient scheduled to receive 3 IV induction doses of guselkumab (Tremfya)?
2. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (adalimumab-atto (Amjevita), infliximab (Inflectra), etc.) are not suitable? If yes, you must list reasoning in Provider Comment section below or attach applicable chart notes.
4. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

Ulcerative Colitis or inflammatory bowel disease-unclassified (IBD-U)

1. Has the patient received, or is the patient scheduled to receive, 3 IV induction doses of guselkumab (Tremfya)?
2. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (infliximab-dyyb (Inflectra), adalimumab-atto (Amjevita), etc.) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
4. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

RATIONALE
Ensure appropriate use consistent with FDA indication.

REFERENCES
"Stable on therapy" means patient is tolerating well, appears to be effective and provider wishes to continue.

Treatment	Relative Contraindications for Psoriasis
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses (ex: systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for psoriasis.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities, active malignancy, and hypersensitivity*
Acitretin	*Women of child potential (cannot consider pregnancy up to 3 years after completion of treatment), pregnancy, lactation, severe hepatic or renal dysfunction, chronically abnormal elevated lipid values, and hypersensitivity*

FDA APPROVED INDICATIONS
Plaque Psoriasis
Psoriatic Arthritis
Crohn's Disease
Ulcerative Colitis

Creation Date: 11/2019
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

IBRUTINIB (IMBRUVICA)

Generic	Brand	HICL	GCN	Exception/Other
IBRUTINIB	IMBRUVICA 70MG, 140MG CAPSULES	40745	44475, 35599	Formulary
IBRUTINIB	IMBRUVICA TABLETS 420MG	40745	44467	Formulary
IBRUTINIB	IMBRUVICA TABLETS 140MG, 280MG	40745	44465, 44466	Nonformulary
IBRUTINIB	IMBRUVICA ORAL SUSPENSION 70MG/ML	40745	52826	Nonformulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is a new member to KPCO within the past 90 days.
2. Medication is prescribed by a CPMG or affiliated Oncologist.
3. Request is for a formulary ibrutinib strength/formulation.
4. Patient is stable on ibrutinib (Imbruvica) for treatment of one of the following indications: primary central nervous system (CNS) lymphoma, chronic lymphocytic leukemia/small lymphocytic leukemia (CLL/SLL), non-germinal center B cell (GCB) diffuse large B-cell lymphoma (DLBCL), hairy cell leukemia, or Waldenstrom macroglobulinemia.

If New Member criteria are met, approve indefinitely at GPID only.
If New Member criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Must be prescribed by a CPMG or affiliated Oncologist.
2. Request must be for a formulary ibrutinib strength/formulation.
3. Must have one of the following indications:
   a. Patient has primary CNS lymphoma and has undergone at least 1 prior line of treatment.
   b. Patient has chronic lymphocytic leukemia/small lymphocytic leukemia (CLL/SLL), or Waldenstrom macroglobulinemia and has CNS involvement of their disease.
   c. Patient 12 years of age or older with a diagnosis of chronic graft versus host disease (GVHD) following allogeneic hematopoietic stem cell transplant (HSCT) and meets all the following:
      i. GVHD is not responsive to systemic corticosteroid treatment, or the patient is unable to taper systemic corticosteroids due to GVHD flares
      ii. Patient has tried and failed or did not tolerate ruxolitinib (Jakafi), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception
   d. Patient under 12 years of age with a diagnosis of chronic graft versus host disease (GVHD) following allogeneic hematopoietic stem cell transplant (HSCT), and GVHD is not responsive to systemic corticosteroid treatment, or the patient is unable to taper systemic corticosteroids due to GVHD flares.
   e. Patient has diagnosis of non-germinal center B cell (GCB) diffuse large B-cell lymphoma (DLBCL), is not a transplant candidate, and has undergone at least 1 prior line of treatment.

f. Patient has diagnosis of hairy cell leukemia and has undergone at least 2 prior lines of treatment.

If initial criteria are met, approve indefinitely at GPID only.
If initial criteria are not met, do not approve.

- [If criteria are failed only because a non-formulary formulation/strength was requested, deny and proactively approve a formulary product in equivalent dosing as the alternative.]
- [If other criteria are not met, do not approve. Alternatives for GVHD include ruxolitinib (Jakafi), formulary steroids, formulary calcineurin inhibitors, imatinib (Gleevec), or formulary mycophenolate. Alternatives for CLL/SLL, or Waldenstrom macroglobulinemia include zanubrutinib (Brukinsa) or acalabrutinib (Calquence).]

ePA Questions

1. Is the patient stable on therapy with ibrutinib (Imbruvica) for treatment of one of the following indications: primary central nervous system (CNS) lymphoma, chronic lymphocytic leukemia/small lymphocytic leukemia (CLL/SLL), non-germinal center B cell (GCB) diffuse large B-cell lymphoma (DLBCL), hairy cell leukemia, or Waldenstrom macroglobulinemia?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Primary CNS lymphoma and has undergone at least 1 prior line of treatment; Chronic lymphocytic leukemia/small lymphocytic leukemia (CLL/SLL), or Waldenstrom macroglobulinemia and has CNS involvement of their disease; Patient 12 years of age or older with chronic graft versus host disease (GVHD) following allogeneic hematopoietic stem cell transplant (HSCT); Patient under 12 years of age with chronic graft versus host disease (GVHD) following allogeneic hematopoietic stem cell transplant (HSCT); Non-germinal center B cell (GCB) diffuse large B-cell lymphoma (DLBCL), is not a transplant candidate, and has undergone at least 1 prior line of treatment; hairy cell leukemia and has undergone at least 2 prior lines of treatment

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   Patient 12 years of age or older with chronic graft versus host disease (GVHD) following allogeneic hematopoietic stem cell transplant (HSCT)

   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   2. Is there reasoning why alternatives (systemic corticosteroids) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

   Patient under 12 years of age with chronic graft versus host disease (GVHD) following allogeneic hematopoietic stem cell transplant (HSCT)

   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   2. Is there reasoning why alternatives (systemic corticosteroids) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

To promote evidence-based, cost-conscious use of oral BTK inhibitor therapy

Commercial formulary strengths/formulations:
Ibrutinib 70 mg capsules, 140 mg capsules, 420 mg tablets

Commercial non-formulary strengths/formulations:

Ibrutinib 140 mg tablets, 280 mg tablets, Ibrutinib 70 mg/mL suspension

FDA APPROVED INDICATIONS
Ibrutinib: CLL/SLL, CLL/SLL with 17p deletion, WM, chronic GVHD after failure of one or more lines of systemic therapy

REFERENCES
1. NCCN Clinical Practice Guidelines in Oncology Central Nervous System Cancers v.1.2023
2. NCCN Clinical Practice Guidelines in Oncology B-Cell Lymphomas v.1.2024
3. NCCN Clinical Practice Guidelines in Oncology Hairy Cell Leukemia v.1.2024
4. Imbruvica prescribing information. Pharmacyclics LLC. Sunnyvale, CA. 02/2024

Creation Date: 03/2022
Effective Date: 06/2024
Reviewed Date: 05/2024
Revised Date: 05/2024

ICS/LABA/LAMA: BUDESONIDE/GLYCOPYRROLATE/FORMOTEROL (BREZTRI AEROSPHERE)

Generic	Brand	HICL	GPID	Comments
BUDESONIDE/GLYCOPYRROLATE/ FORMOTEROL FUMARATE	BREZTRI AEROSPHERE	46753	48435	Non-Formulary COPD only

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

1. Medication is requested for the maintenance treatment of COPD.
2. Patient is 18 years of age or older.
3. Medication is prescribed by Pulmonology.
4. Patient has persistent symptoms and/or COPD exacerbation despite adherence to combined dual LAMA/LABA or ICS/LABA therapy.
5. Patient has tried and failed or has an intolerance or a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    - At least one of the following LAMA + ICS/LABA combinations:
        - Spiriva Respimat (tiotropium) + Wixela Inhub (fluticasone/salmeterol)
        - Spiriva Respimat (tiotropium) + brand or generic Symbicort HFA (budesonide/formoterol)
    - At least one of the following LAMA/LABA + ICS combinations:
        - Stiolto Respimat (tiotropium/olodaterol) + Alvesco HFA (ciclesonide)
        - Stiolto Respimat (tiotropium/olodaterol) + Asmanex HFA (mometasone)

If all criteria are met, approve at HICL indefinitely.
If all criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA, Spiriva Respimat, Stiolto Respimat, Alvesco HFA) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Trelegy Ellipta is a combination of fluticasone furoate, an inhaled corticosteroid (ICS); umeclidinium, an anticholinergic; and vilanterol, a long-acting beta2-adrenergic agonist (LABA).
Budesonide/glycopyrrolate/formoterol fumarate (Breztri Aerosphere) is a combination of an ICS, LAMA, and LABA.

Breztri Aerosphere and Trelegy Ellipta have not been shown to be safer or more cost-effective than use of open triple combination therapy via two separate inhalers (e.g., ICS/LABA plus LAMA).

FDA APPROVED INDICATIONS

Trelegy Ellipta is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema and the maintenance treatment of asthma in patients aged 18 years and older.

Breztri Aerosphere is indicated for the maintenance treatment of patients with COPD. Breztri Aerosphere is NOT indicated for the treatment of asthma.

REFERENCES

Per Health Plan.

Creation Date: 05/2022
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

ICS/LABA/LAMA:
FLUTICASONE FUROATE/UMECLIDINIUM/VILANTEROL (TRELEGY ELLIPTA)

Generic	Brand	HICL	GPID	Comments
FLUTICASONE FUROATE/UMECLIDINIUM/ VILANTEROL	TRELEGY ELLIPTA	44508	43921, 48708	Non-Formulary Asthma and COPD - Breztri preferred over Trelegy for COPD

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following indications and meet all criteria associated with that diagnosis:

A. Chronic Obstructive Pulmonary Disease (COPD) indication
B. Asthma indication

A. **Medication is requested for the maintenance treatment of COPD:** Meets all the following:
1. Patient is 18 years of age or older.
2. Medication is prescribed by Pulmonology.
3. Patient has persistent symptoms and/or COPD exacerbation despite adherence to combined dual LAMA/LABA or ICS/LABA therapy.
4. Patient has tried and failed, or has an intolerance or a contraindication to all the following, or the provider submitted justification and supporting clinical documentation that states one of the following: i) the required drug will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - At least one of the following LAMA + ICS/LABA combinations:
     - Spiriva Respimat (tiotropium) + Wixela Inhub (fluticasone/salmeterol)
     - Spiriva Respimat (tiotropium) + brand or generic Symbicort HFA (budesonide/formoterol)
   - At least one of the following LAMA/LABA + ICS combinations:
     - Stiolto Respimat (tiotropium/olodaterol) + Alvesco HFA (ciclesonide)
     - Stiolto Respimat (tiotropium/olodaterol) + Asmanex HFA (mometasone)
   - Breztri Aerosphere

If all criteria are met, approve at HICL indefinitely.
If all criteria are not met, do not approve.

B. **Medication requested is for the maintenance treatment of asthma:** Meets all the following:
1. Patient is 18 years of age or older.
2. Medication is prescribed by Asthma/Allergy or Pulmonology.
3. Patient has persistent symptoms and/or asthma exacerbation despite adherence to combination medium-to-high dose ICS/LABA therapy.
4. Patient has tried and failed or has an intolerance or a contraindication to at least one of the following ICS/LABA + LAMA combination regimens resulting in triple ingredients, or the provider submitted justification and supporting clinical documentation that states one of the following: i) the required drug will likely cause an adverse reaction or harm; ii) the required drug is ineffective

based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

- Wixela Inhub (fluticasone/salmeterol) + Spiriva Respimat (tiotropium)
- Brand or generic Symbicort HFA (budesonide/formoterol) + Spiriva Respimat (tiotropium)
- Advair HFA (fluticasone/salmeterol) + Spiriva Respimat (tiotropium)

If all criteria are met, approve indefinitely at HICL.
If all criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Asthma; COPD]

QUESTIONS BASED ON DIAGNOSIS SELECTED
Asthma

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

COPD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA, Stiolto Respimat, Spiriva Respimat) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Trelegy Ellipta is a combination of fluticasone furoate, an inhaled corticosteroid (ICS); umeclidinium, an anticholinergic; and vilanterol, a long-acting beta2-adrenergic agonist (LABA).
Budesonide/glycopyrrolate/formoterol fumarate (Breztri Aerosphere) is a combination of an ICS, LAMA, and LABA.

Breztri Aerosphere and Trelegy Ellipta have not been shown to be safer or more cost-effective than use of open triple combination therapy via two separate inhalers (e.g., ICS/LABA plus LAMA).

FDA APPROVED INDICATIONS
Trelegy Ellipta is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema and the maintenance treatment of asthma in patients aged 18 years and older.
Breztri Aerosphere is indicated for the maintenance treatment of patients with COPD. Breztri Aerosphere is NOT indicated for the treatment of asthma.

REFERENCES
Per Health Plan.

Creation Date: 05/2022
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

IMMUNE GLOBULIN (HUMAN)/HYALURONIDASE SUBCUTANEOUS

Generic	Brand	HICL	GPID	Exception/Other
IMMUNE GLOBULIN (HUMAN)/HYALURONIDASE SUBCUTANEOUS	HYQVIA	41391	37105, 37095, 37106, 37107, 37104	

GUIDELINES FOR COVERAGE
Must meet ALL the following:
1. Medication must be self-administered within a home setting.
2. Patient must have trial and failure of, intolerance, or contraindication to Hizentra.

If criteria are met, approve at HICL x 1 year.
If criteria are not met, do not approve.

ePA Questions
1. Will the medication be administered in a home setting by non-healthcare persons?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (Hizentra) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Health Plan.

FDA APPROVED INDICATIONS
Treatment of primary humoral immunodeficiency syndromes (congenital agammaglobulinemia, severe combined immunodeficiency syndromes [SCIDS], common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome)

REFERENCES
Per Health Plan.

Creation date: 09/2018
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

INFLIXIMAB-DYYB SQ (ZYMFENTRA)

Generic	Brand	HICL	GPID	Exception/Other
INFLIXIMAB-DYYB SUBCUTANEOUS (SQ) INJECTION	ZYMFENTRA	43249	55099, 55098	Non-formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient is 18 years of age or older.
2. Medication is prescribed by a gastroenterology provider.
3. Patient has a diagnosis of ulcerative colitis (UC), Crohn's disease (CD), or IBD-unclassified.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - Patient has tried and failed adalimumab-atto (Amjevita) [F], or the patient is stable on maintenance treatment with an infliximab product administered intravenously.
   - Patient has a barrier to infliximab-dyyb (Inflectra) infusions.

If initial criteria are met, approve indefinitely at HICL, max 2 syringes/autoinjectors per 28 days.
If initial criteria are not met, do not approve.

ESCALATION CRITERIA/QTY LIMIT OVERRIDES: Patient must meet Initial Criteria prior to review for Quantity Overrides. Escalation Criteria review only the quantities authorized upon PA approval.

A. Patient diagnosis of Ulcerative Colitis, Crohn's disease or IBD-Unclassified:
   1. For requests to start on escalated frequencies (more than 2 syringes/autoinjectors per 28 days): Patient must have objective signs of persistent or worsening disease activity as demonstrated by at least one of the following:
      a. Colonoscopy or imaging with persistent or worsening activity compared to baseline
      b. Fecal calprotectin greater than 150 [only if patient had an elevated fecal calprotectin prior to medication initiation]
      c. C-reactive protein greater than 2 [only if patient had an elevated C-reactive protein prior to medication initiation]

      If met, approve at HICL x1 year, max 4 syringes/autoinjectors per 28 days [max qty: 4, min ds: 28].
      If not met, deny and offer maximum 2 syringes/autoinjectors per 28 days indefinitely [max qty: 2, min ds: 28].

   2. For requests to continue escalated frequencies (more than 2 syringes/autoinjectors per 28 days):

Patient must have been assessed by a gastroenterologist in the last 1 year, and the gastroenterologist evaluated if the frequency can be de-escalated and determined that the escalated frequency continues to be medically necessary.

If met, approve at HICL x2 years, max 4 syringes/autoinjectors per 28 days [max qty: 4, min ds: 28].
If not met, deny and offer max 2 syringes/autoinjectors per 28 days indefinitely [max qty: 2, min ds: 28].

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (infliximab infusion, Amjevita) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Will infliximab (Zymfentra) be used in combination with another biologic or advanced small molecule for the same indication?

RATIONALE

For patients already stable on an infused infliximab product, we recommend continuing intravenous infusions unless the provider documents that patient has a barrier to infusions. Zymfentra is likely to be of significantly greater cost to patient and coupon cards are not accepted at the pharmacy. For patients planning to newly start on an anti-TNF, we recommend adalimumab-atto (Amjevita) if a SQ option is desired, given significantly lower patient cost and acquisition cost. We additionally recommend intravenous infusions with infliximab-dyyb (Inflectra) unless provider documents that patient has a barrier to infusions. Escalation criteria is included to ensure patients would benefit from a frequency greater than every 2 weeks – with objective signs of disease activity and without presence of high level of anti-drug antibodies.

FDA APPROVED INDICATIONS

Maintenance treatment of moderately to severely active ulcerative colitis (UC) following treatment with an infliximab product administered intravenously.
Maintenance treatment of moderately to severely active Crohn’s disease (CD) following treatment with an infliximab product administered intravenously.

REFERENCES

1. Kaiser Permanente SCPMG and TPMG Zymfentra Position Statement. June 2024.
2. Kaiser Permanente National Drug Use Management. June 2024.
3. Zymfentra [Prescribing Information]. Jersey City, NJ: CELLTRION, Inc. May 2024.

Creation Date: 07/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

INHALED CORTICOSTEROID (ICS) INHALERS
BECLOMETHASONE REDIHALER

Generic	Brand	HICL	GPID	Comments
BECLOMETHASONE DIPROPIONATE	QVAR REDIHALER		43724, 43725	Non-Formulary

Step Therapy Criteria
Must meet ONE of the following criteria, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed, or has an intolerance or a contraindication to, Alvesco HFA.
2. If provider requests an FDA approved product for patient under 12 years of age, must trial/fail Asmanex HFA.

If either criterion is met, approve at HICL indefinitely.
If no criteria are met, do not approve.

STEP THERAPY RULES:

- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Alvesco] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Although the ICSs exert their therapeutic effects through identical mechanisms of action, they differ in their potency, dosing schedules, and dosage form availability. Numerous placebo-controlled trials have demonstrated the efficacy of ICS agents in the treatment of asthma, and these agents are considered the most effective agents in the long-term management of the disease. The results of head-to-head trials directly comparing the ICS products have not demonstrated one agent to be significantly more effective than another, regardless of the potency or dosage form of the ICS agent used.

Alvesco (ciclesonide) HFA (1st line) and Asmanex (mometasone) HFA (2nd line step-therapy criteria) are KPCO formulary ICS inhalers for age 5 years and older. Although FDA approved for age 12 years and older, use of Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference. Flovent HFA 44 mcg inhaler and budesonide nebulized solution are formulary for age < 5 years of age.

KPCO order of preference: Alvesco HFA (ciclesonide) > Asmanex HFA (mometasone) > Asmanex Twisthaler (mometasone) > Flovent HFA (fluticasone propionate) > Flovent Diskus (fluticasone propionate) > Pulmicort Flexhaler (budesonide) > Arnuity Ellipta (fluticasone furoate) > Qvar Redihaler (beclomethasone)

FDA APPROVED INDICATIONS
All ICS inhalers are FDA approved for the maintenance treatment of asthma as prophylactic therapy. Beclomethasone (QVAR®) and fluticasone propionate (Flovent Diskus®, Flovent HFA®) are also indicated for use in asthma patients who require systemic corticosteroid therapy when the addition of an ICS could reduce or eliminate the need for systemic corticosteroids.

GENERIC NAME	BRAND NAME	FORMULARY	FDA APPROVED AGE
ciclesonide	Alvesco HFA	F	12 years and older*
mometasone furoate	Asmanex HFA	F with ST**	5 years and older
fluticasone propionate	Flovent HFA 44 mcg	F (age restriction^: < 5 years older)	4 years and older
mometasone furoate	Asmanex Twisthaler	F with ST**	4 years and older
budesonide	Pulmicort Flexhaler	NF with ST**	6 years and older
fluticasone propionate	Flovent HFA 110 mcg and 220 mcg	NF with ST**	12 years and older
fluticasone propionate	Flovent Diskus	NF with ST**	4 years and older
fluticasone furoate	Arnuity Ellipta	NF with ST**	5 years and older
beclomethasone dipropionate	Qvar Redihaler	NF with ST*	4 years and older

*Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference
^Flovent HFA 44 mcg inhaler has age-restriction criteria and adjudicates for benefit for patients < 5 years of age only.
**Step-Therapy reviews past PBM claims (indefinite look back) for Alvesco HFA or Asmanex HFA; if prior claim for either, RX will adjudicate for copay and if not, RX will reject and sent to PAS for review. [exception: Asmanex HFA and Twisthaler will only look back for Alvesco HFA]

REFERENCES
Per Health Plan.

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

INHALED CORTICOSTEROID (ICS) INHALERS
BUDESONIDE FLEXHALER

Generic	Brand	HICL	GPID	Comments
BUDESONIDE	PULMICORT FLEXHALER		98024, 98025	Non-Formulary

Step Therapy Criteria
Must meet ONE of the following criteria, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed, or has an intolerance or a contraindication to, Alvesco HFA.
2. If provider requests an FDA approved product for patient under 12 years of age, must trial/fail Asmanex HFA.

If either criterion is met, approve at GPID indefinitely.
If no criteria are met, do not approve.

STEP THERAPY RULES:

- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Alvesco] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Although the ICSs exert their therapeutic effects through identical mechanisms of action, they differ in their potency, dosing schedules, and dosage form availability. Numerous placebo-controlled trials have demonstrated the efficacy of ICS agents in the treatment of asthma, and these agents are considered the most effective agents in the long-term management of the disease. The results of head-to-head trials directly comparing the ICS products have not demonstrated one agent to be significantly more effective than another, regardless of the potency or dosage form of the ICS agent used.

Alvesco (ciclesonide) HFA (1st line) and Asmanex (mometasone) HFA (2nd line step-therapy criteria) are KPCO formulary ICS inhalers for age 5 years and older. Although FDA approved for age 12 years and older, use of Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference. Flovent HFA 44 mcg inhaler and budesonide nebulized solution are formulary for age < 5 years of age.

KPCO order of preference: Alvesco HFA (ciclesonide) > Asmanex HFA (mometasone) > Asmanex Twisthaler (mometasone) > Flovent HFA (fluticasone propionate) > Flovent Diskus (fluticasone propionate) > Pulmicort Flexhaler (budesonide) > Arnuity Ellipta (fluticasone furoate) > Qvar Redihaler (beclomethasone)

FDA APPROVED INDICATIONS
All ICS inhalers are FDA approved for the maintenance treatment of asthma as prophylactic therapy. Beclomethasone (QVAR®) and fluticasone propionate (Flovent Diskus®, Flovent HFA®) are also indicated for use in asthma patients who require systemic corticosteroid therapy when the addition of an ICS could reduce or eliminate the need for systemic corticosteroids.

GENERIC NAME	BRAND NAME	FORMULARY	FDA APPROVED AGE
ciclesonide	Alvesco HFA	F	12 years and older*
mometasone furoate	Asmanex HFA	F with ST**	5 years and older
fluticasone propionate	Flovent HFA 44 mcg	F (age restriction^: < 5 years older)	4 years and older
mometasone furoate	Asmanex Twisthaler	F with ST**	4 years and older
budesonide	Pulmicort Flexhaler	NF with ST**	6 years and older
fluticasone propionate	Flovent HFA 110 mcg and 220 mcg	NF with ST**	12 years and older
fluticasone propionate	Flovent Diskus	NF with ST**	4 years and older
fluticasone furoate	Arnuity Ellipta	NF with ST**	5 years and older
beclomethasone dipropionate	Qvar Redihaler	NF with ST*	4 years and older
*Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference ^Flovent HFA 44 mcg inhaler has age-restriction criteria and adjudicates for benefit for patients < 5 years of age only. **Step-Therapy reviews past PBM claims (indefinite look back) for Alvesco HFA or Asmanex HFA; if prior claim for either, RX will adjudicate for copay and if not, RX will reject and sent to PAS for review. [exception: Asmanex HFA and Twisthaler will only look back for Alvesco HFA]			

REFERENCES
Per Health Plan.

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

INHALED CORTICOSTEROID (ICS) INHALERS
FLUTICASONE DISKUS

Generic	Brand	HICL	GPID	Comments
FLUTICASONE PROPIONATE	FLOVENT DISKUS		53633, 53634, 53635	Non-Formulary

Step Therapy Criteria
Must meet ONE of the following criteria, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed, or has an intolerance or a contraindication to, Alvesco HFA.
2. If provider requests an FDA approved product for patient under 12 years of age, must trial/fail Asmanex HFA.

If either criterion is met, approve at GPID indefinitely.
If no criteria are met, do not approve.

STEP THERAPY RULES:

- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Alvesco] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Although the ICSs exert their therapeutic effects through identical mechanisms of action, they differ in their potency, dosing schedules, and dosage form availability. Numerous placebo controlled trials have demonstrated the efficacy of ICS agents in the treatment of asthma, and these agents are considered the most effective agents in the long-term management of the disease. The results of head-to-head trials directly comparing the ICS products have not demonstrated one agent to be significantly more effective than another, regardless of the potency or dosage form of the ICS agent used.

Alvesco (ciclesonide) HFA (1st line) and Asmanex (mometasone) HFA (2nd line step-therapy criteria) are KPCO formulary ICS inhalers for age 5 years and older. Although FDA approved for age 12 years and older, use of Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference. Flovent HFA 44 mcg inhaler and budesonide nebulized solution are formulary for age < 5 years of age.

KPCO order of preference: Alvesco HFA (ciclesonide) > Asmanex HFA (mometasone) > Asmanex Twisthaler (mometasone) > Flovent HFA (fluticasone propionate) > Flovent Diskus (fluticasone propionate) > Pulmicort Flexhaler (budesonide) > Arnuity Ellipta (fluticasone furoate) > Qvar Redihaler (beclomethasone)

FDA APPROVED INDICATIONS
All ICS inhalers are FDA approved for the maintenance treatment of asthma as prophylactic therapy. Beclomethasone (QVAR®) and fluticasone propionate (Flovent Diskus®, Flovent HFA®) are also indicated for use in asthma patients who require systemic corticosteroid therapy when the addition of an ICS could reduce or eliminate the need for systemic corticosteroids.

GENERIC NAME	BRAND NAME	FORMULARY	FDA APPROVED AGE
ciclesonide	Alvesco HFA	F	12 years and older*
mometasone furoate	Asmanex HFA	F with ST**	5 years and older
fluticasone propionate	Flovent HFA 44 mcg	F (age restriction^: < 5 years older)	4 years and older
mometasone furoate	Asmanex Twisthaler	F with ST**	4 years and older
budesonide	Pulmicort Flexhaler	NF with ST**	6 years and older
fluticasone propionate	Flovent HFA 110 mcg and 220 mcg	NF with ST**	12 years and older
fluticasone propionate	Flovent Diskus	NF with ST**	4 years and older
fluticasone furoate	Arnuity Ellipta	NF with ST**	5 years and older
beclomethasone dipropionate	Qvar Redihaler	NF with ST*	4 years and older

*Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference
^Flovent HFA 44 mcg inhaler has age-restriction criteria and adjudicates for benefit for patients < 5 years of age only.
**Step-Therapy reviews past PBM claims (indefinite look back) for Alvesco HFA or Asmanex HFA; if prior claim for either, RX will adjudicate for copay and if not, RX will reject and sent to PAS for review. [exception: Asmanex HFA and Twisthaler will only look back for Alvesco HFA]

REFERENCES
Per Health Plan.

Creation Date: 05/2022
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

INHALED CORTICOSTEROID (ICS) INHALERS
FLUTICASONE FUROATE ELLIPTA

Generic	Brand	HICL	GPID	Comments
FLUTICASONE FUROATE	ARNUITY ELLIPTA		37007, 37008, 44783	Non-Formulary

Step Therapy Criteria
Must meet ONE of the following criteria, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed, or has an intolerance or a contraindication to, Alvesco HFA.
2. If provider requests an FDA approved product for patient under 12 years of age, must trial/fail Asmanex HFA.

If either criterion is met, approve at GPID indefinitely.
If no criteria are met, do not approve.

STEP THERAPY RULES:

- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Alvesco] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Although the ICSs exert their therapeutic effects through identical mechanisms of action, they differ in their potency, dosing schedules, and dosage form availability. Numerous placebo controlled trials have demonstrated the efficacy of ICS agents in the treatment of asthma, and these agents are considered the most effective agents in the long-term management of the disease. The results of head-to-head trials directly comparing the ICS products have not demonstrated one agent to be significantly more effective than another, regardless of the potency or dosage form of the ICS agent used.

Alvesco (ciclesonide) HFA (1st line) and Asmanex (mometasone) HFA (2nd line step-therapy criteria) are KPCO formulary ICS inhalers for age 5 years and older. Although FDA approved for age 12 years and older, use of Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference. Flovent HFA 44 mcg inhaler and budesonide nebulized solution are formulary for age < 5 years of age.

KPCO order of preference: Alvesco HFA (ciclesonide) > Asmanex HFA (mometasone) > Asmanex Twisthaler (mometasone) > Flovent HFA (fluticasone propionate) > Flovent Diskus (fluticasone propionate) > Pulmicort Flexhaler (budesonide) > Arnuity Ellipta (fluticasone furoate) > Qvar Redihaler (beclomethasone)

FDA APPROVED INDICATIONS
All ICS inhalers are FDA approved for the maintenance treatment of asthma as prophylactic therapy. Beclomethasone (QVAR®) and fluticasone propionate (Flovent Diskus®, Flovent HFA®) are also indicated for use in asthma patients who require systemic corticosteroid therapy when the addition of an ICS could reduce or eliminate the need for systemic corticosteroids.

GENERIC NAME	BRAND NAME	FORMULARY	FDA APPROVED AGE
ciclesonide	Alvesco HFA	F	12 years and older*
mometasone furoate	Asmanex HFA	F with ST**	5 years and older
fluticasone propionate	Flovent HFA 44 mcg	F (age restriction^: < 5 years older)	4 years and older
mometasone furoate	Asmanex Twisthaler	F with ST**	4 years and older
budesonide	Pulmicort Flexhaler	NF with ST**	6 years and older
fluticasone propionate	Flovent HFA 110 mcg and 220 mcg	NF with ST**	12 years and older
fluticasone propionate	Flovent Diskus	NF with ST**	4 years and older
fluticasone furoate	Arnuity Ellipta	NF with ST**	5 years and older
beclomethasone dipropionate	Qvar Redihaler	NF with ST*	4 years and older

*Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference
^Flovent HFA 44 mcg inhaler has age-restriction criteria and adjudicates for benefit for patients < 5 years of age only.
**Step-Therapy reviews past PBM claims (indefinite look back) for Alvesco HFA or Asmanex HFA; if prior claim for either, RX will adjudicate for copay and if not, RX will reject and sent to PAS for review. [exception: Asmanex HFA and Twisthaler will only look back for Alvesco HFA]

REFERENCES
Per Health Plan.

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

INHALED CORTICOSTEROID (ICS) INHALERS
FLUTICASONE HFA

Generic	Brand	HICL	GPID	Comments
FLUTICASONE PROPIONATE	FLOVENT HFA (110 MCG AND 220 MCG ONLY)		53636, 53639	Non-Formulary Brand no longer available on market

Step Therapy Criteria
Must meet ONE of the following criteria, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed, or has an intolerance or a contraindication to, Alvesco HFA.
2. If provider requests an FDA approved product for patient under 12 years of age, must trial/fail Asmanex HFA.

If either criterion is met, approve at GPID indefinitely.
If no criteria are met, do not approve.

STEP THERAPY RULES:

- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Alvesco] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Although the ICSs exert their therapeutic effects through identical mechanisms of action, they differ in their potency, dosing schedules, and dosage form availability. Numerous placebo controlled trials have demonstrated the efficacy of ICS agents in the treatment of asthma, and these agents are considered the most effective agents in the long-term management of the disease. The results of head-to-head trials directly comparing the ICS products have not demonstrated one agent to be significantly more effective than another, regardless of the potency or dosage form of the ICS agent used.

Alvesco (ciclesonide) HFA (1st line) and Asmanex (mometasone) HFA (2nd line step-therapy criteria) are KPCO formulary ICS inhalers for age 5 years and older. Although FDA approved for age 12 years and older, use of Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference. Flovent HFA 44 mcg inhaler and budesonide nebulized solution are formulary for age < 5 years of age.

KPCO order of preference: Alvesco HFA (ciclesonide) > Asmanex HFA (mometasone) > Asmanex Twisthaler (mometasone) > Flovent HFA (fluticasone propionate) > Flovent Diskus (fluticasone propionate) > Pulmicort Flexhaler (budesonide) > Arnuity Ellipta (fluticasone furoate) > Qvar Redihaler (beclomethasone)

FDA APPROVED INDICATIONS
All ICS inhalers are FDA approved for the maintenance treatment of asthma as prophylactic therapy. Beclomethasone (QVAR®) and fluticasone propionate (Flovent Diskus®, Flovent HFA®) are also indicated for use in asthma patients who require systemic corticosteroid therapy when the addition of an ICS could reduce or eliminate the need for systemic corticosteroids.

GENERIC NAME	BRAND NAME	FORMULARY	FDA APPROVED AGE
ciclesonide	Alvesco HFA	F	12 years and older*
mometasone furoate	Asmanex HFA	F with ST**	5 years and older
fluticasone propionate	Flovent HFA 44 mcg	F (age restriction^: < 5 years older)	4 years and older
mometasone furoate	Asmanex Twisthaler	F with ST**	4 years and older
budesonide	Pulmicort Flexhaler	NF with ST**	6 years and older
fluticasone propionate	Flovent HFA 110 mcg and 220 mcg	NF with ST**	12 years and older
fluticasone propionate	Flovent Diskus	NF with ST**	4 years and older
fluticasone furoate	Arnuity Ellipta	NF with ST**	5 years and older
beclomethasone dipropionate	Qvar Redihaler	NF with ST*	4 years and older

*Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference
^Flovent HFA 44 mcg inhaler has age-restriction criteria and adjudicates for benefit for patients < 5 years of age only.
**Step-Therapy reviews past PBM claims (indefinite look back) for Alvesco HFA or Asmanex HFA; if prior claim for either, RX will adjudicate for copay and if not, RX will reject and sent to PAS for review. [exception: Asmanex HFA and Twisthaler will only look back for Alvesco HFA]

REFERENCES
Per Health Plan.

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

INHALED CORTICOSTEROID (ICS) INHALERS
MOMETASONE HFA

Generic	Brand	HICL	GPID	Comments
MOMETASONE FUROATE	ASMANEX HFA		37566, 37565, 47599	Formulary

Step Therapy Criteria
Must meet the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
1. Patient has tried and failed, or has an intolerance or a contraindication to, Alvesco HFA.

If met, approve at GPID indefinitely.
If not met, do not approve.

STEP THERAPY RULES:
- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Alvesco] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Although the ICSs exert their therapeutic effects through identical mechanisms of action, they differ in their potency, dosing schedules, and dosage form availability. Numerous placebo-controlled trials have demonstrated the efficacy of ICS agents in the treatment of asthma, and these agents are considered the most effective agents in the long-term management of the disease. The results of head-to-head trials directly comparing the ICS products have not demonstrated one agent to be significantly more effective than another, regardless of the potency or dosage form of the ICS agent used.

Alvesco (ciclesonide) HFA (1st line) and Asmanex (mometasone) HFA (2nd line step-therapy criteria) are KPCO formulary ICS inhalers for age 5 years and older. Although FDA approved for age 12 years and older, use of Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference. Flovent HFA 44 mcg inhaler and budesonide nebulized solution are formulary for age < 5 years of age.

KPCO order of preference: Alvesco HFA (ciclesonide) > Asmanex HFA (mometasone) > Asmanex Twisthaler (mometasone) > Flovent HFA (fluticasone propionate) > Flovent Diskus (fluticasone propionate) > Pulmicort Flexhaler (budesonide) > Arnuity Ellipta (fluticasone furoate) > Qvar Redihaler (beclomethasone)

FDA APPROVED INDICATIONS
All ICS inhalers are FDA approved for the maintenance treatment of asthma as prophylactic therapy. Beclomethasone (QVAR®) and fluticasone propionate (Flovent Diskus®, Flovent HFA®) are also indicated for use in asthma patients who require systemic corticosteroid therapy when the addition of an ICS could reduce or eliminate the need for systemic corticosteroids.

GENERIC NAME	BRAND NAME	FORMULARY	FDA APPROVED AGE
ciclesonide	Alvesco HFA	F	12 years and older*
mometasone furoate	Asmanex HFA	F with ST**	5 years and older
fluticasone propionate	Flovent HFA 44 mcg	F (age restriction^: < 5 years older)	4 years and older
mometasone furoate	Asmanex Twisthaler	F with ST**	4 years and older
budesonide	Pulmicort Flexhaler	NF with ST**	6 years and older
fluticasone propionate	Flovent HFA 110 mcg and 220 mcg	NF with ST**	12 years and older
fluticasone propionate	Flovent Diskus	NF with ST**	4 years and older
fluticasone furoate	Arnuity Ellipta	NF with ST**	5 years and older
beclomethasone dipropionate	Qvar Redihaler	NF with ST*	4 years and older

*Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference
^Flovent HFA 44 mcg inhaler has age-restriction criteria and adjudicates for benefit for patients < 5 years of age only.
**Step-Therapy reviews past PBM claims (indefinite look back) for Alvesco HFA or Asmanex HFA; if prior claim for either, RX will adjudicate for copay and if not, RX will reject and sent to PAS for review. [exception: Asmanex HFA and Twisthaler will only look back for Alvesco HFA]

REFERENCES
Per Health Plan.

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

INHALED CORTICOSTEROID (ICS) INHALERS
MOMETASONE TWISTHALER

Generic	Brand	HICL	GPID	Comments
MOMETASONE FUROATE	ASMANEX TWISTHALER		99721, 18987, 24928, 24929	Formulary

Step Therapy Criteria
Must meet the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
1. Patient has tried and failed, or has an intolerance or a contraindication to, Alvesco HFA.

If met, approve at GPID indefinitely.
If not met, do not approve.

STEP THERAPY RULES:
- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Alvesco] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Although the ICSs exert their therapeutic effects through identical mechanisms of action, they differ in their potency, dosing schedules, and dosage form availability. Numerous placebo-controlled trials have demonstrated the efficacy of ICS agents in the treatment of asthma, and these agents are considered the most effective agents in the long-term management of the disease. The results of head-to-head trials directly comparing the ICS products have not demonstrated one agent to be significantly more effective than another, regardless of the potency or dosage form of the ICS agent used.

Alvesco (ciclesonide) HFA (1st line) and Asmanex (mometasone) HFA (2nd line step-therapy criteria) are KPCO formulary ICS inhalers for age 5 years and older. Although FDA approved for age 12 years and older, use of Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference. Flovent HFA 44 mcg inhaler and budesonide nebulized solution are formulary for age < 5 years of age.

KPCO order of preference: Alvesco HFA (ciclesonide) > Asmanex HFA (mometasone) > Asmanex Twisthaler (mometasone) > Flovent HFA (fluticasone propionate) > Flovent Diskus (fluticasone propionate) > Pulmicort Flexhaler (budesonide) > Arnuity Ellipta (fluticasone furoate) > Qvar Redihaler (beclomethasone)

FDA APPROVED INDICATIONS
All ICS inhalers are FDA approved for the maintenance treatment of asthma as prophylactic therapy. Beclomethasone (QVAR®) and fluticasone propionate (Flovent Diskus®, Flovent HFA®) are also indicated for use in asthma patients who require systemic corticosteroid therapy when the addition of an ICS could reduce or eliminate the need for systemic corticosteroids.

GENERIC NAME	BRAND NAME	FORMULARY	FDA APPROVED AGE
ciclesonide	Alvesco HFA	F	12 years and older*
mometasone furoate	Asmanex HFA	F with ST**	5 years and older
fluticasone propionate	Flovent HFA 44 mcg	F (age restriction^: < 5 years older)	4 years and older
mometasone furoate	Asmanex Twisthaler	F with ST**	4 years and older
budesonide	Pulmicort Flexhaler	NF with ST**	6 years and older
fluticasone propionate	Flovent HFA 110 mcg and 220 mcg	NF with ST**	12 years and older
fluticasone propionate	Flovent Diskus	NF with ST**	4 years and older
fluticasone furoate	Arnuity Ellipta	NF with ST**	5 years and older
beclomethasone dipropionate	Qvar Redihaler	NF with ST*	4 years and older

*Alvesco HFA in pediatric patients, age 5 to 11 years of age, is strongly supported by evidence from clinical trials; and it is recommended by both the GINA asthma guidelines and the 2012 NAEPP Asthma Care Quick Reference
^Flovent HFA 44 mcg inhaler has age-restriction criteria and adjudicates for benefit for patients < 5 years of age only.
**Step-Therapy reviews past PBM claims (indefinite look back) for Alvesco HFA or Asmanex HFA; if prior claim for either, RX will adjudicate for copay and if not, RX will reject and sent to PAS for review. [exception: Asmanex HFA and Twisthaler will only look back for Alvesco HFA]

REFERENCES
Per Health Plan.

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

INPEN SMART INSULIN PEN DEVICE

Generic	Brand	HICL	GPID	Comments
INSULIN ADMINISTRATION DEVICE	INPEN SMART INSULIN PEN	20334	94200	

GUIDELINES FOR COVERAGE
Must meet all the following:
1. Patient has a diagnosis of type 1 diabetes.
2. Must be prescribed by an Endocrinologist.
3. Prescriber has documented a need for detailed electronic monitoring of the patient's insulin dose administered and time of administration.
4. The patient will be using InPen with Humalog, Novolog, or Fiasp U-100 insulin only.

If criteria are met, approve at NDC-9 level indefinitely, maximum quantity of 1 per 365 days.
If criteria are not met, do not approve.

ePA Questions
1. Prescriber has documented a need for detailed electronic monitoring of the patient's insulin dose administered and time of administration. If yes, please attach applicable documentation.
2. Will the patient be using InPen with Humalog, Novolog, or Fiasp U-100 insulin?

RATIONALE
InPen is the only FDA-cleared smart insulin pen system that combines a reusable Bluetooth-enabled insulin pen and mobile app. InPen is a prescription-only product that records insulin injections and recommends doses based on current blood glucose, insulin dose, and current active insulin. The pen injector is compatible with Lily Humalog U-100 3 mL cartridges (KP preferred), Novo Nordisk U-100 3 mL cartridges, and Novo Nordisk Fiasp U-100 3 mL cartridges. The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half unit increments. The InPen system is not intended for anyone unable or unwilling to test blood glucose (BG) levels as recommended by a healthcare provider, maintain sufficient diabetes self-care skills, or visit a healthcare provider regularly. InPen is not recommended for the blind or visually impaired without the assistance of a sighted individual with appropriate training.

Creation Date: 05/2021
Effective Date: 12/2024
Reviewed Date: 11/2024
Revised Date: 11/2024

INSULIN COMBINATION PENS - LISPRO PROTAMIN/LISPRO

Generic	Brand	HICL	GPID	Exception/Other
INSULIN LISPRO PROTAMINE/INSULIN LISPRO	HUMALOG MIX 50/50 KWIKPEN	19949	50461	
INSULIN LISPRO PROTAMINE/INSULIN LISPRO	HUMALOG MIX 75/25 KWIKPEN	19949	93717	

GUIDELINES FOR COVERAGE

Must meet the following:

1. Patient has failed* Humulin 70/30, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
2. Meets one of the following requirements for pen form:
   a. Prescription is written by an Endocrinology specialist.
   b. Patient is under 18 years of age.
   c. Patient is 18 years or older and is unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

*NOTE: Failure can be defined as an adverse drug reaction or intolerance that is not expected to occur with the requested agent.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Humulin 70/30 vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

The use of insulin pens at KPCO is generally reserved for patients under age 18 years and patients with physical and/or cognitive impairment.

FDA APPROVED INDICATIONS

Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation date: 5/4/2017
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

INSULIN COMBINATION PENS - HUMULIN 70/30

Generic	Brand	HICL	GPID	Exception/Other
INSULIN NPH HUMAN ISOPHANE/REG INSULIN HUMAN	HUMULIN 70/30 PEN	06215	890	**Preferred MIX product**

GUIDELINES FOR COVERAGE

Must meet one of the following:

1. Prescription is written by an Endocrinology specialist.
2. Patient is under 18 years of age.
3. Patient is 18 years or older and is unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination.

If criteria are met, approve indefinitely at GPID.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Humulin 70/30 vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

The use of insulin pens at KPCO is generally reserved for patients age < 18 years and patients with physical and/or cognitive impairment.

FDA APPROVED INDICATIONS

Diabetes type 1 and type 2 treatment

REFERENCES

Per Plan

Creation date: 5/4/2017
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

COMBO SHORT LONGER-ACTING INSULIN PENS
NOVOLOG 70/30

Generic	Brand	HICL	GPID	Exception/Other
INSULIN ASPART PROTAMINE/INSULIN ASPART	NOVOLOG MIX 70/30 FLEXPEN	23400	17075	

GUIDELINES FOR COVERAGE
Must meet the following:
1. Patient has failed* Humulin 70/30, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
2. Meets one of the following requirements for pen form:
   a. Prescription is written by an Endocrinology specialist.
   b. Patient is under 18 years of age.
   c. Patient is 18 years or older and is unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

*NOTE: Failure can be defined as an adverse drug reaction or intolerance that is not expected to occur with the requested agent.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Humulin 70/30 vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
The use of insulin pens at KPCO is generally reserved for patients under age 18 years and patients with physical and/or cognitive impairment.

FDA APPROVED INDICATIONS
Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation date: 5/4/2017
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

INSULIN DEGLUDEC U-100 PENS

Generic	Brand	HICL	GPID	Exception/Other
INSULIN DEGLUDEC	TRESIBA FLEXTOUCH U-100	40844	35836	Excluded
INSULIN DEGLUDEC	INSULIN DEGLUDEC U-100 PEN	40844	35836	73070040315

GUIDELINES FOR COVERAGE
Must have one of the following indications and meet all indication-specific criteria as follows:

A. Type I Diabetes
B. Type II Diabetes

A. To Treat DIABETES TYPE 1: Must meet the following:
1. Patient has failed glargine U-100 due to adverse drug reaction/intolerance that is not expected to occur with the requested agent or due to significant hypoglycemia (fingerstick less than 70 ml/dL) despite appropriate insulin management (i.e., basal insulin, bolus/mealtime insulin, hypoglycemia management), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
2. Meets one of the following requirements for pen form:
    d. Prescription is written by an Endocrinology specialist.
    e. Patient is under 18 years of age.
    f. Patient is 18 years or older and unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

B. To Treat DIABETES TYPE 2: Must meet the following:
1. Patient has failed glargine U-100 and NPH due to adverse drug reaction/intolerance that is not expected to occur with the requested agent or significant hypoglycemia (fingerstick less than 70 ml/dL) despite appropriate insulin management (i.e., basal insulin, bolus/mealtime insulin, hypoglycemia management), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
2. Meets one of the following requirements for pen form:
    a. Prescription is written by an Endocrinology specialist.
    b. Patient is under 18 years of age.
    c. Patient is 18 years or older and unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

ePA Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: DM1, DM2]

QUESTIONS BASED ON DIAGNOSIS SELECTED

DM 1

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (glargine-yfgn vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

DM 2

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (glargine-yfgn vials, vials of NPH) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Brand Tresiba is excluded from coverage.

Insulin degludec is an ultra-long acting insulin available in 2 concentrations (U-100 and U-200) and 2 dosage forms (vials and pens). Degludec vial is available only in U-100 concentration. Single-patient-use FlexTouch pens are available in 2 concentrations. FlexTouch U-100 pen contains 300 units, delivers doses in 1 unit increments and can deliver up to 80 units in a single injection**.** FlexTouch U-200 pen contains 600 units, delivers doses in 2 unit increments and can deliver up to 160 units in a single injection. Brand insulin degludec (Tresiba) is excluded from coverage and only unbranded insulin degludec is available for coverage. Unbranded biologic products are identical, including inactive ingredients, to the branded drug product and are packaged and marketed by the brand manufacturer but without the brand name on the label/package.

There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. NPH and insulin glargine are preferred based on their efficacy and safety profiles, as well as their competitive cost advantage for patients and KPCO. The use of insulin pens at KPCO is generally reserved for patients under age 18 years and patients with physical and/or cognitive impairment.

FDA APPROVED INDICATIONS
Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation date: 5/4/2017
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

INSULIN DEGLUDEC U-100 VIALS

Generic	Brand	HICL	GPID	Exception/Other
INSULIN DEGLUDEC	TRESIBA U-100 VIALS	40844	42785	Excluded
INSULIN DEGLUDEC	INSULIN DEGLUDEC U-100 VIALS	40844	42785	73070040011

GUIDELINES FOR COVERAGE
Must have one of the following indications and meet all indication-specific criteria as follows:

B. Type I Diabetes
C. Type II Diabetes

A. To Treat DIABETES TYPE 1: Must meet the following:
1. Patient has failed glargine U-100 due to adverse drug reaction/intolerance that is not expected to occur with the requested agent or due to significant hypoglycemia (fingerstick less than 70 ml/dL) despite appropriate insulin management (i.e., basal insulin, bolus/mealtime insulin, hypoglycemia management), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

B. To Treat DIABETES TYPE 2: Must meet the following:
1. Patient has failed glargine U-100 and NPH due to adverse drug reaction/intolerance that is not expected to occur with the requested agent or significant hypoglycemia (fingerstick less than 70 ml/dL) despite appropriate insulin management (i.e., basal insulin, bolus/mealtime insulin, hypoglycemia management), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

ePA Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: DM1, DM2]
QUESTIONS BASED ON DIAGNOSIS SELECTED
DM 1
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

2. Is there reasoning why alternatives (glargine-yfgn vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

DM 2

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (glargine-yfgn vials, vials of NPH) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Brand Tresiba is excluded from coverage.

Insulin degludec is an ultra-long acting insulin available in 2 concentrations (U-100 and U-200) and 2 dosage forms (vials and pens). Degludec vial is available only in U-100 concentration. Single-patient-use FlexTouch pens are available in 2 concentrations. FlexTouch U-100 pen contains 300 units, delivers doses in 1 unit increments and can deliver up to 80 units in a single injection. FlexTouch U-200 pen contains 600 units, delivers doses in 2 unit increments and can deliver up to 160 units in a single injection. Brand insulin degludec (Tresiba) is excluded from coverage and only unbranded insulin degludec is available for coverage. Unbranded biologic products are identical, including inactive ingredients, to the branded drug product and are packaged and marketed by the brand manufacturer but without the brand name on the label/package.

There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. NPH and insulin glargine are preferred based on their efficacy and safety profiles, as well as their competitive cost advantage for patients and KPCO. The use of insulin pens at KPCO is generally reserved for patients under age 18 years and patients with physical and/or cognitive impairment.

FDA APPROVED INDICATIONS

Diabetes type 1 and type 2 treatment

REFERENCES

Per Plan

Creation date: 5/4/2017
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

INSULIN DEGLUDEC U-200 PENS

Generic	Brand	HICL	GPID	Exception/Other
INSULIN DEGLUDEC	TRESIBA FLEXTOUCH U-200	40844	35837	Excluded
INSULIN DEGLUDEC	INSULIN DEGLUDEC U-200 PEN	40844	35837	73070050315

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet the following:
1. Patient's long-acting insulin (including NPH) dose is 100 units/day or more, but their total daily dose of insulin (basal + bolus) does NOT exceed 200 units/day or 2 units/kg/day.

If met, approve at GPID x2 years.
If not met, do not approve.

RENEWAL CRITERIA: Must meet the following:
1. Patient's long-acting insulin dose exceeds 100 units/day but their total daily dose of insulin (basal + bolus) does NOT exceed 200 units/day or 2 units/kg/day.

If met, approve at GPID x2 years.
If not met, do not approve.

ePA Questions
1. Patient's long-acting insulin dose (units/day):
2. Patient's total daily dose of insulin (units/day):
3. Patient weight (kg):

RATIONALE
Brand Tresiba is excluded from coverage.

Insulin degludec is an ultra-long acting insulin available in 2 concentrations (U-100 and U-200) and 2 dosage forms (vials and pens). Degludec vial is available only in U-100 concentration. Single-patient-use FlexTouch pens are available in 2 concentrations. FlexTouch U-100 pen contains 300 units, delivers doses in 1 unit increments and can deliver up to 80 units in a single injection**.** FlexTouch U-200 pen contains 600 units, delivers doses in 2 unit increments and can deliver up to 160 units in a single injection. Brand insulin degludec (Tresiba) is excluded from coverage and only unbranded insulin degludec is available for coverage. Unbranded biologic products are identical, including inactive ingredients, to the branded drug product and are packaged and marketed by the brand manufacturer but without the brand name on the label/package.

There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. NPH and insulin glargine are preferred based on their efficacy and safety profiles, as well as their competitive cost advantage for patients and KPCO. The use of insulin pens at KPCO is generally reserved for patients age <18 years and patients with physical and/or cognitive impairment.

FDA APPROVED INDICATIONS
Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation date: 5/4/2017
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

INSULIN DETEMIR PENS

Generic	Brand	HICL	GPID	Exception/Other
INSULIN DETEMIR	LEVEMIR FLEXTOUCH PEN	26407	22836	

GUIDELINES FOR COVERAGE
Must have one of the following indications and meet all indication-specific criteria as follows:

A. Type I Diabetes
B. Type II Diabetes

A. To Treat DIABETES TYPE 1: Must meet the following:
1. Patient has failed glargine U-100 due to adverse drug reaction/intolerance that is not expected to occur with the requested agent, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
2. Meets one of the following requirements for pen form:
   a. Prescription is written by an Endocrinology specialist.
   b. Patient is under 18 years of age.
   c. Patient is 18 years of age or older and is unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

B. To Treat DIABETE TYPE 2: Must meet below criteria based on requested dosage form:
1. Patient has failed glargine U-100 and NPH due to adverse drug reaction/intolerance that is not expected to occur with the requested agent, orthe provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
2. Meets one of the following requirements for pen form:
   a. Prescription is written by an Endocrinology specialist.
   b. Patient is under 18 years of age.
   c. Patient is 18 years of age or older and is unable to use insulin vials and syringes to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination

If criteria are met, approve at HICL indefinitely.

If criteria are not met, do not approve.

ePA Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: DM1, DM2]

QUESTIONS BASED ON DIAGNOSIS SELECTED

DM 1

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (glargine-yfgn vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

DM 2

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (glargine-yfgn vials, vials of NPH) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. NPH insulin and insulin glargine are preferred over detemir based on their efficacy and safety profiles, as well as their competitive cost advantage for patients and KPCO. The use of insulin pens at KPCO is generally reserved for patients under age 18 years and patients with physical and/or cognitive impairment.

FDA APPROVED INDICATIONS

Diabetes type 1 and type 2 treatment

REFERENCES

Per Plan

Creation date: 7/2021
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

INSULIN DETEMIR VIALS

Generic	Brand	HICL	GPID	Exception/Other
INSULIN DETEMIR	LEVEMIR VIAL	26407	25305	

GUIDELINES FOR COVERAGE
Must have one of the following indications and meet all indication-specific criteria as follows:

A. Type I Diabetes
B. Type II Diabetes

A. To Treat DIABETES TYPE 1: Must meet the following:
1. Patient has failed glargine U-100 due to adverse drug reaction/intolerance that is not expected to occur with the requested agent, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

B. To Treat DIABETES TYPE 2: Must meet the following:
1. Patient has failed glargine U-100 and NPH due to adverse drug reaction/intolerance that is not expected to occur with the requested agent, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

ePA Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: DM1, DM2]
   QUESTIONS BASED ON DIAGNOSIS SELECTED
   DM 1
   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   2. Is there reasoning why alternatives (glargine-yfgn vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

DM 2

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (glargine-yfgn vials, vials of NPH) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. NPH insulin and insulin glargine are preferred over detemir based on their efficacy and safety profiles, as well as their competitive cost advantage for patients and KPCO. The use of insulin pens at KPCO is generally reserved for patients under age 18 years and patients with physical and/or cognitive impairment.

FDA APPROVED INDICATIONS

Diabetes type 1 and type 2 treatment

REFERENCES

Per Plan

Creation date: 7/2021
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

INSULIN GLARGINE 100u/ml PEN

Generic	Brand	HICL	GPID	Other
INSULIN GLARGINE	LANTUS SOLOSTAR, BASAGLAR KWIKPEN, BASAGLAR TEMPO PEN	22025	98637	NF

GUIDELINES FOR COVERAGE

Must meet the following:

1. Patient has documented allergic reaction or injection site reaction to insulin glargine-yfgn, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
2. Meets one of the following requirements for pen form:
   a. Prescription is written by an Endocrinology specialist.
   b. Patient is under 18 years of age.
   c. Patient is 18 years of age or older and is unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination.

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (glargine-yfgn vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

NOTE: Insulin glargine-yfgn (unbranded Semglee) is an FDA approved, interchangeable, and biosimilar of Lantus (insulin glargine) and is the preferred product at Kaiser Permanente.

There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin glargine-yfgn (unbranded Semglee) is an FDA approved, interchangeable biosimilar of Lantus (insulin glargine) and is the preferred product at Kaiser Permanente. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. Insulin glargine-yfgn is preferred (vial - formulary without PA) based on its efficacy and safety profile, as well as its competitive cost advantage for patients and KPCO. The use of insulin pens at KPCO is generally reserved for patients with physical and/or cognitive impairment.

FDA APPROVED INDICATIONS
Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation Date: 2016-2017
Effective Date: 08/2024
Reviewed Date: 05/2024
Revised Date: 05/2024

INSULIN GLARGINE 300u/ml PEN

Generic	Brand	HICL	GPID	Other
INSULIN GLARGINE	TOUJEO SOLOSTAR PEN U-300	22025	37988	NF
INSULIN GLARGINE	TOUJEO MAX SOLOSTAR PEN U-300	22025	44561	NF

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet the following:
1. Patient's long-acting insulin dose is 100 units/day or more, but their total daily dose of insulin (basal + bolus) does NOT exceed 200 units/day or 2 units/kg/day.
2. Patient must have tried and failed, have a contraindication to or an intolerance to insulin degludec U-200 [unbranded insulin degludec is F, PA], or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve at GPID for 2 years.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following:
1. Patient's long-acting insulin dose exceeds 100 units/day but their total daily dose of insulin (basal + bolus) does NOT exceed 200 units/day or 2 units/kg/day.

If renewal criteria are met, approve at GPID for 2 years.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Patient's long-acting insulin dose (units/day):
3. Patient's total daily dose of insulin (units/day):
4. Patient weight (kg):

Renewal Review Questions
1. Patient's long-acting insulin dose (units/day):
2. Patient's total daily dose of insulin (units/day):
3. Patient weight (kg):

RATIONALE
Toujeo is a unique concentrated insulin glargine, available in a single concentration of 300 units/ml. It comes in 2 single-patient-use prefilled Solostar pens: 1.5-mL pen (450 units/1.5 mL) which can deliver up to 80 units per injection, and a 3-mL Max pen (900 units/3 mL)) which can deliver up to 160 units

per injection. Toujeo Solostar pen is a 2nd linen option after insulin degludec 200 unit/mL for patients requiring insulin doses between 100 and 200 units/day.

FDA APPROVED INDICATIONS
Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation Date: 2016-2017
Effective Date: 08/2024
Reviewed Date: 05/2024
Revised Date: 05/2024

INSULIN GLARGINE-AGLR PEN

Generic	Brand	HICL	GPID	Other
INSULIN GLARGINE-AGLR	REZVOGLAR KWIKPEN	47733	51718	

GUIDELINES FOR COVERAGE

Must meet the following:

1. Patient has documented allergic reaction or injection site reaction to insulin glargine-yfgn, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
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   b. Patient is under 18 years of age.
   c. Patient is 18 years of age or older and is unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination.

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (glargine-yfgn vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

NOTE: Insulin glargine-yfgn (unbranded Semglee) is an FDA approved, interchangeable, and biosimilar of Lantus (insulin glargine) and is the preferred product at Kaiser Permanente.

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FDA APPROVED INDICATIONS

Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation Date: 2016-2017
Effective Date: 08/2024
Reviewed Date: 05/2024
Revised Date: 05/2024

INTERFERON BETA-1A (AVONEX)

Generic	Brand	HICL	GCN	Exception/Other
INTERFERON BETA-1A	AVONEX	11253		Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Must be prescribed by a CPMG or affiliated neurologist.
2. Patient has a diagnosis of a relapsing or active form of multiple sclerosis. (This does not include non-active secondary-progressive MS or primary-progressive MS.)
3. The patient has tried and failed, or has intolerance or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Betaseron
    b. Glatiramer
    c. Dimethyl fumarate

If initial criteria are met, approve x1 year at HICL.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Requesting physician is a CPMG or affiliated neurologist.
2. Patient has a diagnosis of a relapsing or active form of multiple sclerosis. (This does not include non-active secondary-progressive MS or primary-progressive MS.)

If renewal criteria are met, approve x1 year at HICL.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes: relapsing or active form of multiple sclerosis, non-active secondary-progressive MS, primary-progressive MS]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (Betaseron, glatiramer, dimethyl fumarate) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Diagnosis associated with this request: [check boxes: relapsing or active form of multiple sclerosis, non-active secondary-progressive MS, primary-progressive MS]

Disease Modifying Therapies

Class	Generic name	Brand or alternative name	Formulation	Preferred or Non-preferred per IR KP guidelines *(Does NOT refer to formulary status)*
Synthetic Cytokines	Interferon-beta 1a	Avonex	IM injection	NP
	Interferon-beta 1a	Plegridy	SQ/IM injection	NP
	Interferon-beta 1a	Rebif	SQ injection	NP
	Interferon-beta 1b	Extavia	SQ injection	P
		Betaseron	SQ Injection	P
Synthetic Myelin Basic Protein	Glatiramer acetate	Brand: Copaxone	SQ injection	NP
		Generic: Glatopa (Sandoz)	SQ injection	P
		Generic: Glatiramer acetate (Mylan)	SQ injection	NP
Reduced proliferation of activated T and B lymphocytes	Teriflunomide	Aubagio	Oral	NP
	Leflunomide** (pro-drug of teriflunomide)	Generic only (Brand: Arava)	Oral	NP
Stimulator of Nrf2 pathway (aka Fumaric Acid Derivatives)	Dimethyl fumarate (pro-drug of MMF)	Tecfidera	Oral	Generic – P Brand - NP
	Diroximel fumarate (pro-drug of MMF)	Vumerity (bioequivalent to Tecfidera)	Oral	NP
	Monomethyl fumarate (active metabolite)	Bafiertam	Oral	NP
S1P Receptor Modulator	Fingolimod	Gilenya	Oral	P
	Ozanimod	Zeposia	Oral	NP
	Siponimod	Mayzent	Oral	NP
T and B cell Depleting Small Molecule	Cladribine	Mavenclad	Oral	NP
T and B cell Depleting Antibody	Alemtuzumab	Lemtrada	Infusion	NP
Lymphocyte Anti-migration Antibody	Natalizumab	Tysabri	Infusion	NP
B-cell Depleting Antibodies	Rituximab-abbs**	Biosimilar: Truxima	Infusion	NP
	Rituximab-arrx	Biosimilar: Riabni	Infusion	P
	Rituximab-pvvr**	Biosimilar: Ruxience	Infusion	NP
	Rituximab**	Brand: Rituxan	Infusion	NP
	Ocrelizumab	Ocrevus	Infusion	NP
	Ofatumumab	Kesimpta	SQ injection	NP
	Ublituximab	Briumvi	Infusion	NP

Off-label disease modifying therapy for MS

RATIONALE:
The above guideline was developed by combining individual agent guidelines into one (5/2021)

The armamentarium of options for disease management of MS continues to expand and now includes agents with multiple differing methods of administration including injectables, infused as well as oral agents.

Interferon beta-1a products are injectables FDA approved in the treatment of relapsing forms of MS. The remaining injectables are another IFN beta-1a (Rebif), IFN beta-1b (Extavia and Betaseron), and glatiramer acetate (Copaxone and Glatopa). Comparisons across placebo-controlled trials for these

injectables have found similar effects in reducing relapse frequency of relapses, reducing burden of disease and activity on the MRI in comparison to placebo.

There have been 10 non-randomized, uncontrolled head-to-head trials of interferons that have found no difference between efficacy and safety, although there are two randomized, controlled large head-to-head comparison trials suggesting a dose-related improvement in efficacy. The two trials are the Evidence for Interferon Dose-Effect: European-North American Comparative Efficacy (EVIDENCE) trial and the Independent Comparison of Interferon (INCOMIN) trial. The EVIDENCE trial compared the efficacy of 30 micrograms (mcg) of IM IFN-beta-1a weekly with 44 mcg of SC IFN-beta-1a injected 3 times weekly. After 48 weeks of treatment, the relapse rate and MRI measures were significantly better with the higher dose regimen. However, the difference was primarily seen early in the study, during the first 24 weeks, whereas during the subsequent 24 weeks, the relapse rate was similar for the 2 groups. Additionally, the disability measures were not different at the end of the 1-year study period. The INCOMIN showed greater efficacy of IFN-beta-1b given every other day vs IFN-beta-1a given once weekly on relapse rate, MRI measures, and disability progression during the 2-year study. Unfortunately, the study had design limitations, including unblinded patients and examiners, limiting the conclusions that can be drawn. There are no head-to-head comparison trials assessing differences between Rebif and beta interferon 1b.

Comparisons across placebo-controlled trials for glatiramer acetate (GA) and beta - interferons have found similar effects in reducing relapse frequency of relapses, reducing burden of disease and activity on the MRI in comparison to placebo.

There are no current published consensus guidelines for the treatment of RRMS to guide on the roles in therapy for the injectables or the newer agents such as the infused drugs (i.e., Tysabri) or the orals (ie Aubagio, Gilenya, or Tecfidera). However, the trends and evidence for treatment suggest a two-pronged approach: induction and escalation. Induction treatment with a second- or third- line treatment like Tysabri or Gilenya is reserved for those patients with more aggressive disease requiring a more aggressive drug therapy approach at initiation. Whereas escalation is reserved for those patients with nonaggressive disease, in which safety and quality of life are the most significant considerations. First line treatment with injectables such as the beta-interferons may provide full “efficacy” but at a lower level of risk.

Neither of the injectables has any proven efficacy in those patients demonstrating nonrelapsing progressive disease such as those with secondary progressive MS or primary progressive MS. The main differences between the injectables are routes and frequency of administration as well as side effect profile. Additionally, beta - interferons are associated with the development of neutralizing antibodies in a small percentage of patients which may impact efficacy of drugs requiring change in therapy. Though not an absolute contraindication, untreated severe depression may pose a risk with the use beta – interferons in comparison to GA, thus careful selection of treatments is necessary. Similar caution must be used in patients who develop severe infusion reactions with the interferons or severe skin reactions with either of the injectables including GA.

Given no difference in efficacy or long-term safety outcomes between injectable therapies, choice of agent may reflect patient specific outcomes as well as cost-effectiveness of therapy.

FDA APPROVED INDICATIONS
Treatment of relapsing forms of MS

REFERENCES

1. Shilpa and Nikki Hahn, CPS
2. Avonex® [package insert]. Cambridge, MA: Biogen Idec Inc.; July 2023.
3. Plegridy [package insert]. Cambridge, MA: Biogen Idec Inc.; July 2023.
4. Rebif [package insert]. Rockland, MA: EMD Serono, Inc.; July 2023.
5. Clinical bulletin. Information for health professionals. Overview of multiple sclerosis. National Multiple Sclerosis Society. Available at http://www.nationalmssociety.org/for-professionals/healthcareprofessionals/publications/clinical-bulletins/index.aspx. Accessed on: October 23, 2013.
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Creation Date: 05/2021
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

INTERFERON BETA-1A (REBIF)

Generic	Brand	HICL	GCN	Exception/Other
INTERFERON BETA-1A	REBIF	23353		Nonformulary, least preferred

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Must be prescribed by a CPMG or affiliated neurologist.
2. Patient has a diagnosis of a relapsing or active form of multiple sclerosis. (This does not include non-active secondary-progressive MS or primary-progressive MS.)
3. The patient has tried and failed, or has intolerance or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Betaseron
    b. Glatiramer
    c. Dimethyl fumarate

If initial criteria are met, approve x1 year at HICL.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Requesting physician is a CPMG or affiliated neurologist.
2. Patient has a diagnosis of a relapsing or active form of multiple sclerosis. (This does not include non-active secondary-progressive MS or primary-progressive MS.)

If renewal criteria are met, approve x1 year at HICL.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes: relapsing or active form of multiple sclerosis, non-active secondary-progressive MS, primary-progressive MS]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (Betaseron, glatiramer, dimethyl fumarate) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Diagnosis associated with this request: [check boxes: relapsing or active form of multiple sclerosis, non-active secondary-progressive MS, primary-progressive MS]

Disease Modifying Therapies

Class	Generic name	Brand or alternative name	Formulation	Preferred or Non-preferred per IR KP guidelines *(Does NOT refer to formulary status)*
Synthetic Cytokines	Interferon-beta 1a	Avonex	IM injection	NP
	Interferon-beta 1a	Plegridy	SQ/IM injection	NP
	Interferon-beta 1a	Rebif	SQ injection	NP
	Interferon-beta 1b	Extavia	SQ injection	P
		Betaseron	SQ Injection	P
Synthetic Myelin Basic Protein	Glatiramer acetate	Brand: Copaxone	SQ injection	NP
		Generic: Glatopa (Sandoz)	SQ injection	P
		Generic: Glatiramer acetate (Mylan)	SQ injection	NP
Reduced proliferation of activated T and B lymphocytes	Teriflunomide	Aubagio	Oral	NP
	Leflunomide** (pro-drug of teriflunomide)	Generic only (Brand: Arava)	Oral	NP
Stimulator of Nrf2 pathway (aka Fumaric Acid Derivatives)	Dimethyl fumarate (pro-drug of MMF)	Tecfidera	Oral	Generic – P Brand - NP
	Diroximel fumarate (pro-drug of MMF)	Vumerity (bioequivalent to Tecfidera)	Oral	NP
	Monomethyl fumarate (active metabolite)	Bafiertam	Oral	NP
S1P Receptor Modulator	Fingolimod	Gilenya	Oral	P
	Ozanimod	Zeposia	Oral	NP
	Siponimod	Mayzent	Oral	NP
T and B cell Depleting Small Molecule	Cladribine	Mavenclad	Oral	NP
T and B cell Depleting Antibody	Alemtuzumab	Lemtrada	Infusion	NP
Lymphocyte Anti-migration Antibody	Natalizumab	Tysabri	Infusion	NP
B-cell Depleting Antibodies	Rituximab-abbs**	Biosimilar: Truxima	Infusion	NP
	Rituximab-arrx**	Biosimilar: Riabni	Infusion	P
	Rituximab-pvvr**	Biosimilar: Ruxience	Infusion	NP
	Rituximab**	Brand: Rituxan	Infusion	NP
	Ocrelizumab	Ocrevus	Infusion	NP
	Ofatumumab	Kesimpta	SQ injection	NP
	Ublituximab	Briumvi	Infusion	NP

Off-label disease modifying therapy for MS

RATIONALE:
The above guideline was developed by combining individual agent guidelines into one (5/2021)

The armamentarium of options for disease management of MS continues to expand and now includes agents with multiple differing methods of administration including injectables, infused as well as oral agents.

Interferon beta-1a products are injectables FDA approved in the treatment of relapsing forms of MS. The remaining injectables are another IFN beta-1a (Rebif), IFN beta-1b (Extavia and Betaseron), and glatiramer acetate (Copaxone and Glatopa). Comparisons across placebo-controlled trials for these

injectables have found similar effects in reducing relapse frequency of relapses, reducing burden of disease and activity on the MRI in comparison to placebo.

There have been 10 non-randomized, uncontrolled head-to-head trials of interferons that have found no difference between efficacy and safety, although there are two randomized, controlled large head-to-head comparison trials suggesting a dose-related improvement in efficacy. The two trials are the Evidence for Interferon Dose-Effect: European-North American Comparative Efficacy (EVIDENCE) trial and the Independent Comparison of Interferon (INCOMIN) trial. The EVIDENCE trial compared the efficacy of 30 micrograms (mcg) of IM IFN-beta-1a weekly with 44 mcg of SC IFN-beta-1a injected 3 times weekly. After 48 weeks of treatment, the relapse rate and MRI measures were significantly better with the higher dose regimen. However, the difference was primarily seen early in the study, during the first 24 weeks, whereas during the subsequent 24 weeks, the relapse rate was similar for the 2 groups. Additionally, the disability measures were not different at the end of the 1-year study period. The INCOMIN showed greater efficacy of IFN-beta-1b given every other day vs IFN-beta-1a given once weekly on relapse rate, MRI measures, and disability progression during the 2-year study. Unfortunately, the study had design limitations, including unblinded patients and examiners, limiting the conclusions that can be drawn. There are no head-to-head comparison trials assessing differences between Rebif and beta interferon 1b.

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Given no difference in efficacy or long-term safety outcomes between injectable therapies, choice of agent may reflect patient specific outcomes as well as cost-effectiveness of therapy.

FDA APPROVED INDICATIONS
Treatment of relapsing forms of MS

REFERENCES

1. Shilpa and Nikki Hahn, CPS
2. Avonex® [package insert]. Cambridge, MA: Biogen Idec Inc.; July 2023.
3. Plegridy [package insert]. Cambridge, MA: Biogen Idec Inc.; July 2023.
4. Rebif [package insert]. Rockland, MA: EMD Serono, Inc.; July 2023.
5. Clinical bulletin. Information for health professionals. Overview of multiple sclerosis. National Multiple Sclerosis Society. Available at http://www.nationalmssociety.org/for-professionals/healthcareprofessionals/publications/clinical-bulletins/index.aspx. Accessed on: October 23, 2013.
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Creation Date: 05/2021
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

PEGINTERFERON BETA-1A (PLEGRIDY)

Generic	Brand	HICL	GCN	Exception/Other
PEGINTERFERON BETA-1A	PLEGRIDY	41331		Nonformulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Must be prescribed by a CPMG or affiliated neurologist.
2. Patient has a diagnosis of a relapsing or active form of multiple sclerosis. (This does not include non-active secondary-progressive MS or primary-progressive MS.)
3. The patient has tried and failed, or has intolerance or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Betaseron
    b. Glatiramer
    c. Dimethyl fumarate

If initial criteria are met, approve x1 year at HICL.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Requesting physician is a CPMG or affiliated neurologist.
2. Patient has a diagnosis of a relapsing or active form of multiple sclerosis. (This does not include non-active secondary-progressive MS or primary-progressive MS.)

If renewal criteria are met, approve x1 year at HICL.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes: relapsing or active form of multiple sclerosis, non-active secondary-progressive MS, primary-progressive MS]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (Betaseron, glatiramer, dimethyl fumarate) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Diagnosis associated with this request: [check boxes: relapsing or active form of multiple sclerosis, non-active secondary-progressive MS, primary-progressive MS]

Disease Modifying Therapies

Class	Generic name	Brand or alternative name	Formulation	Preferred or Non-preferred per IR KP guidelines *(Does NOT refer to formulary status)*
Synthetic Cytokines	Interferon-beta 1a	Avonex	IM injection	NP
	Interferon-beta 1a	Plegridy	SQ/IM injection	NP
	Interferon-beta 1a	Rebif	SQ injection	NP
	Interferon-beta 1b	Extavia	SQ injection	P
		Betaseron	SQ Injection	P
Synthetic Myelin Basic Protein	Glatiramer acetate	Brand: Copaxone	SQ injection	NP
		Generic: Glatopa (Sandoz)	SQ injection	P
		Generic: Glatiramer acetate (Mylan)	SQ injection	NP
Reduced proliferation of activated T and B lymphocytes	Teriflunomide	Aubagio	Oral	NP
	Leflunomide** (pro-drug of teriflunomide)	Generic only (Brand: Arava)	Oral	NP
Stimulator of Nrf2 pathway (aka Fumaric Acid Derivatives)	Dimethyl fumarate (pro-drug of MMF)	Tecfidera	Oral	Generic – P Brand - NP
	Diroximel fumarate (pro-drug of MMF)	Vumerity (bioequivalent to Tecfidera)	Oral	NP
	Monomethyl fumarate (active metabolite)	Bafiertam	Oral	NP
S1P Receptor Modulator	Fingolimod	Gilenya	Oral	P
	Ozanimod	Zeposia	Oral	NP
	Siponimod	Mayzent	Oral	NP
T and B cell Depleting Small Molecule	Cladribine	Mavenclad	Oral	NP
T and B cell Depleting Antibody	Alemtuzumab	Lemtrada	Infusion	NP
Lymphocyte Anti-migration Antibody	Natalizumab	Tysabri	Infusion	NP
B-cell Depleting Antibodies	Rituximab-abbs**	Biosimilar: Truxima	Infusion	NP
	Rituximab-arrx**	Biosimilar: Riabni	Infusion	P
	Rituximab-pvvr**	Biosimilar: Ruxience	Infusion	NP
	Rituximab**	Brand: Rituxan	Infusion	NP
	Ocrelizumab	Ocrevus	Infusion	NP
	Ofatumumab	Kesimpta	SQ injection	NP
	Ublituximab	Briumvi	Infusion	NP

Off-label disease modifying therapy for MS

RATIONALE:
The above guideline was developed by combining individual agent guidelines into one (5/2021)

The armamentarium of options for disease management of MS continues to expand and now includes agents with multiple differing methods of administration including injectables, infused as well as oral agents.

Interferon beta-1a products are injectables FDA approved in the treatment of relapsing forms of MS. The remaining injectables are another IFN beta-1a (Rebif), IFN beta-1b (Extavia and Betaseron), and glatiramer acetate (Copaxone and Glatopa). Comparisons across placebo-controlled trials for these

injectables have found similar effects in reducing relapse frequency of relapses, reducing burden of disease and activity on the MRI in comparison to placebo.

There have been 10 non-randomized, uncontrolled head-to-head trials of interferons that have found no difference between efficacy and safety, although there are two randomized, controlled large head-to-head comparison trials suggesting a dose-related improvement in efficacy. The two trials are the Evidence for Interferon Dose-Effect: European-North American Comparative Efficacy (EVIDENCE) trial and the Independent Comparison of Interferon (INCOMIN) trial. The EVIDENCE trial compared the efficacy of 30 micrograms (mcg) of IM IFN-beta-1a weekly with 44 mcg of SC IFN-beta-1a injected 3 times weekly. After 48 weeks of treatment, the relapse rate and MRI measures were significantly better with the higher dose regimen. However, the difference was primarily seen early in the study, during the first 24 weeks, whereas during the subsequent 24 weeks, the relapse rate was similar for the 2 groups. Additionally, the disability measures were not different at the end of the 1-year study period. The INCOMIN showed greater efficacy of IFN-beta-1b given every other day vs IFN-beta-1a given once weekly on relapse rate, MRI measures, and disability progression during the 2-year study. Unfortunately, the study had design limitations, including unblinded patients and examiners, limiting the conclusions that can be drawn. There are no head-to-head comparison trials assessing differences between Rebif and beta interferon 1b.

Comparisons across placebo-controlled trials for glatiramer acetate (GA) and beta - interferons have found similar effects in reducing relapse frequency of relapses, reducing burden of disease and activity on the MRI in comparison to placebo.

There are no current published consensus guidelines for the treatment of RRMS to guide on the roles in therapy for the injectables or the newer agents such as the infused drugs (i.e., Tysabri) or the orals (ie Aubagio, Gilenya, or Tecfidera). However, the trends and evidence for treatment suggest a two-pronged approach: induction and escalation. Induction treatment with a second- or third- line treatment like Tysabri or Gilenya is reserved for those patients with more aggressive disease requiring a more aggressive drug therapy approach at initiation. Whereas escalation is reserved for those patients with nonaggressive disease, in which safety and quality of life are the most significant considerations. First line treatment with injectables such as the beta-interferons may provide full “efficacy” but at a lower level of risk.

Neither of the injectables has any proven efficacy in those patients demonstrating nonrelapsing progressive disease such as those with secondary progressive MS or primary progressive MS. The main differences between the injectables are routes and frequency of administration as well as side effect profile. Additionally, beta - interferons are associated with the development of neutralizing antibodies in a small percentage of patients which may impact efficacy of drugs requiring change in therapy. Though not an absolute contraindication, untreated severe depression may pose a risk with the use beta – interferons in comparison to GA, thus careful selection of treatments is necessary. Similar caution must be used in patients who develop severe infusion reactions with the interferons or severe skin reactions with either of the injectables including GA.

Given no difference in efficacy or long-term safety outcomes between injectable therapies, choice of agent may reflect patient specific outcomes as well as cost-effectiveness of therapy.

FDA APPROVED INDICATIONS
Treatment of relapsing forms of MS

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12. Stuve O, Bennett JL, Hemmer B, et al. Pharmacological treatment of early multiple sclerosis. Drugs. 2008;68(1):73–83.
13. Lipsy RJ, Schapiro RT, Prostko CR. Current and future directions of MS management: key considerations for managed care pharmacists. J Manag Care Pharm. 2009;15(9 Suppl a):S2–15.
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Creation Date: 05/2021
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

INTRANASAL DIAZEPAM (VALTOCO)

Generic	Brand	HICL	GPID	Exception/Other
DIAZEPAM NASAL	VALTOCO	01615	47548, 47549, 47551, 47552	Formulary

GUIDELINES FOR COVERAGE

Must meet all the following:
1. The requesting provider is a CPMG or affiliated network neurologist or epileptologist.
2. Patient is 6 years of age or older.
3. Patient has a diagnosis of generalized and/or focal (partial) epilepsy and is on a stable regimen of antiseizure medicine.
4. Patient is experiencing seizure activity that necessitates acute treatment and is different from the patient's usual epilepsy pattern. At least one of the following diagnoses must be present:
    a. Acute repetitive seizures
    b. Intermittent seizure episodes
    c. Seizure clusters
    d. Prolonged convulsive seizures (at least 3 min or longer)
5. Stereotypic episodes of frequent or prolonged seizure activity are occurring with a frequency of no more than one episode every 5 days and no more than 5 episodes per month.

If criteria are met, approve at GPID indefinitely, max 5 boxes (10 units) per 30 days [MDD 0.34].
If criteria are not met, do not approve.

NOTE: Valtoco should NOT be used in combination with another benzodiazepine nasal spray (e.g. injectable midazolam for intranasal use, Valtoco, Nayzilam)

ePA Questions
1. Does the patient have a diagnosis of generalized and/or focal (partial) epilepsy?
2. Is the patient on a stable regimen of antiseizure medications?
3. Is the patient experiencing seizure activity that necessitates acute treatment and is different from the patient's usual epilepsy pattern?
4. Which of the following is the patient experiencing: [check boxes for all diagnoses: Acute repetitive seizures; Intermittent seizure episodes; Seizure clusters; Prolonged convulsive seizures (at least 3 min or longer)]
5. How many days per month does the patient experience stereotypic episodes of frequent or prolonged seizure activity?

RATIONALE
The class of medicines used for the treatment of acute repetitive seizures or clusters has expanded in recent years. The first treatment to be FDA-approved was Diazepam rectal (Diastat®) in 2005 and is indicated for the management of select, refractory participants 2 years of age or older with epilepsy on stable regimens of antiepileptic drugs, who require intermittent use of diazepam to control episodes of increased seizure activity. Diazepam intranasal (Valtoco®) is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from usual seizure pattern in epilepsy participants 6 years of age or older. Lastly, midazolam intranasal (Nayzilam®) is indicated for acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from usual seizure pattern in epilepsy participants 12 years of age or older. All three agents carry the same contraindication of acute narrow-angle glaucoma. Clinical guidelines from both the American Epilepsy Society and Neurocritical Care Society recommend diazepam rectal and midazolam intranasal

(off-label) for acute convulsive seizure management when parenteral benzodiazepines are not available. These guidelines were also published prior to the approval of midazolam and diazepam intranasal therapies and did not specifically identify rescue use and non-hospital settings. As of this writing, the Epilepsy Foundation of America is actively working to develop consensus on best practices for rescue therapies.

FDA APPROVED INDICATIONS

1. **Valtoco:** Indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older

	Ages for use	Formulary	Dosage Strengths	Supplied and packaged in doses of
Diazepam (Valtoco)	6yrs and older	Formulary	5mg, 7.5mg, 10mg in 0.1mL	2 individual blister packs: - 5mg carton: one 5mg nasal spray devise - 10mg carton: one 10mg nasal spray devise - 15mg carton: TWO 7.5mg nasal spray devises - 20mg carton TWO 10mg nasal spray devises
Diazepam (Diastat)	2yrs and older	Formulary	5mg/mL	Prefilled, unit dose, rectal delivery system: - 10mg system (doses are 5mg, 7.5mg, 10mg) - 20mg system (doses are 12.5mg, 15mg, 17.5mg 20mg)
Diazepam (Diastat Acudial)				
Midazolam (Nayzilam)	12yrs and older	Formulary	5mg/0.1mL	Each box contains 2 Single-dose nasal spray units containing 5mg/0.1mL
Midazolam, injectable for use as intranasal	n/a	Formulary	5mg vial	Kit dispensed by KPCO pharmacies

REFERENCES

1. Valtoco [package insert]. San Diego, CA: Neurelis, Inc.; 2023.
2. Nayzilam [package insert]. Smyrna, GA: UCB, Inc.; 2023.
3. Diastat [package insert]. Bridgewater, NJ: Bausch Health US LLC; 2023.
4. Gidal B, Klein P, Hirsch LJ. Seizure clusters, rescue treatments, seizure action plans: Unmet needs and emerging formulations. Epilepsy & Behavior 2020;112:1-10.

Creation Date: 06/2021
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

INTRANASAL MIDAZOLAM (NAYZILAM)

Generic	Brand	HICL	GPID	Exception/Other
MIDAZOLAM NASAL SPRAY	NAYZILAM	10329	46309	Formulary

GUIDELINES FOR COVERAGE

Must meet all the following:
1. The requesting provider is a CPMG or affiliated network neurologist or epileptologist.
2. Patient is 12 years of age or older.
3. Patient has a diagnosis of generalized and/or focal (partial) epilepsy and is on a stable regimen of antiseizure medicine.
4. Patient is experiencing seizure activity that necessitates acute treatment and is different from the patient's usual epilepsy pattern. At least one of the following diagnoses must be present:
    a. Acute repetitive seizures
    b. Intermittent seizure episodes
    c. Seizure clusters
    d. Prolonged convulsive seizures (at least 3 min or longer)
5. Stereotypic episodes of frequent or prolonged seizure activity are occurring with a frequency of no more than one episode every 3 days and no more than 5 episodes per month

If criteria are met, approve indefinitely at GPID, max 10 units per 30 days [MDD 0.34].
If criteria are not met, do not approve.

NOTE: Nayzilam should NOT be used in combination with another benzodiazepine nasal spray (e.g. injectable midazolam for intranasal use, Valtoco, Nayzilam)

ePA Questions
1. Does the patient have a diagnosis of generalized and/or focal (partial) epilepsy?
2. Is the patient on a stable regimen of antiseizure medications?
3. Is the patient experiencing seizure activity that necessitates acute treatment and is different from the patient's usual epilepsy pattern?
4. Which of the following is the patient experiencing: [check boxes for all diagnoses: Acute repetitive seizures; Intermittent seizure episodes; Seizure clusters; Prolonged convulsive seizures (at least 3 min or longer)]
5. How many days per month does the patient experience stereotypic episodes of frequent or prolonged seizure activity?

RATIONALE
The class of medicines used for the treatment of acute repetitive seizures or clusters has expanded in recent years. The first treatment to be FDA-approved was Diazepam rectal (Diastat®) in 2005 and is indicated for the management of select, refractory participants 2 years of age or older with epilepsy on stable regimens of antiepileptic drugs, who require intermittent use of diazepam to control episodes of increased seizure activity. Diazepam intranasal (Valtoco®) is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from usual seizure pattern in epilepsy participants 6 years of age or older. Lastly, midazolam intranasal (Nayzilam®) is indicated for acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from usual seizure pattern in epilepsy participants 12 years of age or older. All three agents carry the same contraindication of acute narrow-angle glaucoma. Clinical guidelines from both the American Epilepsy Society and Neurocritical Care Society recommend diazepam rectal and midazolam intranasal

(off-label) for acute convulsive seizure management when parenteral benzodiazepines are not available. These guidelines were also published prior to the approval of midazolam and diazepam intranasal therapies and did not specifically identify rescue use and non-hospital settings. As of this writing, the Epilepsy Foundation of America is actively working to develop consensus on best practices for rescue therapies.

FDA APPROVED INDICATIONS

1. **Nayzilam:** Indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy (ages 12 years and older)

	Ages for use	**Formulary**	**Dosage Strengths**	**Supplied and packaged in doses of**
Diazepam (Valtoco)	6yrs and older	Formulary	5mg, 7.5mg, 10mg in 0.1mL	2 individual blister packs: - 5mg carton: one 5mg nasal spray devise - 10mg carton: one 10mg nasal spray devise - 15mg carton: TWO 7.5mg nasal spray devises - 20mg carton TWO 10mg nasal spray devises
Diazepam (Diastat)	2yrs and older	Formulary	5mg/mL	Prefilled, unit dose, rectal delivery system: - 10mg system (doses are 5mg, 7.5mg, 10mg) - 20mg system (doses are 12.5mg, 15mg, 17.5mg 20mg)
Diazepam (Diastat Acudial)				
Midazolam (Nayzilam)	12yrs and older	Formulary	5mg/0.1mL	Each box contains 2 Single-dose nasal spray units containing 5mg/0.1mL
Midazolam, injectable for use as intranasal	n/a	Formulary	5mg vial	Kit dispensed by KPCO pharmacies

REFERENCES

1. Valtoco [package insert]. San Diego, CA: Neurelis, Inc.; 2023.
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Creation Date: 06/2021
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

IPRATROPIUM NASAL SPRAY STEP THERAPY

Generic	Brand	HICL	GPID	Exception/Other
IPRATROPIUM NASAL 0.03% & 0.06%	IPRATROPIUM NASAL		42238, 42239	Formulary

Step Therapy Criteria
Must meet ONE of the following:
1. Medication is prescribed by an Allergy, Ear/Nose/Throat, Otolaryngology specialist or a prescriber in the Head & Neck Surgery specialty department
2. Patient has tried and failed, or had an intolerance/allergy to azelastine nasal spray, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

If either criterion is met, approve at GPID indefinitely.
If neither criterion is met, do not approve.

STEP THERAPY RULES:
1. If the prescription is written by Head & Neck, Otolaryngology, or Allergy & Immunology
2. If there is a paid claim for the requested product or azelastine nasal spray in the past 365 days, claims for the requested product will pay without review.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (azelastine nasal spray) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Allergy, Head & Neck Surgery and Health Plan.

The KPCO preferred nasal spray is azelastine and ipratropium nasal should be reserved for failures on azelastine.

Creation date: 09/2020
Effective date: 10/2024
Reviewed date: 09/2024
Revised date: 09/2024

IVACAFTOR (KALYDECO)

Generic	Brand	HICL	GPID	Exception/Other
IVACAFTOR	KALYDECO	38461		

GUIDELINES FOR USE

Requests for IVACAFTOR will be approved if ALL the following are met:
1. Prescribed by a pulmonologist
2. Patient has a diagnosis of cystic fibrosis (CF) with documentation of at least one mutation in the CFTR gene that is responsive to ivacaftor [Consult Kalydeco website to check for eligible mutations: https://www.kalydeco.com/who-kalydeco#table]
3. Patient is **NOT** homozygous for the F508del-CFTR mutation
4. Patient is 1 month and older

If all above criteria are met, approve indefinitely, max #2/day.
If above criteria are not met, do not approve.

ePA Questions
1. Does the patient have at least one mutation in the CFTR gene that is responsive to ivacaftor [Consult Kalydeco website to check for eligible mutations: https://www.kalydeco.com/who-kalydeco#table]? If yes, must list the patient's mutation in Provider Comment section below or attach applicable chart notes.
2. Is the patient homozygous for the F508del mutation?

RATIONALE
Per plan

FDA APPROVED INDICATIONS
Kalydeco is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator indicated for the treatment of cystic fibrosis (CF) in patients age 1 month and older who have one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data.

REFERENCES
Kalydeco [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; 2020.
2020 PDR online revised 12/2018

Creation date: 07/25/2018
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

IXEKIZUMAB (TALTZ)

Generic	Brand	HICL	GPID	SIZE	Exception/Other
IXEKIZUMAB	TALTZ	43193	40848	1	Non-formulary
IXEKIZUMAB	TALTZ 80 MG/ML SYRINGE	43193	40849	1	Non-formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on therapy.
2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
3. Patient has one of the following indications and medication is prescribed by the appropriate specialist as noted:
   a. Patient has a diagnosis of psoriatic arthritis (PsA), ankylosing spondylitis, or nonradiographic axial spondyloarthritis, and requested medication is being prescribed by a CPMG or affiliated rheumatologist.
   b. Patient has a diagnosis of psoriasis, and requested medication is being prescribed by a CPMG or affiliated dermatologist.

If met, approve at HICL indefinitely, max 1 pen/syringe per 28 days [MDD 0.04].
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria below:

A. Psoriatic Arthritis
B. Ankylosing Spondylitis or Nonradiographic Axial Spondyloarthritis
C. Psoriasis

A. Psoriatic Arthritis: All the following must be met:
   1. Patient has a diagnosis of psoriatic arthritis.
   2. Medication is being prescribed by a rheumatologist.
   3. Patient is 18 years of age or older.
   4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   5. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. at least 2 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, leflunomide, sulfasalazine
      b. at least 1 TNF inhibitor (e.g., adalimumab-atto (Amjevita)-preferred [F], infliximab-dyyb (Inflectra)-preferred [F])
      c. at least 1 IL-17 inhibitor (e.g. secukinumab (Cosentyx)-preferred [F, PA])

d. IL 12/23 inhibitor (Ustekinumab-kfce (Yesintek)-preferred [F, PA]), unless patient has documented high disease activity
e. at least 1 IL-23 inhibitor (e.g. guselkumab (Tremfya)-preferred [NF, PA])
f. at least 1 JAK inhibitor [e.g. tofacitinib (Xeljanz)-preferred]

If criteria are met, approve at HICL, max #2 per 28 days [MDD 0.08] x1 month (loading dose), then #1 per 28 days [MDD 0.04] indefinitely.
If criteria are not met, do not approve.

B. Ankylosing Spondylitis or Nonradiographic Axial Spondyloarthritis: All the following must be met:
1. Patient has a diagnosis of ankylosing spondylitis or nonradiographic axial spondyloarthritis.
2. Medication is being prescribed by a rheumatologist.
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
4. Patient has experienced an inadequate response, intolerance, or has a contraindication to, all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Methotrexate or sulfasalazine, or the patient has documented high disease activity in which these medications would not be suitable treatment
   b. at least 1 TNF inhibitor (e.g., adalimumab-atto (Amjevita)-preferred [F], infliximab-dyyb (Inflectra)-preferred [F])
   c. at least 1 IL-17 inhibitor (e.g. secukinumab (Cosentyx) [F, PA])
   d. at least 1 JAK inhibitor [e.g. tofacitinib (Xeljanz)-preferred]

If criteria are met, approve at HICL with the quantity limits below based on indication:
- Ankylosing Spondylitis: max #2 per 28 days [MDD 0.08] x1 month (loading dose), then #1 per 28 days [MDD 0.04] (maintenance) indefinitely.
- Nonradiographic Axial Spondyloarthritis: max #1 per 28 days [MDD 0.04] indefinitely.

If criteria are not met, do not approve.

C. Psoriasis: All the following must be met:
1. Patient has a diagnosis of moderate to severe psoriasis.
2. Medication is prescribed by a dermatologist.
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
4. Must meet all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

a. Patient has experienced an inadequate response, intolerance, or has a contraindication to a topical corticosteroid or topical calcineurin inhibitor (pimecrolimus, tacrolimus), or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate
b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one** or contraindication to at least **two** of the following therapies, or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate: Acitretin, Cyclosporine, Methotrexate, Apremilast (Otezla), Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
c. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one TNF inhibitor (adalimumab (Amjevita) - preferred [F], infliximab (Inflectra) - preferred [F])
d. Patient has experienced an inadequate response, intolerance, or has a contraindication to an IL12-23 inhibitor (ustekinumab-kfce (Yesintek) - preferred [F, PA])
e. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one IL-17 inhibitor (secukinumab (Cosentyx) - preferred [F, PA])
f. For patients 18 years of age or older, patient has experienced an inadequate response, intolerance, or has a contraindication to at least one IL-23 inhibitor: guselkumab (Tremfya) [NF, PA], risankizumab-rzaa (Skyrizi) [NF, PA]

If criteria are met, approve at HICL, max 3 syringes/pens per 28 days [MDD 0.11] x 1 month (loading dose), then max 2 syringes/pens per 28 days [MDD 0.08] for the next two months (loading dose), then max 1 syringe/pen per 28 days [MDD 0.04] (maintenance dose after 12-week load) indefinitely.
If above criteria are not met, do not approve.

ESCALATION CRITERIA/QTY LIMIT OVERRIDES: Patient must meet New Member or Initial Criteria prior to review for Quantity Overrides. Escalation Criteria review only the quantities authorized upon PA approval.

A. Patient diagnosis of PsA or Ankylosing Spondylitis:
   1. Documentation by rheumatology provider of the patient resuming therapy after a gap 3 months or longer in treatment (to reload)

If above criteria are met, approve Ixekizumab (Taltz) at HICL, max #2 per 28 days [MDD 0.08] x1 month (loading dose), then #1 per 28 days [MDD 0.04] (maintenance) indefinitely.
If above criteria are not met, deny and offer 1 pen/syringe per 28 days [MDD 0.04] indefinitely.

B. Patient diagnosis of Psoriasis:
   1. Documentation by dermatology provider of the patient resuming therapy after a gap 3 months or longer in treatment (to reload)

If above criteria are met, then approve at HICL max 3 syringes/pens per 28 days [MDD 0.11] x 1 month (loading dose), then max 2 syringes/pens per 28 days [MDD 0.08] for the next two months (loading dose), then max 1 syringe/pen per 28 days [MDD 0.04] (maintenance dose after 12-week load) indefinitely.
If above criteria are not met, deny and offer 1 pen/syringe per 28 days [MDD 0.04] indefinitely.

ePA Questions
Initial Review Questions
1. Is the patient stable on therapy with ixekizumab?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: ankylosing spondylitis (AS) or nonradiographic axial spondylarthritis (nr-axSpA), psoriatic arthritis (PsA), psoriasis]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Ankylosing Spondylitis (AS) or Nonradiographic Axial Spondylarthritis (nr-axSpA)
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets, adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

Psoriatic Arthritis (PsA)
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg), adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

Psoriasis
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (tacrolimus ointment, acitretin capsules (10 mg, 25 mg), cyclosporine capsules (25 mg, 100 mg), methotrexate tablets (2.5 mg) or injection (25 mg/mL), Otezla tablets, Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy, adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?
4. Current BSA (%):
5. Date of BSA assessment (MMDDYY):

RATIONALE
Per Health Plan - CPS in Derm, CPS in Rheum

FDA APPROVED INDICATIONS
1. Moderate to severe plaque psoriasis in patients 6 years of age and older
2. Ankylosing Spondylitis in adults
3. Psoriatic arthritis in adults

REFERENCES

"Currently stable on medication," means patient is tolerating well, medication appears to be effective, and provider wishes to continue therapy.

Treatment	Relative Contraindications for Psoriasis
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses (ex: systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for psoriasis.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities, active malignancy, and hypersensitivity*
Acitretin	*Women of child potential (cannot consider pregnancy up to 3 years after completion of treatment), pregnancy, lactation, severe hepatic or renal dysfunction, chronically abnormal elevated lipid values, and hypersensitivity*

Creation Date: 11/2019
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

KETOCONAZOLE (ORAL)

Generic	Brand	HICL	GCN	Exception/Other
KETOCONAZOLE	NIZORAL		42590	

GUIDELINES FOR COVERAGE: All the following must be met:
1. Medication is NOT being used to treat a skin and/or nail fungal infection.
2. Medication is being used to treat a systemic fungal infection or Cushing's disease.
3. Medication is being prescribed by an infectious disease, oncology, or endocrinology specialist.

If criteria are met, approve indefinitely.
If criteria are not met, do not approve.

ePA Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: skin and/or nail fungal infection; systemic fungal infection; Cushing's disease]

RATIONALE
Ketoconazole should only be used when other effective antifungal therapy is not available or tolerated and the potential benefits outweigh the potential risks. Ketoconazole tablets are not indicated for the treatment of onychomycosis, cutaneous dermatophyte infections, or Candida infections.

FDA APPROVED INDICATIONS
Treatment of susceptible systemic fungal infections, including blastomycosis, histoplasmosis, paracoccidioidomycosis, coccidioidomycosis, and chromomycosis in patients who have failed or who are intolerant to other antifungal therapies.

REFERENCES
Lexicomp

Creation date: 07/25/2018
Effective date: 12/2024
Reviewed date: 11/2024
Revised date: 11/2023

LAROTRECTINIB (VITRAKVI)

Generic	Brand	HICL	GPID	Exception/Other
LAROTRECTINIB SULFATE	VITRAKVI	45494		Nonformulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA:
1. Patient is new to KPCO within the past 90 days and is stable on therapy.

   If met, approve at HICL indefinitely.
   If not met, do not approve.

INITIAL CRITERIA: Must meet all the following:
1. Must be prescribed by an oncology specialist
2. Must have a solid tumor
3. Must have a confirmed neurotrophic receptor tyrosine kinase (NTRK) gene fusion
4. Must not have a known acquired resistance mutation
5. Must have metastatic disease or non-metastatic disease that cannot be surgically resected without likely resulting in severe morbidity
6. Must have no satisfactory alternative treatment options or must have progressed following alternative treatment
7. Must not have progressed through entrectinib
8. Must have an intolerance or contraindication to entrectinib, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

   If above initial criteria are met, approve at HICL indefinitely.
   If criteria are not met, do not approve; recommend entrectinib if patient has not progressed through, and does not have an intolerance or contraindication to entrectinib.

RATIONALE
Ensure appropriate use consistent with FDA indication
Steer use toward KP preferred alternative entrectinib when appropriate

FDA APPROVED INDICATIONS
Treatment of solid tumors (in adult and pediatric patients) that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation; are metastatic or where surgical resection is likely to result in severe morbidity; and have no satisfactory alternative treatments or that have progressed following treatment.

REFERENCES
1. Larotrectinib [Package Insert], Stamford, CT: Loxo Oncology, Inc: 2018.

Creation Date: 12/31/2020
Effective Date: 02/2025

Reviewed Date: 01/2025
Revised Date: 01/2025

LASMIDITAN (REYVOW)

Generic	Brand	HICL	GPID	Comments
LASMIDITAN	REYVOW	46082	47084, 47083	Oral selective 5HT1f agonist; “Ditan” for acute tx

GUIDELINES FOR COVERAGE
Must meet all the following:
1. Prescribed for acute treatment of migraine with or without aura
2. Patient must be age 18 or older
3. Patient has failed (after at least one month of therapy), or the patient has intolerance or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. at least one triptan
    b. a gepant

If criteria are met, approve indefinitely at HICL, max 8 tablets per 30 days [MDD 0.27].
If criteria are not met, do not approve.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (sumatriptan tablets, rizatriptan tablets, rizatriptan ODT, eletriptan tablets, naratriptan tablets, sumatriptan nasal spray (5 mg/act, 20 mg/act), sumatriptan succinate injectable 6 mg/0.5 mL) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Available triptan/ergotamine options:

Generic	Brand	Formulations available
Almotriptan	Axert	Tablet
Eletriptan	Relpax	Tablet
Frovatriptan	Frova	Tablet
Naratriptan	Amerge	Tablet
Rizatriptan	Maxalt/Maxalt MLT	Tablet, ODT
Sumatriptan	Imitrex, Sumavel, Onzetra, Zembrace	Tablet, nasal spray, injection
Zolmitriptan	Zomig/Zomig ZMT	Tablet, ODT, nasal spray
Ergotamine	Ergomar	Sublingual
Ergotamine/caffeine	Cafergot	Tablet, suppository
Dihydroergotamine	Migranal, Trudhesa D.H.E.	Nasal spray, injection

ODT=orally disintegrating tablet

True contraindications to triptan class

- Ischemic coronary artery disease including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina)
- History of stroke or transient ischemic attack
- Peripheral vascular disease
- Ischemic bowel disease
- Uncontrolled hypertension
- Hemiplegic or basilar migraine
- Wolff-Parkinson-White syndrome

Quantity Limits for Novel Oral Migraine Treatment

Medication	Dosage Strength	Maximum quantity limit for 30 days	Notes
Acute migraine indication			
Ubrogepant (Ubrelvy)	50 mg, 100 mg	10	Tablet splitting of the 100 mg tablet has been approved and should be recommended for all patients prescribed to take a dose of 50 mg at onset of migraine
Rimegepant (Nurtec ODT)	75 mg	8	Tablet splitting n/a
Zavegepant (Zavzpret)	10 mg	6	Available as a ready-to-use, unit-dose disposable nasal spray device that contains 10 mg of zavegepant. Each carton contains 6 nasal spray units.
Lasmiditan (Reyvow)	50 mg, 100 mg	8	Tablet splitting NOT approved Approved doses to take at onset of migraine are 50 mg, 100 mg, or 200 mg, however, only 50 mg and 100 mg tablet strengths are available
Preventive migraine indication			
Atogepant (Qulipta)	10 mg, 30 mg, 60 mg	30	Tablet splitting of the 60 mg tablet has been approved and should be recommended for all patients prescribed 30 mg daily
Rimegepant (Nurtec ODT)	75 mg	16	Tablet splitting n/a

CGRP-Directed Migraine Medications

Generic (Brand)	Route CGRP "class"	Acute Migraine Approval	Preventive Migraine Approval
Eptinezumab (Vyepti)	IV, CGRP-mAb	X	100 mg or 300 mg Q 3 mo
Erenumab	SC, CGRP-mAb	X	70 mg or 140 mg Q mo

(Aimovig)			
Fremanezumab (Ajovy)	SC, CGRP-mAb	X	225 mg Q mo, OR 675 mg Q 3 mo
Galcanezumab (Emgality)	SC, CGRP-mAb	X	240 mg loading dose, then 120 mg Q mo
Atogepant (Qulipta)	Oral, CGRP antagonist "gepant"	X	10 mg, 30 mg or 60 mg daily
Rimegepant (Nurtec ODT)	Orally disintegrating tablet, CGRP antagonist "gepant"	75 mg at onset do NOT repeat dose	75 mg every OTHER day
Ubrogepant (Ubrelvy)	Oral, CGRP antagonist "gepant"	50 mg or 100 mg at onset, may repeat in 2 hours	X
Zavegepant (Zavzpret)	Intranasal, CGRP antagonist "gepant"	10 mg at onset do NOT repeat dose	X

RATIONALE

Acute migraine indication

At this time, there is a lack of compelling data for ubrogepant, rimegepant, or lasmiditan to replace triptans as the gold standard for acute migraine treatment, considering cost and familiarity [1]. The 2019 AHS update briefly mentions role of emerging acute therapies as these options were not approved until about one year after its publication AHS [2]. Reiterated is the role for these novel treatment options, which do not result in constriction of blood vessels, for patients with vascular-related contraindications to triptans. Also acknowledged is the higher cost of these new agents compared to the generic availability of oral triptans and recommendation for ubrogepant, rimegepant, or lasmiditan to be used only in patients who have contraindications to triptans or who have failed to respond or tolerate at least two oral triptans. Patients should treat at least 2 migraine attacks before a provider makes a determination on efficacy and tolerability.

A comparative analysis of ubrogepant, lasmiditan, and rimegepant was performed by the Institute of Clinical and Economic Review (ICER) to assess the effectiveness and safety of these medications. [3] In comparison to placebo, ubrogepant [odds ratio (OR) 2.12], rimegepant [OR 2.11], and lasmiditan [OR 3.01] showed higher odds of achieving pain freedom at 2 hours. The analysis did not demonstrate statistically significant differences among the medications in pain freedom at two hours, absence of the most bothersome symptoms at two hours, and no disability at two hours in comparison to one another. On the other hand, in comparing triptans and ubrogepant, sumatriptan [OR 4.09] and eletriptan [OR 5.6] have shown to have higher odds of pain freedom at two hours than ubrogepant.

With regards to safety, nausea was the most common adverse effect seen with the use of ubrogepant. For single migraine attacks, ubrogepant and rimegepant had similar odds of experiencing any adverse event compared to triptans and placebo, but ubrogepant [OR 5.10] had lower odds for treatment-emergent adverse events compared to lasmiditan. Also, the risk of medication overuse headaches, which is present with triptans, is unknown with repeated use of ubrogepant and rimegepant.

In terms of cost per quality-adjusted life year (QALY) gained threshold, ubrogepant is considered cost effective at $40,000 per QALY gained. Ubrogepant has similar QALY values compared to rimegepant. Comparing ubrogepant and triptans, the cost of ubrogepant is substantially greater than triptans and has less QALYs than sumatriptan and eletriptan.

If choosing a one of these new acute medication options, pharmacokinetics and characteristics of a patient's migraine attacks should be kept in mind. Lasmiditan has pharmacokinetic characteristic similar to faster-acting triptans and most closely similar to almotriptan and eletriptan in regard to onset of action, time to maximum concentration, and half-life. Ubrogepant and rimegepant have slower onsets of action but longer half-lives which may be helpful for patients experiencing migraine recurrence. Dosing recommendations should also be considered when using these new medications including if a dose can be repeated in 2 hours, dose adjustments with other disease states, and potential for drug interactions (Table 1).

As the only gepant medication supplied in a non-oral formulation, zavegepant 10 mg nasal spray could be particularly useful in patients with characteristics associated with guideline-based recommendations for non-oral therapies, including headache attacks with severe nausea or vomiting or rapidly escalating headache pain, as well as for patients in whom oral forms are associated with inadequate response, slow onset of action, or poor tolerability. Additional trials are needed to provide evidence for the long-term safety and consistency of effect over time.

Using triptans as part of a combination therapy regimen can be useful (although possibly underutilized in clinical practice) and careful selection of agents to combine can achieve synergistic pharmacokinetic effects. For example, in patients needing a quick onset of action to relieve the migraine pain but also a longer duration to avoid migraine recurrence, a fast acting triptan (e.g. nasal spray, injectable, or faster-acting oral) can be combined with a long-acting NSAID. Effectiveness and safety of combining gepants or lasmiditan with other acute therapies is less defined. Pertaining to other acute migraine medications that could be utilized, study protocols for phase 3 clinical trials differed slightly, but all included specific recommendations for what patients could or could not take within 24 hours or 48 hours after the initial dose of the study medication. Due to the potential for duplicating mechanisms, it appears logical to avoid the combination of lasmiditan with a triptan, but there may be a role for combining lasmiditan with an analgesic and/or antiemetic if needed. While gepants and triptans do not appear to directly have overlapping mechanisms, they do both target the trigeminovascular system, and thus the utility in combining a gepant with a triptan remains unclear. Given the slower onset of gepants, there may be clinical situations where combining a gepant with a faster acting NSAID could be beneficial. Overall, more data is needed.

More real-world utilization and long-term safety and efficacy data is needed for these new acute medication options, but the development of these therapy options fills a long-standing gap in therapy for patients with multiple trials and failures of triptans or those with contraindications to this class.

FDA APPROVED INDICATIONS

Lasmiditan: Acute treatment of migraine with or without aura in adults

REFERENCES

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2. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache. 2019;59(1):1-18.
3. Atlas S, Touchette D, Agboola F, et al. Acute Treatments for Migraine: Effectiveness and Value. Institute for Clinical and Economic Review. February 25, 2020. Available at: icer-review.org/wp-content/uploads/2019/06/ICER_Acute-Migraine_Final-Evidence-Report_updated_030320.pdf. Accessed August 27, 2020.
4. Ashina M. Migraine. N Engl J Med 2020;383:1866-76.

5. Yang CP, Liang CS, Chang CM, et al. Comparison of new pharmacologic agents with triptans for treatment of migraine: a systematic review and meta-analysis. JAMA Netw Open. 2021;4(10):e2128544.

Creation Date: 08/2020
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

LEBRIKIZUMAB-LBKZ (EBGLYSS)

Generic	Brand	HICL	GPID	Size	COMMENTS
LEBRIKIZUMAB-LBKZ	EBGLYSS 250 mg/ 2mL pen	49658	55845	2	Non-Formulary, Specialty tier
LEBRIKIZUMAB-LBKZ	EBGLYSS 250 mg/ 2mL prefilled syringe	49658	56133	2	Non-Formulary, Specialty tier

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Medication is prescribed by a dermatologist or allergist
2. Patient is new to KPCO within the past 90 days, noted as stable on therapy, and has one of the following indications:
   a. Atopic Dermatitis (Moderate/Severe)
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication

If met, approve indefinitely at HICL, max 4 mL per 28 days [MDD 0.15].
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following indications and meet indication-specific criteria as noted:

A. Patient between 12-17 years of age with moderate to severe atopic dermatitis
B. Patient 18 years of age or older with moderate to severe atopic dermatitis

A. Patient is between 12-17 years of age with moderate to severe atopic dermatitis:
   1. Medication is prescribed by a CPMG or an affiliated dermatologist or allergist.
   2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   3. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Patient has experienced an inadequate response, intolerance, or has a contraindication to **one** of the below, or the patient is reported as having very high disease activity (greater than 50% BSA) or prior atopic dermatitis biologic or oral JAK inhibitor therapy within the past 4 months making these therapies inappropriate:
         - Topical corticosteroid
         - Topical calcineurin inhibitor
      b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one**, or contraindication to at least **two** of the following therapies, or the patient is reported as having very high disease activity (greater than 50% BSA) or prior atopic dermatitis biologic or oral JAK inhibitor therapy within the past 4 months making these therapies inappropriate:
         - Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy

- Azathioprine
- Cyclosporine
- Methotrexate
- Mycophenolate

c. Patient has experienced an inadequate response (after at least 3 months), intolerance, or has a contraindication to all the following:
- One IL-13 inhibitor: Tralokinumab (Adbry) – preferred [F, PA]
- IL-4/IL-13 inhibitor: Dupilumab (Dupixent) – [F, PA]
- IL-31 inhibitor: nemolizumab-ilto (Nemluvio) – [NF, PA]

If above criteria are met, approve at HICL x1 fill, max 8 mL per 28 days [MDD: 0.29] (loading dose), then indefinitely at HICL, max 4 mL per 28 days [MDD: 0.15] (maintenance dose).
If above criteria are not met, do not approve.

B. Patient is 18 years of age or older with moderate to severe atopic dermatitis:
1. Medication is prescribed by a CPMG or an affiliated dermatologist or allergist.
2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
3. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Patient has experienced an inadequate response, intolerance, or has a contraindication to **one** of the below:
      - Topical corticosteroid
      - Topical calcineurin inhibitor
   b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one**, or contraindication to at least **two** of the following therapies, or the patient is reported as being on prior atopic dermatitis biologic or oral JAK inhibitor therapy within the past 4 months making these therapies inappropriate:
      - Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
      - Azathioprine
      - Cyclosporine
      - Methotrexate
      - Mycophenolate
   c. Patient has experienced an inadequate response (after at least 3 months), intolerance, or has a contraindication to all the following:
      - One IL-13 inhibitor: Tralokinumab-ldrm (Adbry) – preferred [F, PA]
      - IL-4/IL-13 inhibitor: Dupilumab (Dupixent) – [F, PA]
      - One IL-31 inhibitor: nemolizumab-ilto (Nemluvio) – [NF, PA]

If above criteria are met, approve at HICL x1 fill, max 8 mL per 28 days [MDD: 0.29] (loading dose), then indefinitely at HICL, max 4 mL per 28 days [MDD: 0.15] (maintenance dose).
If above criteria are not met, do not approve.

RATIONALE
Per Health Plan

FDA APPROVED INDICATIONS
Atopic Dermatitis (Moderate to Severe) in patients 12 years of age and older.

REFERENCES
1. Ebglyss [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company, November 2024.

Table 1: Relative contraindications of various treatments

Treatment	
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses* (ex: *systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for atopic dermatitis.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities,* active malignancy, *and hypersensitivity*
Mycophenolate	*Hypersensitivity to mycophenolate, active malignancy, pregnancy, breastfeeding, women of childbearing age not using highly effective contraceptive methods. Mycophenolate requires REMS program for females of childbearing age.*

ePA Questions
1. Is the patient stable on therapy with lebrikizumab (Ebglyss)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Percent body surface area (BSA) impacted:
4. Will the patient use lebrikizumab (Ebglyss) in combination with another biologic or advanced small molecule for the same indication?
5. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
6. Is there reasoning why alternatives (topical corticosteroids, tacrolimus ointment, phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy, azathioprine tablets (50 mg), cyclosporine capsules (25 mg, 100 mg), methotrexate 2.5 mg tablets or 25mg/ml vials, mycophenolate mofetil 250 mg capsules or 500 mg tablets) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Creation Date: 05/2025
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: N/A

HARVONI (LEDIPASVIR/SOFOSBUVIR)

Generic	Brand	HICL	GCN	Exception/Other
LEDIPASVIR/SOFOSBUVIR	HARVONI	41457		Formulary (generic)

GUIDELINES FOR COVERAGE
Must meet all general criteria, have one of the following diagnoses, and meet diagnosis-specific criteria below:

A. General criteria for all requests
B. Diagnosis of Hepatitis C virus (HCV)+ transplant recipient
C. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis
D. Diagnosis of chronic Hepatitis C virus (HCV) with compensated cirrhosis
E. Diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis with past failure of a sofosbuvir-based treatment
F. Diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis without past failure of a sofosbuvir-based treatment
G. Diagnosis of pediatric chronic Hepatitis C virus (HCV) and weight < 35 kg

A. General criteria for all requests: Must meet all the following:
1. Patient is at least 3 years old and currently supervised by a gastroenterologist, infectious disease specialist, provider specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model.
2. Patient has genotype 1, 4, 5 or 6.
3. Patient has intolerance or contraindication to sofosbuvir/velpatasvir.
4. Patient does not have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
5. Patient is not currently taking any medications that have a clinically significant interaction with the Hepatitis C medication ordered.*

B. The patient is receiving or has received an HCV+ transplant: Must meet all the following:
1. Request must be for 90-400 mg strength.

If criteria are met, approve x12 weeks at GPID-G. Must "Override Force Flag" in the "Override Restriction" field to allow dispense by the Mayo pharmacy in Arizona (post-transplant).
If criteria are not met, do not approve.

Note: Only if patient is out of state at Mayo Clinic and immediate post-HCV+ liver transplant may you place a force override to allow the Hep C drug to be dispensed by a non-KP pharmacy.

C. The patient has diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis: Must meet all the following:
1. Patient has a detectable HCV RNA level.
2. Patient does not have a suspected acute HCV exposure in the last 6 months.
3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
4. Patient is treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir).
5. Request must be for 90-400 mg strength.

6. Provider attests patient is HIV-uninfected and HCV RNA level < 6 million IU/mL.

   If criteria are met and provider notes patient is HIV-uninfected and HCV RNA level < 6 million IU/mL, approve x8 weeks at GPID-G.
   If criteria are met and provider notes patient has HIV or HCV RNA level ≥ 6 million, approve x12 weeks at GPID-G.
   If criteria are not met, do not approve.

D. The patient has diagnosis of chronic Hepatitis C virus (HCV) with compensated cirrhosis: Must meet all the following:

1. Patient has a detectable HCV RNA level.
2. Patient does not have a suspected acute HCV exposure in the last 6 months
3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
4. Patient is treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir).
5. Request must be for 90-400 mg strength.

   If met, approve x12 weeks at GPID-G.
   If not met, do not approve.

E. The patient has diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis and has past failure of a sofosbuvir-based treatment: Must meet all the following:

1. Patient has a detectable HCV RNA level.
2. Patient does not have a suspected acute HCV exposure in the last 6 months.
3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
4. The provider confirms the patient will use ribavirin in combination with ledipasvir-sofosbuvir*.
5. Request must be for 90-400 mg strength.

   If met, approve x24 weeks at GPID-G.
   If not met, do not approve. [*Ledipasvir-sofosbuvir is not indicated in this patient population without ribavirin.]

F. The patient has diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis and no past failure of a sofosbuvir-based treatment: Must meet all the following:

1. Patient has a detectable HCV RNA level.
2. Patient does not have a suspected acute HCV exposure in the last 6 months.
3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
4. Patient is treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir).
5. The provider confirms the patient will use ribavirin in combination with ledipasvir-sofosbuvir, or the provider notes that the patient has an intolerance or contraindication to ribavirin.

6. Request must be for 90-400 mg strength.

   If criteria are met and provider notes use of ribavirin, approve x12 weeks at GPID-G.
   If criteria are met and provider notes patient has intolerance or contraindication to ribavirin, approve x24 weeks at GPID-G.
   If criteria are not met, do not approve.

G. The patient has diagnosis of pediatric chronic Hepatitis C virus (HCV) and weighs < 35 kg:
Must meet all the following:

1. Patient has a detectable HCV RNA level.
2. Patient does not have a suspected acute HCV exposure in the last 6 months.
3. Patient is treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir).

   If met, approve x12 weeks at HICL.
   If not met, do not approve.

ePA Questions

1. Hep C Genotype:
2. Has the patient failed other treatments for this indication? If yes, must list the medication, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Does the patient have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions?
4. Is the patient taking any medications that have a clinically significant interaction with the Hepatitis C medication ordered?
5. Diagnosis/Indication associated with this request: [check boxes for all diagnoses listed in criteria: Hepatitis C virus (HCV)+ transplant recipient; Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis; Diagnosis of chronic Hepatitis C virus (HCV) with compensated cirrhosis; Diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis with past failure of a sofosbuvir-based treatment; Diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis without past failure of a sofosbuvir-based treatment; Diagnosis of pediatric chronic Hepatitis C virus (HCV) and weight < 35 kg]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Is the patient HIV+?
5. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
6. Is the patient treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)?

Diagnosis of chronic Hepatitis C virus (HCV) with compensated cirrhosis

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?

4. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
5. Is the patient treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)?

Diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis with past failure of a sofosbuvir-based treatment

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
5. Yes/No: The provider confirms the patient will use ribavirin in combination with ledipasvir-sofosbuvir.

Diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis without past failure of a sofosbuvir-based treatment

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
5. Is the patient treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)?
6. Yes/No: The provider confirms the patient will use ribavirin in combination with ledipasvir-sofosbuvir, or the provider notes that the patient has an intolerance or contraindication to ribavirin.

Diagnosis of pediatric chronic Hepatitis C virus (HCV) and weight < 35 kg

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Is the patient treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)?

RATIONALE

*Clinically significant is defined as an interaction that is moderate to severe and cannot be mitigated easily

Note: There are no renewal criteria as reviews using above criteria apply for a one-time treatment regimen.

FDA APPROVED INDICATIONS

Hepatitis C

REFERENCES

AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C
Kaiser Permanente Inter-Regional Consensus Hepatitis C Treatment Recommendations

Creation date: 05/2024
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: n/a

LEMBOREXANT (DAYVIGO)

Generic	Brand	HICL	GPID	Comments
LEMBOREXANT	DAYVIGO	46275		Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all General Criteria and all Age Criteria in applicable age section

A. **General Criteria for All Requests:** Must meet all the following:
   1. Medication is prescribed by Behavioral Health or Sleep Medicine provider
   2. Patient must be age 18 or older
   3. Diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance
   4. Potential factors contributing to sleep disturbances have been addressed (e.g., inappropriate sleep hygiene, sleep environment issues and co-morbid conditions contributing to insomnia)
   5. Patient has no history of narcolepsy

B. **Age 65 Years or Older:** Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to trazodone
   2. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to ramelteon or OTC melatonin

   If initial criteria are met, approve at HICL indefinitely, max daily dose of 1 tablet.
   If initial criteria are not met, do not approve.

C. **Age Less Than 65 Years:** Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to trazodone
   2. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to ramelteon or OTC melatonin
   3. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to at least ONE of the following sedative-hypnotic alternatives: zolpidem (F), zaleplon (NF), eszopiclone (NF)

   If initial criteria are met, approve at HICL indefinitely, max daily dose of 1 tablet.
   If initial criteria are not met, do not approve.

ePA Questions
1. Have factors that could contribute to sleep disturbances been addressed (e.g., inappropriate sleep hygiene, sleep environment issues and co-morbid conditions contributing to insomnia)?
2. Does the patient have history of narcolepsy?
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (OTC melatonin, trazodone, zolpidem IR tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

FDA APPROVED INDICATIONS
Dayvigo (lemborexant) and Belsomra (suvorexant), and Quviviq (daridorexant) are indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

REFERENCES
Per Health Plan

Creation Date: 03/2021
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

LHRH ANTAGONIST ORGOVYX PA CRITERIA

Generic	Brand	HICL	GPID	Comments
RELUGOLIX	ORGOVYX	47035	49005	Nonformulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

1. Patient must be age 18 or older
2. Must be prescribed by a CPMG or affiliated Oncologist or Urologist
3. Must have biopsy-confirmed prostate adenocarcinoma
4. Serum PSA level at diagnosis is greater than 2ng/mL
5. Must have metastatic disease or biochemical recurrence
6. No active uncontrolled Crohn's disease or active peptic ulcer disease or history of gastric bypass surgery or gastrectomy
7. Patient is unable to use leuprolide* (Eligard, Lupron) due to one of the following clinical features, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Patient has a history of a major cardiovascular event (myocardial infarction, angina, symptomatic ischemic heart disease, CHF, ventricular arrhythmias, 2nd degree heart block, stroke, history of CABG and/or cardiac stents)
   b. Patient is at immediate risk of serious complications due to their prostate cancer (e.g., spinal cord compression, severe bone pain, risk of bone fracture due to metastases)
   c. Patient is intolerant to 2 androgen blockers (bicalutamide, flutamide or nilutamide) and newly beginning androgen deprivation therapy (ADT) [i.e., unable to prevent tumor flare when starting leuprolide]
8. Patient has an intolerance or contraindication to degarelix (Firmagon), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient had biopsy confirmation of diagnosis?
2. Serum PSA at diagnosis:
3. Does the patient have metastatic disease?
4. Does the patient have biochemical recurrence?
5. Does the patient have active uncontrolled Crohn's disease?
6. Does the patient have active peptic ulcer disease?
7. Does the patient have history of gastric bypass surgery or gastrectomy?

8. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
9. Is there reasoning why alternatives (leuprolide) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
*Leuprolide – administered in office for treatment of prostate cancer; does not require coverage review. Eligard 22.5 mg (q3 months) or 45 mg (q6 months) are preferred, stocked products at KPCO.

To promote cost-conscious, evidence-based use of the medication

FDA APPROVED INDICATIONS
Advanced prostate cancer

REFERENCES

Creation Date: 3/2021
Effective Date: 06/2024
Reviewed Date: 05/2024
Revised Date: 05/2024

LINACLOTIDE (LINZESS)

Generic	Brand	HICL	GPID	Exception/Other
LINACLOTIDE	LINZESS	39583	42975, 33187, 33188	Non-Formulary

GUIDELINES FOR COVERAGE
Must meet one of the following indications and meet all indication-specific criteria:

A. Irritable Bowel Syndrome with Constipation (IBS-C) or Chronic Idiopathic Constipation (CIC)
B. Pediatric Functional Constipation

A. Irritable Bowel Syndrome with Constipation (IBS-C) or Chronic Idiopathic Constipation (CIC)
   1. The patient is 18 years of age or older with a diagnosis of IBS-C or CIC
   2. The patient has tried and failed all the following diagnosis specific preferred alternatives; or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. For IBS-C:
         i. at least one bulk-forming laxative (a bulk forming laxative contains psyllium, methylcellulose, or polycarbophil and examples may include Metamucil, Citrucel, FiberCon)
         ii. at least one osmotic laxative (an osmotic laxative contains magnesium hydroxide, polyethylene glycol, lactulose, magnesium citrate, or glycerin and examples may include milk of magnesia or Miralax)
         iii. lubiprostone
         iv. Trulance
      b. For CIC:
         i. at least one bulk-forming laxative (a bulk forming laxative contains psyllium, methylcellulose, or polycarbophil and examples may include Metamucil, Citrucel, FiberCon)
         ii. at least one osmotic laxative (an osmotic laxative contains magnesium hydroxide, polyethylene glycol, lactulose, magnesium citrate, or glycerin and examples may include milk of magnesia or Miralax)
         iii. lubiprostone
         iv. Trulance
         v. Motegrity (CIC diagnosis only)

If criteria are met, approve indefinitely at HICL, max 1 capsule per day.
If criteria are not met, do not approve.

B. Pediatric Functional Constipation
   1. The request is for Linzess 72mcg capsules
   2. The patient is 6-17 years old with a diagnosis of pediatric functional constipation
   3. The patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on

known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

a. at least one bulk-forming laxative (a bulk forming laxative contains psyllium, methylcellulose, or polycarbophil and examples may include Metamucil, Citrucel, FiberCon)
b. at least one osmotic laxative (an osmotic laxative contains magnesium hydroxide, polyethylene glycol, lactulose, magnesium citrate, or glycerin and examples may include milk of magnesia or Miralax)

If criteria are met, approve indefinitely at GPID, max 1 capsule per day.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (bulk-forming laxative, osmotic laxative, or others) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Per Plan.

REFERENCES

Per Plan.

Creation date: 3/15/2017
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2025

LISDEXAMFETAMINE (VYVANSE)

Generic	Brand	HICL	GPID	Exception/Other
LISDEXAMFETAMINE	VYVANSE	34486		

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA:

A. Patient is new to KPCO within the past 90 days and stable on lisdexamfetamine therapy and has ONE of the following diagnoses [for patients with BED and ADHD/ADD, must meet criteria for either diagnosis]:
   1. Requested medication is prescribed for the treatment of Binge Eating Disorder (BED)
   2. Requested medication is prescribed for treatment of attention-deficit/hyperactivity disorder (ADHD) or attention deficit disorder (ADD), and the patient meets the following age criteria:
      a. The patient is 18 years old or younger
      b. The patient is 19 years or older and has failed an adequate trial* of, experienced adverse events with, or has an allergy or contraindication to an amphetamine product** regardless of dosage form, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

   If met, approve indefinitely at HICL.
   If not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following diagnoses and meet all associated criteria [for patients with BED and ADHD/ADD, must meet criteria for either diagnosis]:

A. Binge Eating Disorder
B. Patient 6-18 years of age with ADHD or attention deficit disorder (ADD)
C. Patient 19 years of age or older with ADHD or attention deficit disorder (ADD)

A. Diagnosis of Binge Eating Disorder: Must meet the following:
   1. Prior adequate trial* (6 weeks) and failure of, or intolerance to at least one formulary selective serotonin reuptake inhibitor (SSRI), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

   If initial criteria are met, approve indefinitely at HICL.
   If initial criteria are not met, do not approve.

B. Patient 6-18 years of age with a diagnosis of ADHD or attention deficit disorder (ADD): Must meet the following:
   1. Prior adequate trial* (7 days) and therapeutic failure or adverse event with a long-acting amphetamine product that is not resolved by adjusting the dose or frequency, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

      If initial criteria are met, approve indefinitely at HICL.
      If initial criteria are not met, do not approve.

C. Patient 19 years of age or older with a diagnosis of ADHD or attention deficit disorder (ADD): Must meet all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Prior adequate trial* (7 days) and failure, or has a contraindication, or allergy to methylphenidate OR dexmethylphenidate regardless of dosage form
   2. Prior adequate trial* (7 days) and failure, or has a contraindication, or allergy to an amphetamine product regardless of dosage form

      If initial criteria are met, approve indefinitely at HICL.
      If initial criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient stable on therapy with lisdexamfetamine?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Binge Eating Disorder; ADHD or attention deficit disorder (ADD)]

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   Binge Eating Disorder
   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   2. Is there reasoning why alternatives (citalopram tablets/solution, escitalopram tablets, fluoxetine capsules/solution, paroxetine IR tablets, sertraline tablets/suspension) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

   ADHD or attention deficit disorder (ADD)
   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

2. Is there reasoning why alternatives (methylphenidate IR tablets, methylphenidate ER (Metadate ER) tablets, methylphenidate ER (Metadate CD) capsules, methylphenidate ER (Concerta) tablets; dexmethylphenidate IR tablets or ER capsules; dextroamphetamine IR tablets or ER capsules; dextroamphetamine-amphetamine IR tablets or ER capsules) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
To provide guidelines for consistent non-formulary review of the non-formulary medication.

FDA APPROVED INDICATIONS
Lisdexamfetamine is FDA approved for the treatment of attention-deficit/hyperactive disorder (ADHD) in adults and pediatric patients 6 years of age and older. It is also FDA approved for treatment of binge eating disorder in adults

REFERENCES
***** Adequate trial of a long-acting agent is further defined as wearing off that is not resolved by increasing the dose AND adding a short-acting agent OR increasing frequency to twice daily OR clinically significant side effects related to the dosage form that cannot be resolved by adjusting the dose or timing.

** Amphetamine products may include any of the following:

Drug	Initial suggested SIGs
Amphetamine mixed salts (Adderall XR capsule)	10 mg Daily
Amphetamine mixed salts (Adderall IR tablet)	5 mg BID
Dextroamphetamine ER (Dexedrine SR Spansules)	10 mg Daily
Dextroamphetamine IR (Dexedrine IR tablet)	5 mg BID

Creation Date: 07/2022
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

LISINOPRIL 1 MG/ML SOLUTION - AGE RESTRICTION CRITERIA

Generic	Brand	HICL	GPID	Exception/Other
LISINOPRIL SOLUTION 1 MG/ML	QBRELIS	00132	41984	Formulary

GUIDELINES FOR COVERAGE

INITIAL AND RENEWAL CRITERIA: ONE of the following criteria must be met:
1. Patient is 10 years old or younger.
2. Patient is using an alternative administration route, such as a gastrostomy tube.
3. Dose cannot be obtained by using half, whole, or combination of the lisinopril tablet (2.5 mg, 5 mg, 10 mg, or 20 mg, 30 mg, or 40 mg)
4. Patient cannot swallow tablets whole, halved, or crushed (with or without mixing in applesauce)

If any criterion is met, approve at GPID x1 year.
If no criteria are met, do not approve. May suggest using tablet strengths that can be halved or used in combination, or crushing lisinopril tablets before administration and taking with or without applesauce.

ePA Questions
1. Is the patient using an alternative administration route, such as a gastrostomy tube? If yes, must attach applicable chart notes.
2. Is the patient unable to swallow tablets whole, halved, or crushed (with or without mixing in applesauce)? If yes, must attach applicable chart notes.

RATIONALE
Per Health Plan.

General Clinical Criteria for solutions/suspension
1. Age is less than or equal to 10 years old
2. Presence of gastrostomy
3. Dose does not allow use of halved, whole or combo of tablet
4. Dose does not use whole capsule (cannot “cut” capsules in half)
5. Clinical condition where unable to swallow crushed/opened tablets/capsules (i.e., esophageal stricture)

FDA APPROVAL
1. Adjunctive therapy to reduce signs and symptoms of systolic heart failure
2. Management of hypertension in adult and pediatric patients ≥6 years of age
3. Treatment of acute MI within 24 hours in hemodynamically stable patients to improve survival

Creation Date: 07/2024
Effective Date: 08/2024
Reviewed Date:
Revised Date:

LONAPEGSOMATROPIN-TCGD (SKYTROFA)

Generic	Brand	HICL	GCN	Exception/Other
LONAPEGSOMATROPIN-TCGD	SKYTROFA	47565		Once weekly non-preferred; Omnitrope is preferred/formulary

GUIDELINES FOR COVERAGE
Must meet all the following:
1. Patient has a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH)
2. Medication is prescribed by an Endocrinologist
3. Patient is between 1-18 years of age and weighs at least 11.5 kg
4. Patient has tried and failed, or has an intolerance or contraindication to Omnitrope cartridges, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Growth Hormone Deficiency alone or associated with hormone deficiencies resulting from pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma; Growth failure due to inadequate secretion of endogenous growth hormone (GH)]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (Omnitrope cartridges) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Ensure appropriate use of growth hormones with respect to evidence-based guidelines and direct usage to formulary agents. KPCO generally does not consider frequency of dosing and/or lack of compliance to dosing regimens an indication of medical necessity.

Growth Hormone medications in order of formulary preference (most preferred to least): Omnitrope cartridges, Genotropin, Omnitrope vials, Saizen, Nutropin, Humatrope, Norditropin, Norditropin, Zomacton, Sogroya, Skytrofa

OMNITROPE (KPCO preferred GH therapy) is indicated for Pediatric Patients: Treatment of children with growth failure due to growth hormone deficiency (GHD), Prader-Willi Syndrome, Small for Gestational Age, Turner syndrome, and Idiopathic Short Stature. Adult Patients: Treatment of adults with either adult onset or childhood onset GHD.

SKYTROFA is a human growth hormone indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).

REFERENCES

1. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children – 2003 update. Endocr Pract 2003; 9(1):64-76.
2. Consensus guidelines for the diagnosis and treatment of growth hormone (GH) deficiency in childhood and adolescence: summary statement of the GH Research Society. JCE & M 2000; 85(11):3990-3.
3. Wilson, T et al. Update of Guidelines for the Use of Growth Hormone in Children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. J Pediatr 2003; 143:314-21.
4. Vance M, Mauras N. Growth hormone therapy in adults and children. NEJM 1999; 341(16):1206-16.
5. Sandoz GmbH. Omnitrope package insert. Austria. June 2010.
6. Lonapegsomatropin-tcgd (Skytrofa). New drug review. IPD Analytics RxInsights. September 2021
7. Allen DB, Backeljauw P, Bidlingmaier M, Biller BMK, et al. GH safety workshop position paper: a critical appraisal of recombinant human GH therapy in children and adults. European Journal of Endocrinology (2016) 174 (2). doi:10.1530/EJE-15-0873 (ghresearchsociety.org)
8. Grimberg A, DiVall SA, Polychronakos C, Allen DB, Cohen LE, Quintos JB, Rossi WC, Feudtner C, Murad MH; Drug and Therapeutics Committee and Ethics Committee of the Pediatric Endocrine Society. Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency. Horm Res Paediatr. 2016;86(6):361-397. doi: 10.1159/000452150.

Creation Date: 05/2024
Effective Date: 06/2024
Reviewed Date:
Revised Date:

LONG-ACTING BETA AGONIST (LABA): FORMOTEROL FUMARATE (PERFOROMIST)

Generic	Brand	HICL	GPID	Comments
FORMOTEROL FUMARATE	PERFOROMIST		98776	Non-Formulary Nebulized inhalation solution

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

1. Medication is requested for the maintenance treatment of chronic obstructive pulmonary disease (COPD).
2. Patient must be age 18 years or older.
3. Patient has tried and failed, or has an intolerance or a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - arformoterol (Brovana) or Striverdi Respimat
   - Spiriva Respimat
   - Stiolto Respimat

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Stiolto Respimat, Spiriva Respimat, Striverdi Respimat) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Striverdi Respimat (olodaterol) is KPCO preferred long-acting beta agonist (LABA) inhaler on the formulary. Non-preferred LABA agents should be reserved after Striverdi and more established treatments for COPD such as long-acting muscarinic antagonist (LAMA). Either LABA or LAMA are acceptable for patients with group B COPD but LAMA generally preferred over LABA in COPD as it is recommended for group C and D in COPD.

LABA should not be used as monotherapy in patients with asthma. Use of more established therapies, such as inhaled corticosteroid (ICS) and ICS/LABA combination agents, are preferred over LABA in asthma.

FDA APPROVED INDICATIONS

All LABAs are indicated for the maintenance treatment of bronchospasm associated with COPD. In addition, Serevent Diskus (salmeterol) is also indicated for the treatment of asthma in patients aged 4 years and older with an ICS and prevention of exercise-induced bronchospasm (EIB) in patients aged 4 years and older.

REFERENCES
Per Health Plan.

Creation Date: 05/2022
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

LONG-ACTING BETA AGONIST (LABA): SALMETEROL XINAFOATE (SEREVENT DISKUS)

Generic	Brand	HICL	GPID	Comments
SALMETEROL XINAFOATE	SEREVENT DISKUS	07393	64012	NF- Comm, Hx, Fed; F- SF Dry powder inhaler

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following indications and meet all criteria associated with that diagnosis:

A. Chronic Obstructive Pulmonary Disease (COPD) indication
B. Asthma indication

A. **For the maintenance treatment of chronic obstructive pulmonary disease (COPD):**
1. Patient must be age 18 years or older
2. Patient has tried and failed, or has an intolerance or a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - Striverdi Respimat
   - Spiriva Respimat
   - Stiolto Respimat

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

B. **For the treatment of asthma:**
1. Patient must be age 4 years or older
2. Requested medication is Serevent Diskus
3. Patient is not using as monotherapy for maintenance treatment of asthma
4. Patient has tried and failed, or has intolerance or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - One inhaled corticosteroid [formulary agents: Alvesco HFA, Asmanex HFA]
   - At least one inhaled corticosteroid/long-acting beta agonist (ICS/LABA) combination products [formulary agents: Wixela Inhub, Breyna HFA (generic Symbicort)]

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Asthma or Asthma with COPD; COPD]

QUESTIONS BASED ON DIAGNOSIS SELECTED
Asthma or Asthma with COPD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

COPD

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA, Stiolto Respimat, Spiriva Respimat) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Striverdi Respimat (olodaterol) is KPCO preferred long-acting beta agonist (LABA) inhaler on the formulary. Non-preferred LABA agents should be reserved after Striverdi and more established treatments for COPD such as long-acting muscarinic antagonist (LAMA). Either LABA or LAMA are acceptable for patients with group B COPD but LAMA generally preferred over LABA in COPD as it is recommended for group C and D in COPD.

LABA should not be used as monotherapy in patients with asthma. Use of more established therapies, such as inhaled corticosteroid (ICS) and ICS/LABA combination agents, are preferred over LABA in asthma.

FDA APPROVED INDICATIONS
All LABAs are indicated for the maintenance treatment of bronchospasm associated with COPD. In addition, Serevent Diskus (salmeterol) is also indicated for the treatment of asthma in patients aged 4 years and older with an ICS and prevention of exercise-induced bronchospasm (EIB) in patients aged 4 years and older.

REFERENCES
Per Health Plan.

Creation Date: 05/2022
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

LONG-ACTING MUSCARINIC ANTAGONIST (LAMA) CLASS
ACLIDINIUM (TUDORZA PRESSAIR)

Generic	Brand	HICL	GPID	Comments
ACLIDINIUM BROMIDE	TUDORZA PRESSAIR		33084	Non-Formulary Dry powder inhaler

Step Therapy Criteria
Must meet the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or likely will cause an adverse reaction or harm; ii) based on supporting clinical documentation provided, the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and a received step therapy exception:

1. Patient has tried and failed or has an intolerance or a contraindication to Spiriva Respimat 2.5 mcg/actuation.

If met, approve at HICL indefinitely.
If not met, do not approve.

STEP THERAPY RULES:

- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Spiriva Respimat] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Spiriva Respimat (tiotropium) is the preferred LAMA therapy based on cost-effectiveness of reducing COPD exacerbations and is the only LAMA with an indication for the management of asthma. Spiriva Respimat 1.25 mcg/actuation inhaler (sig: 2 inhalations once daily) is FDA labeled for asthma and 2.5 mcg/actuation inhaler (sig: 2 inhalations once daily) is FDA labeled for COPD. However, the 2.5 mcg/actuation inhaler (sig: 1 or 2 inhalations once daily) can be used off-label for asthma [5 mcg once daily has been recommended for patients with insufficient response to inhaled corticosteroid plus long-acting beta agonist (GINA 2020) with efficacy found in adults with severe asthma (ERS/ATS, Holguin 2019)]. All other LAMAs, including Spiriva Handihaler, are indicated for COPD only.

KPCO order of preference: Spiriva Respimat (tiotropium inhalation mist) 2.5 mcg > Spiriva Respimat (tiotropium inhalation mist) 1.25 mcg > Spiriva Handihaler (tiotropium dry powder) > Incruse Ellipta (umeclidinium) > Tudorza Pressair (aclidinium) > Yupelri (revefenacin)

FDA APPROVED INDICATIONS
Anticholinergic bronchodilators are indicated for the long-term maintenance treatment of COPD. Spiriva (tiotropium) is also indicated for reducing COPD exacerbations and management of asthma (Respimat device only for asthma).

REFERENCES
Per Health Plan.

Creation Date: 05/2024

Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: n/a

LONG-ACTING MUSCARINIC ANTAGONIST (LAMA) CLASS
REVEFENACIN (YUPELRI)

Generic	Brand	HICL	GPID	Comments
REVEFENACIN	YUPELRI		45742	Non-Formulary Nebulized solution

Step Therapy Criteria
Must meet the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or likely will cause an adverse reaction or harm; ii) based on supporting clinical documentation provided, the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and a received step therapy exception:

1. Patient has tried and failed or has an intolerance or a contraindication to Spiriva Respimat 2.5 mcg/actuation.

If met, approve at HICL indefinitely.
If not met, do not approve.

STEP THERAPY RULES:

- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Spiriva Respimat] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Spiriva Respimat (tiotropium) is the preferred LAMA therapy based on cost-effectiveness of reducing COPD exacerbations and is the only LAMA with an indication for the management of asthma. Spiriva Respimat 1.25 mcg/actuation inhaler (sig: 2 inhalations once daily) is FDA labeled for asthma and 2.5 mcg/actuation inhaler (sig: 2 inhalations once daily) is FDA labeled for COPD. However, the 2.5 mcg/actuation inhaler (sig: 1 or 2 inhalations once daily) can be used off-label for asthma [5 mcg once daily has been recommended for patients with insufficient response to inhaled corticosteroid plus long-acting beta agonist (GINA 2020) with efficacy found in adults with severe asthma (ERS/ATS, Holguin 2019)]. All other LAMAs, including Spiriva Handihaler, are indicated for COPD only.

KPCO order of preference: Spiriva Respimat (tiotropium inhalation mist) 2.5 mcg > Spiriva Respimat (tiotropium inhalation mist) 1.25 mcg > Spiriva Handihaler (tiotropium dry powder) > Incruse Ellipta (umeclidinium) > Tudorza Pressair (aclidinium) > Yupelri (revefenacin)

FDA APPROVED INDICATIONS
Anticholinergic bronchodilators are indicated for the long-term maintenance treatment of COPD. Spiriva (tiotropium) is also indicated for reducing COPD exacerbations and management of asthma (Respimat device only for asthma).

REFERENCES
Per Health Plan.

Creation Date: 05/2024

Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: n/a

LONG-ACTING MUSCARINIC ANTAGONIST (LAMA) CLASS
TIOTROPIUM BROMIDE (SPIRIVA HANDIHALER)

Generic	Brand	HICL	GPID	Comments
TIOTROPIUM BROMIDE	SPIRIVA HANDIHALER		17853	Non-Formulary (Respimat 2.5 mcg/actuation formulary preferred)

Step Therapy Criteria
Must meet the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or likely will cause an adverse reaction or harm; ii) based on supporting clinical documentation provided, the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and a received step therapy exception:

1. Patient has tried and failed or has an intolerance or a contraindication to Spiriva Respimat 2.5 mcg/actuation.

If met, approve at GPID indefinitely.
If not met, do not approve.

STEP THERAPY RULES:
- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Spiriva Respimat] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Spiriva Respimat (tiotropium) is the preferred LAMA therapy based on cost-effectiveness of reducing COPD exacerbations and is the only LAMA with an indication for the management of asthma. Spiriva Respimat 1.25 mcg/actuation inhaler (sig: 2 inhalations once daily) is FDA labeled for asthma and 2.5 mcg/actuation inhaler (sig: 2 inhalations once daily) is FDA labeled for COPD. However, the 2.5 mcg/actuation inhaler (sig: 1 or 2 inhalations once daily) can be used off-label for asthma [5 mcg once daily has been recommended for patients with insufficient response to inhaled corticosteroid plus long-acting beta agonist (GINA 2020) with efficacy found in adults with severe asthma (ERS/ATS, Holguin 2019)]. All other LAMAs, including Spiriva Handihaler, are indicated for COPD only.

KPCO order of preference: Spiriva Respimat (tiotropium inhalation mist) 2.5 mcg > Spiriva Respimat (tiotropium inhalation mist) 1.25 mcg > Spiriva Handihaler (tiotropium dry powder) > Incruse Ellipta (umeclidinium) > Tudorza Pressair (aclidinium) > Yupelri (revefenacin)

FDA APPROVED INDICATIONS
Anticholinergic bronchodilators are indicated for the long-term maintenance treatment of COPD. Spiriva (tiotropium) is also indicated for reducing COPD exacerbations and management of asthma (Respimat device only for asthma).

REFERENCES
Per Health Plan.

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: n/a

LONG-ACTING MUSCARINIC ANTAGONIST (LAMA) CLASS
TIOTROPIUM BROMIDE (SPIRIVA RESPIMAT 1.25MG)

Generic	Brand	HICL	GPID	Comments
TIOTROPIUM BROMIDE	SPIRIVA RESPIMAT 1.25 MCG/ACTUATION		39587	Non-Formulary (Respimat 2.5 mcg/actuation formulary preferred with no restriction)

GUIDELINES FOR COVERAGE

Must meet all the following:
1. Patient has a diagnosis of asthma.
2. Patient is 6 years of age or older.
3. Patient has persistent symptoms and/or asthma exacerbation despite adherence to combination medium-to-high dose ICS/LABA therapy.
4. Patient has tried and failed or has an intolerance or a contraindication to Spiriva Respimat 2.5 mcg/actuation, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If all criteria are met, approve at GPID indefinitely.
If all criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Spiriva Respimat (tiotropium) is the preferred LAMA therapy based on cost-effectiveness of reducing COPD exacerbations and is the only LAMA with an indication for the management of asthma. Spiriva Respimat 1.25 mcg/actuation inhaler (sig: 2 inhalations once daily) is FDA labeled for asthma and 2.5 mcg/actuation inhaler (sig: 2 inhalations once daily) is FDA labeled for COPD. However, the 2.5 mcg/actuation inhaler (sig: 1 or 2 inhalations once daily) can be used off-label for asthma [5 mcg once daily has been recommended for patients with insufficient response to inhaled corticosteroid plus long-acting beta agonist (GINA 2020) with efficacy found in adults with severe asthma (ERS/ATS, Holguin 2019)]. All other LAMAs, including Spiriva Handihaler, are indicated for COPD only.

KPCO order of preference: Spiriva Respimat (tiotropium inhalation mist) 2.5 mcg > Spiriva Respimat (tiotropium inhalation mist) 1.25 mcg > Spiriva Handihaler (tiotropium dry powder) > Incruse Ellipta (umeclidinium) > Tudorza Pressair (aclidinium) > Yupelri (revefenacin)

FDA APPROVED INDICATIONS
Anticholinergic bronchodilators are indicated for the long-term maintenance treatment of COPD. Spiriva (tiotropium) is also indicated for reducing COPD exacerbations and management of asthma (Respimat device only for asthma).

REFERENCES
Per Health Plan.

Creation Date: 05/2022
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

LONG-ACTING MUSCARINIC ANTAGONIST (LAMA) CLASS
UMECLIDINIUM BROMIDE (INCRUSE ELLIPTA)

Generic	Brand	HICL	GPID	Comments
UMECLIDINIUM BROMIDE	INCRUSE ELLIPTA		36574	Non-Formulary Dry powder inhaler

Step Therapy Criteria
Must meet the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or likely will cause an adverse reaction or harm; ii) based on supporting clinical documentation provided, the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and a received step therapy exception:

1. Patient has tried and failed or has an intolerance or a contraindication to Spiriva Respimat 2.5 mcg/actuation.

If met, approve at HICL indefinitely.
If not met, do not approve.

STEP THERAPY RULES:
- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Spiriva Respimat] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Spiriva Respimat (tiotropium) is the preferred LAMA therapy based on cost-effectiveness of reducing COPD exacerbations and is the only LAMA with an indication for the management of asthma. Spiriva Respimat 1.25 mcg/actuation inhaler (sig: 2 inhalations once daily) is FDA labeled for asthma and 2.5 mcg/actuation inhaler (sig: 2 inhalations once daily) is FDA labeled for COPD. However, the 2.5 mcg/actuation inhaler (sig: 1 or 2 inhalations once daily) can be used off-label for asthma [5 mcg once daily has been recommended for patients with insufficient response to inhaled corticosteroid plus long-acting beta agonist (GINA 2020) with efficacy found in adults with severe asthma (ERS/ATS, Holguin 2019)]. All other LAMAs, including Spiriva Handihaler, are indicated for COPD only.

KPCO order of preference: Spiriva Respimat (tiotropium inhalation mist) 2.5 mcg > Spiriva Respimat (tiotropium inhalation mist) 1.25 mcg > Spiriva Handihaler (tiotropium dry powder) > Incruse Ellipta (umeclidinium) > Tudorza Pressair (aclidinium) > Yupelri (revefenacin).

FDA APPROVED INDICATIONS
Anticholinergic bronchodilators are indicated for the long-term maintenance treatment of COPD. Spiriva (tiotropium) is also indicated for reducing COPD exacerbations and management of asthma (Respimat device only for asthma).

REFERENCES
Per Health Plan.

Creation Date: 05/2024

Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: n/a

LONG-ACTING MUSCARINIC ANTAGONIST/LONG-ACTING BETA AGONIST (LAMA/LABA) STEP THERAPY: ANORO ELLIPTA

Generic	Brand	HICL	GPID	Comments
UMECLIDINIUM/VILANTEROL	ANORO ELLIPTA	40852	35903	Non-Formulary

Step Therapy Criteria
Must meet the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed or has an intolerance or a contraindication to Stiolto Respimat (tiotropium/olodaterol).

If met, approve at HICL indefinitely.
If not met, do not approve.

STEP THERAPY RULES:

- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Stiolto Respimat] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Stiolto Respimat (tiotropium/olodaterol) is the most cost-effective LAMA/LABA inhaler with no significant difference in safety or efficacy among the different LAMA/LABA inhalers.

KPCO order of preference: Stiolto Respimat (tiotropium/olodaterol) > Anoro Ellipta (umeclidinium/vilanterol) > Bevespi Aerosphere (glycopyrrolate/formoterol) > Duaklir Pressair (aclidinium/formoterol)

FDA APPROVED INDICATIONS
Combination LAMA/LABA inhalers are FDA approved for the maintenance treatment of patients with COPD.

REFERENCES
Per Health Plan.

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: n/a

LONG-ACTING MUSCARINIC ANTAGONIST/LONG-ACTING BETA AGONIST (LAMA/LABA) STEP THERAPY: BEVESPI AEROSPHERE

Generic	Brand	HICL	GPID	Comments
GLYCOPYRROLATE/ FORMOTEROL	BEVESPI AEROSPHERE		41199	Non-Formulary

Step Therapy Criteria
Must meet the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed or has an intolerance or a contraindication to Stiolto Respimat (tiotropium/olodaterol).

If met, approve at HICL indefinitely.
If not met, do not approve.

STEP THERAPY RULES:

- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Stiolto Respimat] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Stiolto Respimat (tiotropium/olodaterol) is the most cost-effective LAMA/LABA inhaler with no significant difference in safety or efficacy among the different LAMA/LABA inhalers.

KPCO order of preference: Stiolto Respimat (tiotropium/olodaterol) > Anoro Ellipta (umeclidinium/vilanterol) > Bevespi Aerosphere (glycopyrrolate/formoterol) > Duaklir Pressair (aclidinium/formoterol)

FDA APPROVED INDICATIONS
Combination LAMA/LABA inhalers are FDA approved for the maintenance treatment of patients with COPD.

REFERENCES
Per Health Plan.

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: n/a

LONG-ACTING MUSCARINIC ANTAGONIST/LONG-ACTING BETA AGONIST (LAMA/LABA) STEP THERAPY: DUAKLIR PRESSAIR

Generic	Brand	HICL	GPID	Comments
ACLIDINIUM/FORMOTEROL	DUAKLIR PRESSAIR	41692	37735	Non-Formulary

Step Therapy Criteria
Must meet the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has tried and failed or has an intolerance or a contraindication to Stiolto Respimat (tiotropium/olodaterol).

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

STEP THERAPY RULES:

- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Stiolto Respimat] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Stiolto Respimat (tiotropium/olodaterol) is the most cost-effective LAMA/LABA inhaler with no significant difference in safety or efficacy among the different LAMA/LABA inhalers.

KPCO order of preference: Stiolto Respimat (tiotropium/olodaterol) > Anoro Ellipta (umeclidinium/vilanterol) > Bevespi Aerosphere (glycopyrrolate/formoterol) > Duaklir Pressair (aclidinium/formoterol)

FDA APPROVED INDICATIONS
Combination LAMA/LABA inhalers are FDA approved for the maintenance treatment of patients with COPD.

REFERENCES
Per Health Plan.

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: n/a

LUMACAFTOR/IVACAFTOR (ORKAMBI)

Generic	Brand	HICL	GPID	Exception/Other
LUMACAFTOR/IVACAFTOR	ORKAMBI	42235		

GUIDELINES FOR COVERAGE

Requests for LUMACAFTOR/IVACAFTOR will be approved if ALL the following are met:
1. Prescribed by a pulmonologist
2. Patient has a diagnosis of cystic fibrosis (CF) and is homozygous for the F508del mutation (verified by testing)
3. Patient is at least 1 year old

If all above criteria are met, approve indefinitely, max #4 tablets/day or #2 packets/day.
If criteria are not met, do not approve.

ePA Questions
1. Is the patient homozygous for the F508del mutation? If yes, must attach supporting chart notes.

RATIONALE
Per Health Plan.

FDA APPROVED INDICATIONS
Treatment of cystic fibrosis (CF) in patients 1 year and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene.

Limitations of use: Efficacy and safety have not been established in patients with CF other than those homozygous for the F508del mutation.

REFERENCES
1. Per Health Plan.
2. Orkambi [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; 2019

Creation date: 07/2018
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2023

OPSUMIT (MACITENTAN)

Generic	Brand	HICL	GCN	Exception/Other
MACITENTAN	OPSUMIT	40677	35443	

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet the following:
1. Patient is new to KPCO within the past 90 days and is currently stable on Opsumit

If met, approve indefinitely.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Prescriber must be either a pulmonologist or a cardiologist
2. Patient has a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) verified by right heart catheterization
3. Patient currently has WHO Functional Class II, III or IV symptoms
4. Patient has tried and failed or has an intolerance to or a contraindication to ambrisentan (Letairis) or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If Initial Criteria are met, approve indefinitely.
If Initial Criteria are not met, do not approve.

RATIONALE
Ensure appropriate use consistent with FDA indication.

FDA APPROVED INDICATIONS
Treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to reduce risks of disease progression and hospitalization

REFERENCES
1. Opsumit (macitentan) [product monograph]. Toronto, Ontario, Canada: Jassen Inc; July 2020.
2. Opsumit (macitentan) [prescribing information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc; Jan 2021.

Creation Date: 3/25/2021
Effective Date: 06/2024
Reviewed Date: 05/2024
Revised Date: 05/2024

OPSYNVI (MACITENTAN-TADALAFIL)

Generic	Brand	HICL	GPID	Other
MACITENTAN-TADALAFIL	OPSYNVI	47644	55466, 51671	

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet the following:
1. Patient is new to KPCO within the past 90 days and is currently stable on Opsynvi.

If met, approve indefinitely at HICL.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Prescriber must be either a pulmonologist or a cardiologist.
2. Patient has a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) verified by right heart catheterization.
3. Patient currently has WHO Functional Class II, III or IV symptoms.
4. Patient has tried and failed or has an intolerance to or a contraindication to ambrisentan (Letairis), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If Initial Criteria are met, approve indefinitely at HICL.
If Initial Criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with Opsynvi?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Pulmonary Arterial Hypertension (PAH, WHO Group 1) verified by right heart catheterization]
4. Patient's current WHO Functional Class:
5. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
6. Is there reasoning why alternatives (ambrisentan tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Ensure appropriate use consistent with FDA indication.

Creation Date: 05/2024
Effective Date: 06/2024
Reviewed Date:
Revised Date:

MARALIXIBAT (LIVMARLI)

Generic	Brand	HICL	GPID	Comments
MARALIXIBAT	LIVMARLI	47604	51256	Non-Formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days.
2. Medication is prescribed by a gastroenterology specialist.
3. Patient has a diagnosis of Alagille syndrome (ALGS) or cholestatic pruritus due to Progressive Familial Intrahepatic Cholestasis (PFIC) and is stable on therapy.

If met, approve indefinitely.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following diagnoses and meet all the diagnosis-specific criteria below:

A. Diagnosis of cholestatic pruritus due to Alagille syndrome (ALGS), a type of genetic disorder
B. Diagnosis of cholestatic pruritus due to progressive familial intrahepatic cholestasis (PFIC), a type of genetic disorder, without type 2 specific ABCB11 variants

A. Cholestatic pruritus due to ALGS: Must meet all the following:
   1. Patient is at least 3 months old.
   2. Medication is prescribed by a gastroenterology specialist.
   3. Patient has tried and failed, or has an intolerance or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      - ursodiol
      - a bile acid sequestrant (ex: cholestyramine or colesevelam) or rifampin

If initial criteria are met, approve indefinitely, max 3 mL per day. [Dose must not exceed 28.5 mg once a day (FDA approved dosing)].
If initial criteria are not met, do not approve.

B. Cholestatic pruritus due to PFIC without type 2 specific ABCB11 variants: Must meet all the following:
   1. Patient is at least 5 years old.
   2. Medication is prescribed by a gastroenterology specialist.
   3. Patient has tried and failed, or has an intolerance or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological

class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

- ursodiol
- a bile acid sequestrant (ex: cholestyramine or colesevelam) or rifampin

If initial criteria are met, approve indefinitely, max 4 mL per day. [Dose must not exceed 38 mg once a day (FDA approved dosing).]
If initial criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with the requested medication?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Cholestatic pruritus due to Alagille syndrome (ALGS), a type of genetic disorder; Cholestatic pruritus due to progressive familial intrahepatic cholestasis (PFIC), a type of genetic disorder, without type 2 specific ABCB11 variants]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Cholestatic pruritus due to Alagille syndrome (ALGS)
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (ursodiol tablets, colesevelam tablets, cholestyramine powder, colestipol tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Cholestatic pruritus due to progressive familial intrahepatic cholestasis (PFIC)
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (ursodiol tablets, colesevelam tablets, cholestyramine powder, colestipol tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

- Use should be reserved last line for patients with ALGS syndrome or PFIC without type 2 specific ABCB11 variants who have not found adequate relief with off label currently available therapies such as ursodiol, cholestyramine, colesevelam, antihistamines rifampin, naltrexone.
- No comparator trials exist.
- For ALGS the FDA approval of maralixibat was based on the Phase 2b ICONIC study, in 31 pediatric patients with ALGS with cholestasis and pruritus. All patients in the study had the *JAG1* mutation, at least three times the normal serum bile acid levels and intractable pruritus at baseline. More than 90% of enrolled patients were receiving ursodeoxycholic acid, rifampicin, or both, baseline. The study met its primary endpoint in the 15 patients who met the ≥50% serum bile acid reduction from baseline criteria.
- **For PFIC** the FDA approval was based on the phase 3 March-PFIC trial in 93 patients 5 years of age and older, most patients were also receiving ursodeoxycholic acid (89% or rifampin (51%). Results showed treatment with maralixibat met the primary endpoint demonstrating a statistically significant difference from placebo in pruritus symptoms based on the mean change in average

morning ItchRO(Obs) pruritus severity score between baseline and weeks 15 to 26 (mean difference from placebo, -1.2 [95% CI, -1.7, -0.7]; *P* <.0001).

- Cost: $558,000 for a 5 kg to 29 kg patient and up to $1,674,000 for a 70kg patient at max dose compared to off label therapies of $144-672 per year
- Maralixibat can only be purchased from Mirum Pharmaceuticals' own specialty pharmacy, MAP.

FDA APPROVED INDICATIONS

ALGS syndrome or PFIC without type 2 specific ABCB11 variants

REFERENCES

1. Mirum Pharmaceuticals' Livmarli receives FDA approval for treatment of cholestatic pruritus in patients with progressive familial intrahepatic cholestasis. News release. Mirum Pharmaceuticals. March 13, 2024. Accessed March 14, 2024.
2. Efficacy and safety of maralixibat treatment in patients with Alagille syndrome and cholestatic pruritus (ICONIC): a randomized phase 2 study. www.thelancet.com Vol 398 October 30, 2021.
3. Livmarli. Package insert. Mirum Pharmaceuticals; 2024. Accessed March 14, 2024. https://files.mirumpharma.com/livmarli/livmarli-prescribinginformation.pdf.

Creation Date: 07/2024
Effective Date: 08/2024
Reviewed Date:
Revised Date:

MAVACAMTEN (CAMZYOS)

Generic	Brand	HICL	GPID	Exception/Other
MAVACAMTEN	CAMZYOS	47972	52233, 52234, 52235, 48867	

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet the following:
1. Patient is new to KPCO within the past 90 days and is currently stable on Camzyos (mavacamten).

If met, approve indefinitely at HICL.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Patient must be age 18 years or older.
2. Symptomatic obstructive hypertrophic cardiomyopathy (oHCM, HOCM) demonstrated by both of the following:
   a. Peak LVOT gradient ≥50 mm Hg
   b. NYHA class II to III symptoms
3. Left ventricular ejection fraction (LVEF) ≥55%
4. No history of syncope or sustained ventricular tachycardia in previous 6 months.
5. QTc interval ≤ 500 ms
6. Patient has not had successful treatment with septal reduction therapy in the previous 6 months
7. Therapeutic failure of (e.g. still symptomatic), failure to tolerate, or contraindication to a beta blocker and/or a nondihydropyridine calcium channel blocker, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

If all the above are met, approve indefinitely at HICL.
If any of the above are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with the requested medication?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Symptomatic obstructive hypertrophic cardiomyopathy (oHCM, HOCM) demonstrated by a peak LVOT gradient greater than or equal to 50 mmHg and NYHA class II to III symptoms? If yes, must attach applicable chart notes with supporting documentation.
4. Does the patient have left ventricular ejection fraction (LVEF) greater than or equal to 55%? If yes, must attach applicable chart notes with supporting documentation.
5. Does the patient have history of syncope or sustained ventricular tachycardia in previous 6 months?
6. Is the patient's QTc interval less than or 500 ms? If yes, must attach applicable chart notes with supporting documentation.
7. Has the patient had successful treatment with septal reduction therapy in the previous 6 months?
8. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

9. Is there reasoning why alternatives (atenolol tablets, metoprolol IR/ER tablets, bisoprolol tablets, carvedilol tablets, labetalol tablets, acebutolol capsules, propranolol ER capsules (60 mg, 80 mg, 120 mg, 160 mg) or IR tablets; diltiazem SR [once-daily dosing] capsules (120 mg, 180 mg, 240 mg, 300 mg, 360 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
KP Interregional Practice Recommendations for Mavacamten (Camzyos) 5/15/2022

FDA APPROVED INDICATIONS
Treatment of adults with symptomatic NYHA class II-III obstructive hypertrophic cardiomyopathy

REFERENCES

- KP Interregional Practice Recommendations for Mavacamten (Camzyos) 5/15/2022
- Olivotto I, Oreziak A, Barriales-Villa R, et al. Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet 2020; 396:759-69.
- Camzyos [package insert]. Brisban, CA: MyoKardia, Inc, a wholly-owned subsidiary of Bristol Myers Squibb; revised 4/2024.

Creation Date: 07/2022
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

MEDICAL NECESSITY CRITERIA

GUIDELINES FOR COVERAGE

General Medical Necessity Review Criteria: Must meet all the following:

1. The treatment is not investigational, experimental, or otherwise excluded as defined by the member's contract.
2. The KPCO Pharmacy & Therapeutics (P&T) Committee has not pre-determined that the requested treatment or indication is excluded from coverage.
3. The treatment has been shown to be effective for clinically important outcomes by high-quality studies in the clinical situation for which it is prescribed.
4. The safety record for the treatment is sufficient to ensure that it does not cause harm.
5. The patient has allergies, intolerances, contraindications, or has history of inadequate response to our preferred formulary alternatives, or there is no formulary alternative; or either of the following are met:
    a. The provider has submitted justification and supporting clinical documentation that demonstrates any of the following are met:
        i. the required drug(s) is contraindicated or will likely cause an adverse reaction or harm;
        ii. the required drug(s) is/are ineffective based on known clinical characteristics of the patient and the known characteristics of the drug regimen;
        iii. the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event;
        iv. the patient is stable on the requested drug for the medical condition under consideration after undergoing step therapy or after having sought and received a step therapy exception.
    b. The requested drug is for treatment of a serious mental illness[1] and the member has tried and failed one prescription drug, other than the drug prescribed by the provider, for the same indication; or, if the member's provider attests on a form established by the division[2] that any of the criteria specified in subsections (4)(a)(I) to (4)(a)(IV) of § 10-16-145, C.R.S. are met.

RATIONALE

This guideline establishes criteria for determining medical necessity in medication reviews. It ensures that requested treatments are supported by evidence-based medical literature, demonstrates safety and efficacy, and aligns with plan benefit coverage. The policy applies to medications subject to utilization restrictions (UM) that either lack specific criteria approved by the Pharmacy and Therapeutics (P&T) Committee or do not yet have established criteria for the requested indication.

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[1] *Serious mental illness, as defined by the American Psychiatric Association in the most recent version of the Diagnostic and Statistical Manual of Mental Disorders: (I) Bipolar disorders (hypomanic, manic, depressive, and mixed); (II) Depression in childhood and adolescence; (III) Major depressive disorders (single episode or recurrent); (IV) Obsessive-compulsive disorders; (V) Paranoid and other psychotic disorders; (VI) Schizoaffective disorders (bipolar or depressive); and (VII) Schizophrenia.*

[2] *KPCO Serious Mental Illness Step Therapy Exception Form*

REFERENCES

Per KPCO Health Plan, Pharmacy Benefits Department
Per CRS 10-16-145 Step Therapy (4.5) (a) and (b)
Per CRS 10-16-145 Step Therapy (4)(a) (I-IV)

Creation Date: 05/2025
Effective Date: 06/2025
Reviewed Date: n/a
Revised Date: n/a

NUCALA (MEPOLIZUMAB) - COGS

Generic	Brand	HICL	GPID	Exception/Other
MEPOLIZUMAB	NUCALA	42775	46413, 46414	NF- Comm, Hx, Fed; F-SF

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Medication is prescribed by an Allergist, Pulmonologist, ENT Specialist, or Rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient is new to KPCO within the past 90 days, noted as stable on therapy with Nucala, and meets one of the following indication-specific criteria:
   a. Patient has a diagnosis of EGPA (Churg-Strauss syndrome)
   b. Patient has a diagnosis of Chronic rhinosinusitis with nasal polyposis (CRSwNP) and has failed therapy with, or has contraindications to Dupixent, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
   c. Patient has a diagnosis of asthma and has failed therapy with, or has contraindications to Fasenra, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
   d. Patient has a diagnosis of hematologic hypereosinophilic syndromes

If criteria are met for hematologic hypereosinophilic syndromes, approve to finish total therapy duration of 8 months, max 1 dose per 28 days.
If criteria are met for other indications, approve indefinitely, max 1 dose per 28 days.
If criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following diagnoses and meet the diagnosis-specific criteria below:

A. Eosinophilic granulomatosis with polyangiitis (EGPA - i.e. Churg-Strauss syndrome)
B. Chronic rhinosinusitis with nasal polyposis (CRSwNP)
C. Asthma (moderate/severe)
D. Hematologic hypereosinophilic syndromes

A. Eosinophilic granulomatosis with polyangiitis (EGPA - i.e. Churg-Strauss syndrome): Must meet all the following:
   1. Medication is prescribed by an Allergist, Pulmonologist, or Rheumatologist.
   2. Medication is not being used in combination with another biologic for the same indication.

If initial criteria are met, approve indefinitely, max 1 dose per 28 days.
If initial criteria are not met, do not approve.

B. Chronic rhinosinusitis with nasal polyposis (CRSwNP): Must meet all the following:
   1. Medication is prescribed by an Allergist, Pulmonologist, or ENT specialist.
   2. Medication is not being used in combination with another biologic for the same indication.
   3. Patient has persistent rhinosinusitis symptoms (lasting longer than 12 weeks) with severe nasal obstruction and rhinorrhea or reduced sense of smell.
   4. Patient has had sinus surgery.
   5. Patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      - At least one intranasal corticosteroid [e.g. fluticasone, mometasone, etc.]
      - At least one antileukotriene antagonists [e.g. montelukast, zafirlukast, zileuton]
      - Two or more courses of oral corticosteroids in the past year
      - Dupilumab [PA required]

      If initial criteria are met, approve indefinitely, max 1 dose per 28 days.
      If initial criteria are not met, do not approve.

C. Asthma (moderate / severe): Must meet all the following:
   1. Medication is prescribed by an Allergist or Pulmonologist.
   2. Medication is not being used in combination with another biologic for the same indication.
   3. Must have uncontrolled asthma as evidenced by ANY one of the following:
      - Two or more asthma exacerbations requiring systemic corticosteroids (3 or more days each) in the past 12 months
      - one asthma-related hospitalization in the past 12 months
      - Asthma Control Test (ACT) consistently less than 20
   4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      - Patient is adherent (more than 75% proportion of days covered) to optimized triple drug therapy with high-dose ICS-LABA plus tiotropium (Spiriva Respimat) for the previous 6 months.
      - Patient has tried and failed benralizumab (Fasenra) [PA required].

      If initial criteria are met, approve indefinitely, max 1 dose per 28 days.
      If initial criteria are not met, do not approve.

D. Hematologic hypereosinophilic syndromes: Must meet all the following:
   1. Medication is prescribed by a hematologist.
   2. Medication is not being used in combination with another biologic for the same indication.
   3. Patient has an absolute eosinophil count of greater than 1.5 cells/μL on 2 occasions more than 1 month apart or tissue showing 20% involvement on bone marrow or other tissue infiltration.
   4. Patient has documented end organ dysfunction caused by this syndrome.
   5. FIP1L1-PDGFRA mut negative
   6. Patient has been diagnosed for at least 6 months.
   7. Patient has had disease relapse after at least 2 previous trials of systemic corticosteroids in conjunction with hydroxyurea, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

      If initial criteria are met, approve x8 months, max 1 dose per 28 days.
      If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following criteria:
1. Patient was previously authorized for coverage of Nucala for the treatment of EGPA, asthma, or CRSwNP.

If met, approve indefinitely, max 1 dose per 28 days.
If renewal criteria are not met, do not approve.
[Nucala for the treatment of hematologic hyper-eosinophilic syndromes is not designed as an open-ended intervention.]

ePA Questions
1. Is the patient using another biologic for the same indication?
2. Is the patient stable on therapy with the requested medication?
3. For patients noted stable on therapy, start date of therapy (MMDDYY):
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Eosinophilic Granulomatosis with Polyangiitis (EGPA, i.e. Churg-Strauss Syndrome); Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP); Asthma (Moderate/Severe); Hematologic Hypereosinophilic Syndromes]

QUESTIONS BASED ON DIAGNOSIS SELECTED

CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS (CRSwNP)
1. Does the patient have persistent rhinosinusitis symptoms (lasting longer than 12 weeks) with severe nasal obstruction and rhinorrhea or reduced sense of smell?
2. Has the patient had sinus surgery?
3. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone, mometasone, etc.], antileukotriene antagonists [e.g., montelukast]) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

5. How many courses of oral corticosteroids has the patient taken for this indication in the past year?

Moderate/Severe Asthma

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (triple drug therapy with high-dose ICS-LABA plus tiotropium (Spiriva Respimat)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.
3. Has the patient experienced any of the following (check any/all boxes that apply):
   a. Two or more asthma exacerbations requiring systemic corticosteroids (at least 3 days each) in the past 12 months
   b. one asthma-related hospitalization in the past 12 months
   c. Asthma Control Test (ACT) consistently less than 20

Hematologic Hypereosinophilic Syndromes

1. Has the patient had an absolute eosinophil count of greater than 1.5 on 2 occasions more than 1 month apart or tissue showing 20% involvement on bone marrow or other tissue infiltration? If yes, you must attach applicable chart notes with supporting documentation.
2. Does the patient have end organ dysfunction caused by this syndrome? If yes, you must attach applicable chart notes with supporting documentation.
3. Does the patient have FIP1L1-PDGFRA mutation?
4. Date of diagnosis for this patient (MMDDYY):
5. Has the patient had disease relapse after at least 2 previous trials of systemic corticosteroids in conjunction with hydroxyurea? If yes, you must attach applicable chart notes with supporting documentation.

RATIONALE

Per Health Plan and current treatment guidelines.

Although other agents may also be effective for EGPA and are reasonable, mepolizumab generally has the largest body of evidence to support its use.

New member criteria notes: Patients coming into KPCO stable on therapy with Nucala for any indication other than EGPA could/should be considered for transition to KPCO's more preferred therapies as outlined in Initial Criteria.

FDA APPROVED INDICATIONS

Asthma, severe eosinophilic: Add-on maintenance treatment of severe asthma in adults and pediatric patients ≥6 years of age with an eosinophilic phenotype.

Eosinophilic granulomatosis with polyangiitis (Churg-Strauss): Treatment of adult patients with eosinophilic granulomatosis with polyangiitis.

Hypereosinophilic syndrome: Treatment of adult and pediatric patients ≥12 years of age with hypereosinophilic syndrome for ≥6 months without an identifiable nonhematologic secondary cause.

Rhinosinusitis with nasal polyps: Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps in adults with an inadequate response to nasal corticosteroids.

REFERENCES

Table 1: High-dose ICS and High-dose ICS plus LABA combinations for Age ≥12 years

fluticasone/salmeterol DPI (Advair Diskus) 500/50 mcg, 1 inh twice daily
fluticasone/salmeterol MDI (Advair HFA) 230/21 mcg, 2 puffs twice daily
mometasone/formoterol MDI (Dulera) 200/5 mcg, 2 puffs twice daily
ciclesonide MDI (Alvesco) 160 mcg, 2 puffs twice daily
fluticasone MDI (Flovent HFA) 220 mcg, 2 puffs twice daily
Budesonide DPI (Pulmicort Flexhaler) 180 mcg, 4 inh twice daily
Mometasone MDI (Asmanex HFA) 200 mcg, 2 puffs twice daily
Mometasone DPI (Asmanex Twisthaler) 220 mcg, 2 inh twice daily

Creation Date: 10/2021
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

METHYLNALTREXONE (RELISTOR) - INJECTABLE FORMS

Generic	Brand	HICL	GPID	Exception/Other
METHYLNALTREXONE	RELISTOR	35611	99722, 31278, 31279	Non-Formulary Available as oral and injectable forms. This criteria specific to injections.

GUIDELINES FOR COVERAGE
Must meet all the following:

1. The patient is 18 years of age or older
2. The patient uses opioids chronically and has a diagnosis of opioid induced constipation (OIC)
3. The patient is unable to take oral medications or unable to use any oral laxatives through feeding tube
4. The patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. one stimulant laxative (contains sennosides or bisacodyl and examples may include Senokot, Ex-Lax, and Dulcolax)
    b. one osmotic laxative (contains magnesium hydroxide, polyethylene glycol, lactulose, magnesium citrate, or glycerin and examples may include milk of magnesia or Miralax)
    c. lubiprostone
    d. Movantik, Symproic, or oral Relistor

If criteria are met, approve indefinitely at HICL.
If criteria are not met, do not approve.

ePA Questions

1. Is the patient currently using opioids chronically?
2. Is the patient unable to take medications orally or through feeding tube?
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (stimulant laxative, osmotic laxative) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Plan.

NOTE: KPCO Palliative Care department is now the KPCO Supportive Care department, if looking through KPHC you may find notes from Supportive Care which is the same as palliative care.

Creation date: 4/6/2020
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2025

METHYLNALTREXONE (RELISTOR) - ORAL

Generic	Brand	HICL	GPID	Exception/Other
METHYLNALTREXONE	RELISTOR	35611	41923	Non-Formulary Available as oral form injectable forms. This criteria specific to oral form.

GUIDELINES FOR COVERAGE
Must meet all the following:
1. The patient is 18 years of age or older
2. The patient uses opioids chronically and has a diagnosis of opioid induced constipation (OIC)
3. The patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. one stimulant laxative (contains sennosides or bisacodyl and examples may include Senokot, Ex-Lax, and Dulcolax)
    b. one osmotic laxative (contains magnesium hydroxide, polyethylene glycol, lactulose, magnesium citrate, or glycerin and examples may include milk of magnesia or Miralax)
    c. lubiprostone
    d. Movantik and/or Symproic

If criteria are met, approve indefinitely at GPID, max 1 tablet per day.
If criteria are not met, do not approve.

ePA Questions
1. Is the patient currently using opioids chronically?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (stimulant laxative, osmotic laxative) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Plan.

NOTE: KPCO Palliative Care department is now the KPCO Supportive Care department, if looking through KPHC you may find notes from Supportive Care which is the same as palliative care

REFERENCES
Per Plan.

Creation date: 4/6/2020
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2024

METRONIDAZOLE 500 MG/5 ML SUSPENSION - AGE RESTRICTION CRITERIA

Generic	Brand	HICL	GPID	Exception/Other
METRONIDAZOLE 500 MG/5 ML	LIKMEZ	04157	54839	Formulary

GUIDELINES FOR COVERAGE

INITIAL AND RENEWAL CRITERIA: ONE of the following criteria must be met:
1. Patient is 10 years old or younger.
2. Patient is using an alternative administration route, such as a gastrostomy tube.
3. Dose cannot be obtained by using half, whole, or combination of the metronidazole tablets (250 mg, 500 mg) or capsules (375 mg)
4. Patient cannot swallow tablets whole, halved, or crushed (with or without mixing in applesauce)

If any criterion is met, approve x1 year at GPID.
If no criteria are met, do not approve. May suggest using tablet strengths that can be halved or used in combination, or crushing/opening metronidazole tablets/capsules before administration and taking with or without applesauce.

ePA Questions
1. Is the patient using an alternative administration route, such as a gastrostomy tube? If yes, must attach applicable chart notes.
2. Is the patient unable to swallow tablets whole, halved, or crushed (with or without mixing in applesauce)? If yes, must attach applicable chart notes.

RATIONALE
Per Health Plan.

General Clinical Criteria for solutions/suspension
1. Age is less than or equal to 10 years old
2. Presence of gastrostomy
3. Dose does not allow use of halved, whole or combo of tablet
4. Dose does not use whole capsule (cannot “cut” capsules in half)
5. Clinical condition where unable to swallow crushed/opened tablets/capsules (i.e., esophageal stricture)

FDA APPROVAL
1. Amebiasis: Treatment of acute intestinal amebiasis (amebic dysentery) and extraintestinal amebiasis (liver abscess).
2. Anaerobic bacterial infections (caused by Bacteroides spp., including the B. fragilis group):
   a. Bone and joint infections: Treatment (adjunctive therapy) of bone and joint infections.
   b. CNS Infections: Treatment of CNS infections, including meningitis and brain abscess.
   c. Endocarditis: Treatment of endocarditis.
   d. Gynecologic infections: Treatment of gynecologic infections including endometritis, endomyometritis, tubo-ovarian abscess, and postsurgical vaginal cuff infection (also caused by Clostridium spp., Peptococcus spp., Peptostreptococcus spp., and Fusobacterium spp.).
   e. Intra-abdominal infections: Treatment of intra-abdominal infections, including peritonitis, intra-abdominal abscess, and liver abscess (also caused by Clostridium spp., Eubacterium spp., Peptococcus spp., and Peptostreptococcus spp.).
   f. Lower respiratory tract infections: Treatment of lower respiratory tract infections, including pneumonia, empyema, and lung abscess.

g. Sepsis: Treatment of sepsis including bloodstream infection (also caused by Clostridium spp.).
h. Skin and skin structure infections: Treatment of skin and skin structure infections (also caused by Clostridium spp., Peptococcus spp., Peptostreptococcus spp., and Fusobacterium spp.).

3. Surgical prophylaxis (colorectal surgery): Injection: Preoperative, intraoperative, and postoperative prophylaxis to reduce the incidence of postoperative infection in patients undergoing elective colorectal surgery classified as contaminated or potentially contaminated.
4. Trichomoniasis: Treatment of infections caused by Trichomonas vaginalis, including treatment of asymptomatic sexual partners.

Creation Date: 07/2024
Effective Date: 08/2024
Reviewed Date:
Revised Date:

MIFEPRISTONE (KORLYM)

Generic	Brand	HICL	GPID	Exception/Other
MIFEPRISTONE 300MG	KORLYM		31485	Non-Formulary

NOTE: only the 300mg strength follows this guideline

GUIDELINES FOR COVERAGE

All the following must be met:

1. Must be prescribed by an Endocrinologist
2. Patient has diagnosis of endogenous Cushing's syndrome with type 2 diabetes or glucose intolerance
3. Patient has tried and failed or has a contraindication to oral ketoconazole, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception
4. Patient has tried and failed, is not a candidate for, or is awaiting surgical/radiologic interventions

If criteria are met, approve indefinitely, at GPID, max daily dose of 4 tablets.
If criteria are not met, do not approve.

ePA Questions

1. Does the patient have endogenous Cushing's syndrome, with type 2 diabetes or glucose intolerance?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (ketoconazole tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
4. Regarding surgical/radiologic intervention, please check the box that most accurately describes this patient:
   a. The patient is not a candidate for surgical/radiologic intervention
   b. The patient is awaiting surgical/radiologic intervention
   c. The patient has failed surgical/radiologic intervention

RATIONALE

To ensure appropriate use of Korlym.

FDA APPROVED INDICATIONS

• Korlym is a cortisol receptor antagonist indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing’s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery
• Korlym should not be used for the treatment of diabetes type 2 unrelated to endogenous Cushing’s syndrome.

REFERENCES

1. Korlym [Prescribing Information]. Menlo Park, CA: Corcept Therapeutics; March 2012.

2. Hamrahian, AH et al. AACE/ACE diiseasse state clinical review: medical management of Cushing's disease. Endo Practice. 20(7); July 7, 2014.

Creation date: 11/28/2016
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2024

MIGLUSTAT (ZAVESCA, YARGESA)

Generic	Brand	HICL	GPID	Other
MIGLUSTAT	ZAVESCA, YARGESA	25098	19453	Specialty Non-formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

A. Request is for generic miglustat, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

B. Must be prescribed by, or in consultation with a specialist in the area of the patient's diagnosis (e.g., endocrinologist, hematologist or geneticist).

C. Must be prescribed as monotherapy and is not given in combination with other SRT agents or enzyme replacement therapies [velaglucerase (Vpriv), imiglucerase (Cerezyme), or taliglucerase (Elelyso)].

D. Must have one of the following diagnoses and meet the disease specific criteria below:

1. **Gaucher Disease Type 1.** Must meet all the following:
   a. Patient must be age 18 or older
   b. Prior to any treatment for the intended diagnosis, patient has had at least ONE of the following clinical presentations:
      - Anemia (Hgb <13 g/dL in men, <12 g/dL in women)
      - Thrombocytopenia (platelet count <100,000/µL)
      - Hepatomegaly
      - Splenomegaly
      - Growth failure
      - Evidence of bone disease not due to other causes
   c. Patient has documented mild-to-moderate Type 1 Gaucher disease in whom enzyme replacement therapy [Elelyso (taliglucerase alfa) is KP preferred] is not a therapeutic option (e.g. due to allergy, hypersensitivity, or poor venous access), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

   If initial criteria are met, approve at GPID-g x12 months (unless provider notes failure of generic, then approve at GPID).
   If initial criteria are not met, do not approve.

2. **Niemann-Pick disease Type C.** Must meet all the following
   a. Patient must be age 4 or older

b. Documented mild-to-moderate neurologic manifestations (e.g., ataxia, vertical supranuclear gaze palsy), psychiatric manifestations (e.g., psychosis), cognitive manifestations, or splenomegaly.

If initial criteria are met, approve at GPID-g x12 months (unless provider notes failure of generic, then approve at GPID).
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following disease specific criteria:
1. Gaucher Disease Type 1: Patient has demonstrated clinical symptom improvement or stability since starting on the drug, and no new contraindications to use, to at least one of the following:
   - Hemoglobin level
   - Platelet count
   - Liver volume
   - Spleen volume
   - Growth
   - Bone pain or crisis
2. Niemann-Pick disease Type C: Patient has demonstrated clinical improvement or stability in neurologic, psychiatric, or cognitive symptoms since starting on the drug and has no new contraindications to use.

   If renewal criteria are met, approve at GPID-g x12 months (unless provider notes failure of generic, then approve at GPID).
   If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Will the requested medication be used in combination with other SRT agents or enzyme replacement therapies [velaglucerase (Vpriv), imiglucerase (Cerezyme), or taliglucerase (Elelyso)]? If yes, must provide explanation in Provider Comment section below or attach applicable chart notes.
2. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Gaucher Disease Type 1; Niemann-Pick disease Type C]
   QUESTIONS BASED ON DIAGNOSIS SELECTED
   Gaucher Disease Type 1
   1. Prior to any treatment for the intended diagnosis, has the patient had any of the following clinical presentations: [check boxes for all diagnoses listed in criteria: Anemia (Hgb <13 g/dL in men, <12 g/dL in women); Thrombocytopenia (platelet count <100,000/µL); Hepatomegaly; Splenomegaly; Growth failure; Evidence of bone disease not due to other causes]
   2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   3. Is there reasoning why alternatives (enzyme replacement therapy [Elelyso (taliglucerase alfa)] is not a therapeutic option (e.g. due to allergy, hypersensitivity, or poor venous access)? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

   Niemann-Pick disease Type C
   1. Has the patient had any of the following clinical presentations: [check boxes for all diagnoses listed in criteria: neurologic manifestations (e.g., ataxia, vertical supranuclear

gaze palsy); psychiatric manifestations (e.g., psychosis); cognitive manifestations; splenomegaly]

Renewal Review Questions

Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Gaucher Disease Type 1; Niemann-Pick disease Type C]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Gaucher Disease Type 1

1. Please indicate by checking the applicable box(es) which clinical symptoms have improved since starting eliglustat (Cerdelga): [Hemoglobin level; Platelet count; Liver volume; Spleen volume; Growth; Bone pain or crisis]

Niemann-Pick disease Type C

1. Has the patient demonstrated clinical improvement or stability in neurologic, psychiatric, or cognitive symptoms since starting on the drug?
2. Does the patient have new contraindications to use?

RATIONALE

Cerdelga (eliglustat) has been shown to be non-inferior to enzyme replacement therapy (ERT) and is a first-line option for Gaucher Disease. Zavesca (miglustat) is a second-line alternative to ERT.

Per the 2018 consensus guidelines for Niemann-Pick Disease Type C (NPC), miglustat is the only disease modifying medication that may be used in the treatment of neurological manifestations of NPC. Miglustat may halt or attenuate disease progression in some patients. Miglustat is currently used off-label in treatment of NPC in the United States.

FDA APPROVED INDICATIONS

Cerdelga (eliglustat): Treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers, intermediate metabolizers, or poor metabolizers.

Zavesca (miglustat): Treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (eg, due to allergy, hypersensitivity, or poor venous access).

REFERENCES

1. Bennett LL, Fellner C. Pharmacotherapy of Gaucher Disease: Current and Future Options. *P T*. 2018;43(5):274-309.
2. Rosenbloom BE, Cox TM, Drelichman GI, et al. Encore - a randomized, controlled, open-label non-inferiority study comparing ELIGLUSTAT to imiglucerase in Gaucher disease type 1 patients stabilized on enzyme replacement therapy: 24-month results. *Blood*. 2014;124(21):1406-1406. Doi:10.1182/blood.v124.21.1406.1406
3. Geberhiwot T, Moro A, Dardis A, et al. Consensus clinical management guidelines for Niemann-Pick disease type C. Orphanet J Rare Dis. 2018;13(1):50. Published 2018 Apr 6. Doi:10.1186/s13023-018-0785-7

Creation Date: 07/2022
Effective Date: 10/2024
Reviewed Date: 09/2024
Revised Date: 09/2024

MILNACIPRAN

Generic	Brand	HICL	GPID	Other
MILNACIPRAN	SAVELLA	21229		Formulary

GUIDELINES FOR COVERAGE

Must meet all the following:

1. Patient is 18 years of age or older.
2. Patient has a diagnosis of fibromyalgia.
3. Patient has tried and failed or has an intolerance or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. At least one TCA or cyclobenzaprine (IF < 65 years of age)
    b. At least one SNRI
    c. gabapentin or pregabalin

If criteria are met, approve indefinitely at HICL, max daily dose of 2 tablets.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (gabapentin tablets (600 mg, 800 mg) or capsules (100 mg, 300 mg, 400 mg), pregabalin capsules; duloxetine capsules (20 mg, 30 mg, 60 mg), venlafaxine ER capsules; amitriptyline tablets, nortriptyline capsules, desipramine tablets, imipramine tablets; cyclobenzaprine 10 mg tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Ensure appropriate utilization of preferred drug therapies

FDA APPROVED INDICATIONS

Fibromyalgia in adults.

REFERENCES

1. KPHC Fibromyalgia SmartRx
2. Pregabalin Drug Use Guidelines: https://cl.kp.org/natl/home/refcontainerpage.dam.html?damrefpath=/content/dam/clinicallibrary/co/operations/department/pharmacy/PriorAuth/lyrica.pdf

Creation Date: 09/2020
Effective Date: 12/2024
Reviewed Date: 11/2024
Revised Date: 11/2024

MIRABEGRON (MYRBETRIQ)

Generic	Brand	HICL	GPID	Exception/Other
MIRABEGRON	MYRBETRIQ TABLETS AND GRANULES (8MG/ML SUS ER REC)	39357	32766, 32767, 49454	Nonformulary with max daily dose of 1/day

GUIDELINES FOR COVERAGE
Must have one of the following diagnoses and meet all the diagnosis-specific criteria:

A. OVERACTIVE BLADDER AND MYASTHENIA GRAVIS
B. OVERACTIVE BLADDER WITHOUT MYASTHENIA GRAVIS
C. PEDIATRIC PATIENTS WITH NEUROGENIC DETRUSOR OVERACTIVITY

A. PATIENTS WITH A DIAGNOSIS OF OVERACTIVE BLADDER AND MYASTHENIA GRAVIS: Must meet all of the following criteria:
   1. Patient has a diagnosis of overactive bladder, urge incontinence, urgency, urinary frequency or bladder spasm.
   2. Patient has a diagnosis of myasthenia gravis.
   3. Request is for generic mirabegron, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

   If criteria are met, approve at HICL-g indefinitely (unless provider notes failure of generic, then approve at HICL), max daily dose of 1 tablet.
   If criteria are not met, do not approve.

B. PATIENTS WITH A DIAGNOSIS OF OVERACTIVE BLADDER WITHOUT A DIAGNOSIS OF MYASTHENIA GRAVIS: Must meet all the following criteria:
   1. Patient has a diagnosis of overactive bladder, urge incontinence, urgency, urinary frequency or bladder spasm.
   2. Request is for generic mirabegron, and the patient has failed at least one of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception [listed in preferential order]:
      - oxybutynin IR/ER
      - solifenacin
      - trospium IR
      - tolterodine IR/ER

If criteria are met, approve at HICL-g indefinitely (unless provider notes failure of generic, then approve at HICL), max daily dose of 1 tablet.
If criteria are not met, do not approve.

C. PEDIATRIC PATIENTS WITH A DIAGNOSIS OF NEUROGENIC DETRUSOR OVERACTIVITY: Must meet all the following criteria:
   1. Patient has a diagnosis of neurogenic detrusor overactivity.
   2. Request is for mirabegron (Myrbetriq) granules (8 mg/ml susp).
   3. Patient is between the ages of 3 and 17 years, and meets the following based on age:
      a. Patients 5 to 17 years of age: Trial/failure of, intolerance or contraindication to oxybutynin (ER or syrup preferred) and/or solifenacin (if able to swallow tablets and dose amenable with current tablet strength), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
      b. Patients 3 to 4 years of age: no additional requirements

If criteria above are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (trospium 20 mg tablets, solifenacin (5 mg, 10 mg), oxybutynin IR (5 mg) or ER (5 mg, 10 mg, 15 mg) tablets, OTC* oxybutynin patches (Oxytrol)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Per Health Plan.

- An adequate response is defined as one less episode of frequency or incontinence per day after an adequate trial of 4-6 weeks. Patients with a diagnosis of myasthenia gravis should avoid the use of anticholinergic agents.
- Preferred formulary agents, in order: oxybutynin ER, oxybutynin IR, solifenacin, trospium IR and oxybutynin syrup.
- Oral oxybutynin is not preferred in patients with dementia or cognitive impairment. Darifenacin is a preferred non-formulary option for patients with history of cognitive issues after solifenacin and trospium IR.
- Preferred nonformulary agents in order: tolterodine IR, tolterodine ER, darifenacin, fesoterodine, trospium ER, mirabegron and vibegron, Oxybutynin gel (Gelnique) and oxybutynin patch (Oxytrol) are excluded from coverage.
- Mirabegron granules are FDA approved for pediatric patients 3 to 17 years of age for neurogenic detrusor overactivity. Both oxybutynin (ER formulation) and solifenacin are FDA approved for neurogenic detrusor overactivity.

FDA APPROVED INDICATIONS
See individual medication.

REFERENCES

Creation Date: 9/26/2019
Effective Date: 10/2024
Reviewed Date: 09/2024
Revised Date: 09/2024

SYNAREL (NAFARELIN)

Generic	Brand	HICL	GPID	Comments
NAFARELIN	SYNAREL	21103	84354	Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Must be prescribed by an Obstetrician/Gynecologist or an Endocrinologist
2. Must have a diagnosis of either endometriosis or central precocious puberty
3. Must have trial and failure of, or intolerance or contraindication to, leuprolide acetate, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

If initial criteria are met, approve at GPID x 6 months.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Adherence to nafarelin therapy
2. Significant improvement of treated condition:
   a. Endometriosis: Pain, abnormal menstrual bleeding, or other symptoms of endometriosis
   b. Central precocious puberty: Suppression of pubertal growth as measured by height, bone measurements, etc.

If renewal criteria are met, approve at GPID x 12 months.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication(s), strength, date(s) of treatment, and reasoning for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there a reason alternative (leuprolide acetate) are not suitable? If yes, must list reasoning in the Provider Comment section below or attach applicable chart notes.

Renewal Questions
1. Diagnosis associated with this request [check boxes for all diagnoses listed in criteria: endometriosis or central precocious puberty]
   QUESTIONS BASED ON DIAGONSIS SELECTED
   Endometriosis
   1. Has the patient had significant improvement in pain, abnormal menstrual bleeding, or other symptoms of endometriosis?
   Central precocious puberty
   1. Has the patient had suppression of pubertal growth as measured by height, bone, measurements, etc.?

RATIONALE
Per Health Plan and current treatment guidelines

FDA APPROVED INDICATIONS
Endometriosis
Central precocious puberty

REFERENCES

Creation Date: 10/2021
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 09/2023

NALDEMEDINE (SYMPROIC)

Generic	Brand	HICL	GPID	Exception/Other
NALDEMEDINE	SYMPROIC	44176		Non-Formulary

GUIDELINES FOR COVERAGE
Must meet all the following:
1. The patient is 18 years of age or older
2. The patient uses opioids chronically and has a diagnosis of opioid induced constipation (OIC)
3. The patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. one stimulant laxative (contains sennosides or bisacodyl and examples may include Senokot, Ex-Lax, and Dulcolax)
    b. one osmotic laxative (contains magnesium hydroxide, polyethylene glycol, lactulose, magnesium citrate, or glycerin and examples may include milk of magnesia or Miralax)
    c. lubiprostone
    d. Movantik

If criteria are met, approve indefinitely at HICL, max 1 tablet per day.
If criteria are not met, do not approve.

ePA Questions
1. Is the patient currently using opioids chronically?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (stimulant laxative, osmotic laxative) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Plan.

NOTE: KPCO Palliative Care department is now the KPCO Supportive Care department, if looking through KPHC you may find notes from Supportive Care which is the same as palliative care

Creation date: 4/6/2020
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2024

NALOXEGOL (MOVANTIK)

Generic	Brand	HICL	GPID	Exception/Other
NALOXEGOL	MOVANTIK	41686		Non-Formulary

GUIDELINES FOR COVERAGE
Must meet all the following:
1. The patient is 18 years of age or older
2. The patient uses opioids chronically and has a diagnosis of opioid induced constipation (OIC)
3. The patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. one stimulant laxative (contains sennosides or bisacodyl and examples may include Senokot, Ex-Lax, and Dulcolax)
    b. one osmotic laxative (contains magnesium hydroxide, polyethylene glycol, lactulose, magnesium citrate, or glycerin and examples may include milk of magnesia or Miralax)
    c. lubiprostone

If criteria are met, approve indefinitely at HICL, max 1 tablet per day.
If criteria are not met, do not approve.

ePA Questions
1. Is the patient currently using opioids chronically?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (stimulant laxatives, osmotic laxatives) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Plan.

NOTE: KPCO Palliative Care department is now the KPCO Supportive Care department, if looking through KPHC you may find notes from Supportive Care which is the same as palliative care

Creation date: 4/6/2020
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2024

NEDOSIRAN SODIUM (RIVFLOZA)

Generic	Brand	HICL	GPID	Exception/Other
NEDOSIRAN	RIVFLOZA	49234	54817	Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

1. Patient has a diagnosis of primary hyperoxaluria type 1 (PH1) with documented genetic testing confirming *AGXT* mutation.
2. Medication is prescribed by a nephrologist or urologist specialist.
3. Metabolic testing demonstrating:
   i. Elevated 24-hour urine oxalate level – OR –
   ii. Elevated spot urine oxalate:creatinine ratio
4. The patient is maintaining appropriate fluid intake as advised by the treating physician.
5. The patient has a pretreatment estimated glomerular filtration rate (eGFR) greater than or equal to 30mL/min/1.73m^2.
6. No history of liver or kidney transplant.
7. No clinical evidence of systemic oxalosis.
8. The patient is not pregnant or breastfeeding.
9. The patient has tried and failed an appropriate dose of, experienced adverse events with, or has an allergy or contraindication to lumasiran (Oxlumo), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
10. Nedosiran will not be used in combination with lumasiran.
11. Nedosiran will be self-administered.

If initial criteria are met, approve x 1 year at HICL with the following quantity limits:

- 80mg/0.5mL: #1 mL per 30 days [MDD: 0.04mL]
- 128 mg/0.8mL: #0.8mL per 30 days [MDD: 0.03mL]
- 160 mg/mL: #1 mL per 30 days [MDD: 0.04mL]

If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:

1. Documented positive response to therapy (e.g., decrease or normalization in urinary and/or plasma oxalate levels, improvement in kidney function).

If renewal criteria are met, approve x 1 year at HICL with the following quantity limits:

- 80mg/0.5mL: #1 mL per 30 days [MDD: 0.04mL]
- 128 mg/0.8mL: #0.8mL per 30 days [MDD: 0.03mL]
- 160 mg/mL: #1 mL per 30 days [MDD: 0.04mL]

If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Does the patient have a diagnosis of primary hyperoxaluria type 1 (PH1) with documented genetic testing confirming *AGXT* mutation? If yes, must attach applicable chart notes documenting this.
2. Will Nedosiran (Rivfloza) be self-administered?
3. Will Nedosiran (Rivfloza) be used in combination with lumasiran?
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
5. Is there a reasoning why alternatives (e.g., lumasiran (Oxlumo)) is/are not suitable? If yes, must list reasoning in the Provider Comment section below or attach applicable chart notes.
6. Does the patient have clinical evidence of systemic oxalosis?
7. Is the patient maintaining appropriate fluid intake as advised by the treating physician?
8. Does the patient have a history of liver or kidney transplant?
9. Is the patient pregnant or breastfeeding?
10. Pretreatment estimated glomerular filtration rate (eGFR) lab:
11. Date of pretreatment estimated glomerular filtration rate (eGFR) lab (MMDDYY):
12. Has the patient had metabolic testing demonstrating either an elevated 24-hour urine oxalate level – or – an elevated spot urine oxalate:creatinine ratio?

Renewal Review Questions:
1. Has the patient had documented positive response to therapy (e.g., decrease or normalization in urinary and/or plasma oxalate levels, improvement in kidney function, etc.)?

RATIONALE
Ensure appropriate use consistent with FDA-approved indications.

FDA APPROVED INDICATIONS
Primary hyperoxaluria type 1 (PH1) in children 9 years of age and older and adults with relatively preferred kidney function, e.g., estimated glomerular filtration rate (eGFR) of greater than or equal to 30 mL/min/1.73m^2**.**

REFERENCES
Rivfloza Package insert, Costa Mesa, CA: Pyramid Laboratories: 2023.

Creation Date: 11/2024
Effective Date: 12/2024
Reviewed Date:
Revised Date:

NEMOLIZUMAB-ILTO (NEMLUVIO)

Generic	Brand	HICL	GPID	Size	Comments
NEMOLIZUMAB-ILTO	NEMLUVIO	49814	56138	1	Non-Formulary, Specialty tier

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Medication is prescribed by a dermatologist or allergist
2. Patient is new to KPCO within the past 90 days, noted as stable on therapy, and has one of the following indications:
   a. Atopic dermatitis (moderate to severe) in patients 12 years of age and older
   b. Prurigo nodularis in patients 18 years of age and older
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication

If above criteria are met, approve indefinitely at HICL, with the following quantity limits based on indication
- Atopic Dermatitis: max 1 pen per 28 days [MDD: 0.04].
- Prurigo Nodularis: max 2 pens per 28 days [MDD: 0.08].

If above criteria are not met, review by Initial Criteria

INITIAL CRITERIA: Must have one of the following diagnoses and meet all the diagnosis-specific criteria below:

A. GENERAL CRITERIA FOR ALL REQUESTS
B. Patient 12-17 years of age with MODERATE/SEVERE ATOPIC DERMATITIS
C. Patient 18 years of age or older with MODERATE/SEVERE ATOPIC DERMATITIS
D. Patient 12 years of age or older with PRURIGO NODULARIS

A. GENERAL CRITERIA FOR ALL REQUESTS:
1. Must be prescribed by a CPMG or an affiliated dermatologist or allergist
2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication

B. Patient 7-17 years of age with MODERATE/SEVERE ATOPIC DERMATITIS: Must meet all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
1. Patient has experienced an inadequate response, intolerance, or has a contraindication to **one** of the below, or the patient is reported as having very high disease activity (greater than 50% BSA) or prior atopic dermatitis biologic or oral JAK inhibitor therapy within the past 4 months making these therapies inappropriate:
   - Topical corticosteroid
   - Topical calcineurin inhibitor

2. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one**, or contraindication to at least **two** of the following therapies, or the patient is reported as having very high disease activity (greater than 50% BSA) or prior atopic dermatitis biologic or oral JAK inhibitor therapy within the past 4 months making these therapies inappropriate:
    - Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
    - Azathioprine
    - Cyclosporine
    - Methotrexate
    - Mycophenolate
3. Patient has experienced an inadequate response (after at least 3 months), intolerance, or has a contraindication to both of the following:
    - One IL-13 inhibitor: Tralokinumab (Adbry) – preferred [F, PA]
    - One IL-4/IL-13 inhibitor: Dupilumab (Dupixent)

If above criteria are met, approve at HICL x1 fill, max 2 pens per 28 days [MDD: 0.08] (loading dose), then indefinitely at HICL, max 1 pen per 28 days [MDD: 0.04] (maintenance dose).
If above criteria are not met, do not approve.

C. Patient 18 years of age or older with MODERATE/SEVERE ATOPIC DERMATITIS: Must meet all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has experienced an inadequate response, intolerance, or has a contraindication to **one** of the below, or the patient is reported as being on prior atopic dermatitis biologic or oral JAK inhibitor therapy within the past 4 months making these therapies inappropriate:
    - Topical corticosteroid
    - Topical calcineurin inhibitor
2. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one**, or contraindication to at least **two** of the following therapies, or the patient is reported as being on prior atopic dermatitis biologic or oral JAK inhibitor therapy within the past 4 months making these therapies inappropriate:
    - Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
    - Azathioprine
    - Cyclosporine
    - Methotrexate
    - Mycophenolate
3. Patient has experienced an inadequate response (after at least 3 months), intolerance, or has a contraindication to both of the following:
    - One IL-13 inhibitor: Tralokinumab (Adbry) – preferred [F, PA]
    - One IL-4/IL-13 inhibitor: Dupilumab (Dupixent)

If above criteria are met, approve at HICL x1 fill, max 2 pens per 28 days [MDD: 0.08] (loading dose), then indefinitely at HICL, max 1 pen per 28 days [MDD: 0.04] (maintenance dose).
If above criteria are not met, do not approve.

D. DIAGNSOSIS OF PRURIGO NODULARIS: Must meet age criteria and all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Age 18 years of age or older.
   2. Patient with inadequate response (after at least 3 months) or intolerance to ONE of the following:
      - Topical corticosteroid
      - Topical calcineurin inhibitor
      - Intralesional corticosteroid (at least 2 administrations)
   3. Patient with inadequate response (after at least 3 months), intolerance, or contraindication to phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy.
   4. Patient with inadequate response (after at least 2 months) or intolerance to at least **TWO** of the following: (can be within the same drug category):
      - Topical vitamin D analogue (calcipotriene, calcitriol)
      - Gabapentinoid: gabapentin or pregabalin
      - Antidepressant: tricyclic antidepressant, selective serotonin reuptake inhibitor (SSRI), or serotonin and norepinephrine reuptake inhibitor (SNRI)
      - Immunosuppressant: Methotrexate
      - Topical lidocaine (with or without topical amitriptyline and gabapentin)
   5. Patient has experienced an inadequate response (after at least 3 months), intolerance, or has a contraindication to dupilumab (Dupixent)

If above criteria are met, approve indefinitely at HICL, max 2 pens per 28 days [MDD: 0.08].
If above criteria are not met, do not approve.

RATIONALE
Per Health Plan

FDA APPROVED INDICATIONS
Atopic dermatitis (moderate to severe) in patients 12 years of age and older.
Prurigo nodularis in patients 18 years of age and older.

REFERENCES
1. Nemluvio [Prescribing Information]. Dallas, TX: Galderma Laboratories, L.P, December 2024.

Table 1: Relative contraindications of various treatments

Treatment	
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses* (ex: *systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for atopic dermatitis.*

Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities,* active malignancy, *and hypersensitivity*
Mycophenolate	*Hypersensitivity to mycophenolate, active malignancy, pregnancy, breastfeeding, women of childbearing age not using highly effective contraceptive methods. Mycophenolate requires REMS program for females of childbearing age.*

ePA Questions

1. Is the patient stable on therapy with nemolizumab (Nemluvio)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Will the patient use nemolizumab (Nemluvio) in combination with another biologic or advanced small molecule for the same indication?
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Moderate to Severe Atopic Dermatitis; Prurigo Nodularis]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Moderate to Severe Atopic Dermatitis

1. Percent body surface area (BSA) impacted:
2. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (topical corticosteroids, tacrolimus ointment, phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy, azathioprine tablets (50 mg), cyclosporine capsules (25 mg, 100 mg), methotrexate 2.5 mg tablets or 25mg/ml vials, mycophenolate mofetil 250 mg capsules or 500 mg tablets) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Prurigo Nodularis

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (topical corticosteroids, tacrolimus ointment, intralesional corticosteroids, phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy, topical calcipotriene/calcitriol, gabapentin, pregabalin, amitriptyline tablets, nortriptyline capsules, sertraline tablets, escitalopram tablets, citalopram tablets, venlafaxine capsules, duloxetine capsules, methotrexate tablets, topical lidocaine, etc.) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Creation Date: 05/2025
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: N/A

NITAZOXANIDE (ALINIA)

Generic	Brand	HICL	GPID	Comments
NITAZOXANIDE	ALINIA	13845	42761,42763	Specialty tier

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following diagnoses and meet the specific criteria noted below:

A. Cryptosporidiosis
B. Cystoisosporiasis
C. Microsporidiosis, E. bieneusi GI disease
D. Giardiasis
E. H. pylori
F. Ascariasis
G. Balantidiasis
H. Blastocystosis
I. Hymenolepiasis (Hymenolepis nana) dwarf tapeworm
J. Fascioliasis (Fasciola hepatica)

A) Cryptosporidiosis: Must meet one of the following:
1. Patient is severely immunocompromised (e.g. uncontrolled HIV infection but is receiving antiretroviral therapy [ART], solid organ transplant)
2. Patient is immunocompetent but either has severe disease or continued symptoms 2 weeks after symptom onset

If either criterion is met, approve x1 fill, max 14-day supply.
If criteria are not met, do not approve.

B) Cystoisosporiasis: Must meet all the following:
1. Trial and failure of, or intolerance to each of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. trimethoprim/sulfamethoxazole DS
    b. ciprofloxacin

If all criteria are met, approve x1 fill, max 3-day supply.
If criteria are not met, do not approve.

C) Microsporidiosis, E. bieneusi GI disease: Must meet all the following:
1. Diagnosis of E. bieneusi strain specifically
2. Immunocompromised (e.g. uncontrolled HIV infection but is receiving ART, solid organ transplant)
3. Trial and failure of, or intolerance to albendazole, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will

likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If all criteria are met, approve x2 months.
If criteria are not met, do not approve.

D) Giardiasis: Must meet all the following:
1. Trial and failure of, or intolerance to metronidazole (F) or tinidazole (NF), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If met, approve x1 fill, max 3-day supply.
If criteria are not met, do not approve.

E) H. pylori: Must meet all the following:
1. 18 years or older
2. Trial and failure of, intolerance/allergy to, or drug resistance to regimens containing the following therapies, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Clarithromycin
    b. Amoxicillin
    c. Metronidazole

If all criteria are met, approve x1 fill, max 10-day supply.
If criteria are not met, do not approve.

F) Ascariasis: Must meet all the following:
1. Trial and failure of, or intolerance to each of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

a. albendazole (F)
b. ivermectin (F)
c. pyrantel pamoate (NF)

If all criteria are met, approve x1 fill, max 3-day supply.
If criteria are not met, do not approve.

G) Balantidiasis: Must meet all the following:
1. Trial and failure of, or intolerance to each of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. a tetracycline antibiotic
    b. metronidazole (F) or tinidazole (NF)

If all criteria are met, approve x1 fill, max 3-day supply.
If criteria are not met, do not approve.

H) Blastocystosis: Must meet all the following:
1. Severe or prolonged (2 weeks of symptoms) disease
2. Trial and failure of, or intolerance to each of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. metronidazole (F) or tinidazole (NF)
    b. trimethoprim/sulfamethoxazole DS

If all criteria are met, approve x1 fill, max 3-day supply.
If criteria are not met, do not approve.

I) Hymenolepiasis (Hymenolepis nana) dwarf tapeworm: Must meet all the following:
1. Trial and failure of, or intolerance to praziquantel, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
2. At least 11 kg in weight

If all criteria are met, approve x1 fill, max 7-day supply.

If criteria are not met, do not approve.

J) Fascioliasis (Fasciola hepatica): Must meet all the following:
1. Trial and failure of, or intolerance to triclabendazole (NF), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

   If all criteria are met, approve x1 fill, max 7-day supply.
   If criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Minimal to no improvement in symptoms after completion of treatment
2. Confirmation of diagnosis after treatment completion

If criteria are met, approve x1 additional fill.
If criteria are not met, do not approve.

ePA Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Cryptosporidiosis; Cystoisosporiasis; Microsporidiosis, E. bieneusi GI disease; Giardiasis; H. pylori; Ascariasis; Balantidiasis; Blastocystosis; Hymenolepiasis (Hymenolepis nana) dwarf tapeworm; Fascioliasis (Fasciola hepatica)]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Cryptosporidiosis
1. Is the patient severely immunocompromised (e.g. uncontrolled HIV infection but is receiving antiretroviral therapy [ART], solid organ transplant)?
2. Is the patient immunocompetent but either has severe disease or continued symptoms 2 weeks after symptom onset?

Cystoisosporiasis
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (trimethoprim/sulfamethoxazole DS; ciprofloxacin) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Microsporidiosis, E. bieneusi GI disease
1. Is the patient severely immunocompromised (e.g. uncontrolled HIV infection but is receiving antiretroviral therapy [ART], solid organ transplant)?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (albendazole tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Giardiasis

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (metronidazole) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

H. pylori

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (clarithromycin, amoxicillin, metronidazole) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Ascariasis

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (albendazole tablets, ivermectin tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Balantidiasis

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (tetracycline antibiotic; metronidazole) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Blastocystosis

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (trimethoprim/sulfamethoxazole DS; metronidazole) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Hymenolepiasis (Hymenolepis nana) dwarf tapeworm

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (praziquantel tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Fascioliasis (Fasciola hepatica)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (triclabendazole) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Alinia is used to treat many parasitic infections; however, it is costly and may not be the most appropriate first option. This is in place to ensure appropriate use for uncommon infections.

FDA APPROVED INDICATIONS

Infectious Diarrhea

- Cryptosporidiosis

- Giardiasis

REFERENCES

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Creation Date: 01/2022
Effective Date: 12/2024
Reviewed Date: 11/2024
Revised Date: 11/2024

NONFORMULARY MEDICATIONS

GUIDELINES FOR USE OF NONFORMULARY MEDICATIONS (EXCLUDING BRANDS WHEN A GENERIC IS AVAILABLE)

NONFORMULARY USE GUIDELINE FOR Commercial, Healthcare Exchange, Self-Funded & Level Funded Members:
Nonformulary medications, when not excluded from benefit coverage, will be approved when either 1) and 3) – OR – 2) and 3) are met:

1) For medications prescribed for treatment of serious mental illness* the member has tried and failed one prescription drug, other than the drug prescribed by the provider, for the same indication; or, if the member's provider attests on a form established by the division** that any of the criteria specified in subsections (4)(a)(I) to (4)(a)(IV) of CRS 10-16-145 are met, the medication will be covered without requiring step therapy[3].
2) For medications **NOT** being prescribed for treatment of a serious mental illness*, formulary medications treating the same indication have been tried at adequate dosage, taken for an adequate duration, and have been documented as failed, and/or would have adverse effects and/or would be contraindicated, based on individual needs and circumstances, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception[4].
3) The use of the drug must be evidence-based, and either be for an FDA-approved indication or have supporting evidence in CMS approved compendia.

NONFORMULARY USE GUIDELINE FOR Federal Group Members (Groups 600 & 44596):
Nonformulary medications, when not excluded from benefit coverage, will be approved when either 1) and 3) – OR – 2) and 3) are met:

1) For medications prescribed for treatment of serious mental illness* the member has tried and failed one prescription drug, other than the drug prescribed by the provider, for the same indication; or, if the member's provider attests on a form established by the division** that any of the criteria specified in subsections (4)(a)(I) to (4)(a)(IV) of CRS 10-16-145 are met, the medication will be covered without requiring step therapy.
2) For medications **NOT** being prescribed for treatment of a serious mental illness*, formulary medications treating the same indication have been tried at adequate dosage, taken for an adequate duration, and have been documented as failed, and/or would have adverse effects and/or would be contraindicated, based on individual needs and circumstances, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of

[3] CRS 10-16-145 Step Therapy, section (4.5)
[4] CRS 10-16-145 Step Therapy, section (4)(a)

efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
3) The use of the drug must be evidence-based, and either be for an FDA-approved indication or if off-label its use is supported by the clinical evidence from established compendia or peer-reviewed literature and is consistent with generally accepted medical practice. Per OPM Carrier Letter No 2024-05, February 12, 2024, page 7

NONFORMULARY USE GUIDELINE FOR CHP+ Members:
Nonformulary medications, when not excluded from benefit coverage, will be approved when either 1) and 4) are met, 2) and 4) are met, OR 3) and 4) are met:

1) For medications prescribed for treatment of serious mental illness* the member has tried and failed one prescription drug, other than the drug prescribed by the provider, for the same indication; or, if the member's provider attests on a form established by the division** that any of the criteria specified in subsections (4)(a)(I) to (4)(a)(IV) of CRS 10-16-145 are met, the medication will be covered without requiring step therapy.
2) For medications **NOT** being prescribed for treatment of a serious mental illness*, formulary medications treating the same indication have been tried at adequate dosage, taken for an adequate duration, and have been documented as failed, and/or would have adverse effects and/or would be contraindicated, based on individual needs and circumstances, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
3) For select prescribed drugs that are non-formulary outpatient drugs (including drugs authorized for import by the Food and Drug Administration) will be covered when medically necessary during drug shortages identified by the Food and Drug Administration and posted on the linked document: Colorado Covered Prescribed Drugs[5]
4) The use of the drug must be medically necessary: Use of the nonformulary drug is consistent with accepted standards of medical practice; and it is not experimental, investigational, unproven, unusual, or not customary.

CONTRACEPTIVE PRODUCT NONFORMULARY USE GUIDELINE FOR Commercial non-grandfathered plans:
Per Emergency Regulation 23-E-07, Contraceptive Benefit Requirements for Health Benefit Plans, effective 1/1/2024:

- All requests for nonformulary contraceptives are considered to be EXPEDITED
- Carriers must cover all FDA-approved contraceptive products, regardless of OTC or Rx status, without cost sharing.
- If the prescriber determines the contraceptive to be medically necessary, that determination shall be final
- We may outreach the prescriber and ask if they would consider changing to one of our formulary alternatives
- Nonformulary requests for contraceptives cannot be denied

[5] Per MSB 24-05-29-B, Revision to the Medical Assistance Act, section 8.800.4.B

RATIONALE

**Serious mental illness means the following psychiatric illnesses, as defined by the American Psychiatric Association in the most recent version of the Diagnostic and Statistical Manual of Mental Disorders:*
(I) Bipolar disorders (hypomanic, manic, depressive, and mixed);
(II) Depression in childhood and adolescence;
(III) Major depressive disorders (single episode or recurrent);
(IV) Obsessive-compulsive disorders;
(V) Paranoid and other psychotic disorders;
(VI) Schizoaffective disorders (bipolar or depressive); and
(VII) Schizophrenia.

***KPCO Serious Mental Illness Step Therapy Exception Form*

Per KPCO Health Plan, Pharmacy Benefits Department
1 Per CRS 10-16-145 Step Therapy (4.5)(a) and (b)
2 Per CRS 10-16-145 Step Therapy (4)(a)(I-IV)
3To comply with MSB 24-05-29-B, Revision to the Medical Assistance Act concerning the Coverage of FDA-Approved Imported Drugs, Section 8.800.4.B. and provide coverage of any medically necessary non-formulary drugs listed as a prescribed drug when there is a drug shortage identified by the FDA on the linked state document (Covered Prescribed Drugs.pdf).

Created: 1/2019
Effective: 04/2025
Reviewed: 03/2025
Revised: 03/2025

KAISER PERMANENTE

KAISER COLORADO HMO MR GUIDELINES

NON GLP-1 WEIGHT LOSS MEDICATIONS
NALTREXONE-BUPROPION (CONTRAVE)

Generic	Brand	HICL	GPID	Other
NALTREXONE - BUPROPION	CONTRAVE	41389	37096	Nonformulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient must have benefit plan with coverage for weight loss medications.
2. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
3. Patient must have an initial body mass index (BMI) greater than or equal to 30 kg/m2, OR an initial BMI greater than or equal to 27 kg/m2 with at least one weight-related comorbid condition, such as hypertension, dyslipidemia, or type 2 diabetes.
4. Provider attests to patient being on a reduced calorie diet with increased physical activity.
5. Patient has documented intolerance, contraindication*, or failure to lose and maintain at least 5% body weight after a 3-month trial to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception [listed below in preferential order]:
   - either phentermine or diethylpropion
   - Qsymia

   If initial criteria are met, approve at HICL x6 months.
   If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
2. Patient must have achieved and maintained at least a 5% weight loss from baseline (objectively measured with in-office weight checks).

   If met, approve x 1 year at HICL.
   If not met, do not approve.

ePA Questions
Initial Review Questions
1. Patient's current (within the past 4 weeks) weight (lbs):
2. Date of weight (MMDDYY):
3. Patient's current (within the past 4 weeks) BMI:
4. Date of BMI (MMDDYY):
5. Does the provider attest that the patient is on a reduced calorie diet with increased physical activity?

6. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
7. Is there reasoning why alternatives (phentermine 37.5 mg tablets, diethylpropion tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions

1. Patient's current (within the past 4 weeks) weight (lbs):
2. Date of weight (MMDDYY):

RATIONALE

*pregnancy/breast feeding, hyperthyroidism, closed angle glaucoma, uncontrolled HTN, tachycardia, uncontrolled anxiety, recent (14 days) use of MAOI, substance abuse history, hx of cardiovascular disease (arrhythmias, CAD, CVA, systolic CHF), ADHD/ADD meds

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Setmelanotide (Imcivree) for Rare Genetic Disorders of Obesity – Interregional Practice Recommendations
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Creation Date: 3/2020
Effective Date: 10/2024
Reviewed Date: 09/2024
Revised Date: 09/2024

NON GLP-1 WEIGHT LOSS MEDICATIONS
SETMELANOTIDE (IMCIVREE)

Generic	Brand	HICL	GPID	Other
SETMELANOTIDE	IMCIVREE	47002	48922	Nonformulary Specialty tier

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

1. Prescribed by an endocrinologist, a geneticist, or a board-certified obesity medicine specialist.
2. Patient has at least one FDA approved indication:
   a. Obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by:
      i. Genetic testing demonstrating variants in POMC, PCSK1 or LEPR genes
      ii. The genetic variant is interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
   b. Bardet-Biedl Syndrome (BBS) confirmed by generic testing or highly suspected BBS based on review and evaluation by specialist
3. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
4. Patient meets one of the following criteria (a or b):
   a. Patient is 18 years of age or older with a body mass index (BMI) greater than or equal to 30 kg/m2
   b. Patient is 6 to 17 years of age with a BMI above the 95th percentile for age and gender

   If initial criteria are met, approve based on patient age:
   - 18 years of age or older: x6 months at HICL.
   - Under 18 years of age: x12 months at HICL.

   If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:

1. Prescribed by an endocrinologist, a geneticist, or a board-certified obesity medicine specialist.
2. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
3. Patient must have achieved and maintained at least a 5% weight loss from baseline, or 5% of baseline BMI (objectively measured with in-office weight checks).

   If met, approve x 1 year at HICL.
   If not met, do not approve.

ePA Questions
Initial Review Questions

1. Diagnosis associated with this request: [check boxes: Obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency; Bardet-Biedl Syndrome (BBS)]
2. Patient's current (within the past 4 weeks) weight (lbs):
3. Date of weight (MMDDYY):
4. Patient's current (within the past 4 weeks) BMI:
5. Date of BMI (MMDDYY):

QUESTIONS BASED ON DIAGNOSIS SELECTED

Obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency

1. Is the diagnosis confirmed by genetic testing demonstrating variants in POMC, PCSK1 or LEPR genes? If yes, must attach chart notes with supporting documentation.
2. Is the genetic variant is interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)? If yes, must attach chart notes with supporting documentation.

Bardet-Biedl Syndrome (BBS)

1. Is the diagnosis confirmed by generic testing or highly suspected BBS based on review and evaluation by specialist? If yes, must attach chart notes with supporting documentation.

Renewal Review Questions

1. Patient's current (within the past 4 weeks) weight (lbs):
2. Date of weight (MMDDYY):
3. Patient's current (within the past 4 weeks) BMI:
4. Date of BMI (MMDDYY):

RATIONALE

Setmelanotide (Imcivree) is considered experimental, investigation or unproven for ANY other use including the following (this may not be all inclusive):

* Other Genetic Obesity Syndromes (examples: Prader-Willi syndrome, Alstrom syndrome)
* General Obesity

REFERENCES

Setmelanotide (Imcivree) for Rare Genetic Disorders of Obesity – Interregional Practice Recommendations
https://cl.kp.org/co/home/refcontainerpage.html/content/clinicallibrary/natl/cmi/interregional/genetic_obesity/imcivree.nohf.ref.html?q=imcivree&context=shareform

An Interregional Consultative Physician Panel review is recommended prior to initiating treatment with setmelanotide.

Creation Date: 3/2020
Effective Date: 10/2024
Reviewed Date: 09/2024
Revised Date: 09/2024

NON GLP-1 WEIGHT LOSS MEDICATIONS
PHENTERMINE-TOPIRAMATE (QSYMIA)

Generic	Brand	HICL	GPID	Other
PHENTERMINE - TOPIRAMATE	QSYMIA	39347	32744, 32745, 32746, 32515	Formulary w/PA

GUIDELINES FOR COVERAGE
INITIAL CRITERIA: Must have one of the following indications and meet indication-specific criteria as follows:

A. Patients 12 years of age or older for weight loss
B. Moderate to severe obstructive sleep apnea (OSA) in adults with obesity

A. Patients 12 years of age or older for weight loss: Must meet all of the following:
1. Patient must have benefit plan with coverage for weight loss medications.
2. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
3. Patient must have an initial body mass index (BMI) greater than or equal to 30 kg/m2, OR an initial BMI greater than or equal to 27 kg/m2 with at least one weight-related comorbid condition, such as hypertension, dyslipidemia, or type 2 diabetes.
4. Provider attests to patient being on a reduced calorie diet with increased physical activity.
5. Patient has documented failure to lose and maintain at least 5% body weight after a 3-month trial to phentermine or diethylpropion, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve at HICL x6 months.
If initial criteria are not met, do not approve.

B. Moderate to severe obstructive sleep apnea (OSA) in adults with obesity: Must meet all of the following:
1. Prescribed by or in consultation with a Sleep Medicine provider.
2. Patient is ≥ 18 years of age
3. Patient has a diagnosis of moderate-to-severe OSA confirmed on a recent (within 12 months) ambulatory or in-lab polysomnogram demonstrating an apnea/hypopnea index (AHI) ≥ 15 events per hour.
4. Patient has positive airway pressure (PAP) treatment failure, defined as an inability to achieve AHI < 15 events per hour with PAP use, or an inability to use PAP therapy for greater than 4 hours for 70% of nights in a 30 day period
5. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
6. Patient must have an initial body mass index (BMI) of greater than or equal to 30 kg/m2, calculated using the current weight (as defined in initial criteria #5).
7. Patient is not taking a GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.

8. Provider attests to patient being on a reduced calorie diet and has increased physical activity.
9. Patient does not have a diagnosis of diabetes.

If initial criteria are met, approve x6 months at HICL.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following criteria based on diagnosis:

A. Patients 12 years of age or older for weight loss
B. Moderate to severe obstructive sleep apnea (OSA) in adults with obesity

A. Patients 12 years of age or older for weight loss
1. Patient has a current (within the past 4 weeks) weight on file (objectively measured with in-office weight check).
2. Patient must have achieved and maintained at least a 5% weight loss from baseline (objectively measured with in-office weight checks).

   If met, approve x 1 year at HICL.
   If not met, do not approve.

B. Moderate to severe obstructive sleep apnea (OSA) in adults with obesity
1. Patient experienced a decrease from the baseline apnea/hypoapnea index (AHI) (specifically, the baseline AHI used to meet initial criteria #3)
2. Patient is not taking a GLP-1 or GLP/GIP (e.g., tirzepatide) containing product.

If renewal criteria are met, approve x 1 year at HICL
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria]: Patients 12 years of age or older for weight loss; Moderate to severe obstructive sleep apnea (OSA) in adults with obesity

QUESTIONS BASED ON DIAGNOSIS SELECTED
Patients 12 years of age or older for weight loss
1. Patient’s current (within the past 4 weeks) weight (lbs):
2. Date of weight (MMDDYY):
3. Patient's current (within the past 4 weeks) BMI:
4. Date of BMI (MMDDYY):
5. Does the provider attest that the patient is on a reduced calorie diet with increased physical activity?
6. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
7. Is there reasoning why alternatives (phentermine 37.5 mg tablets, diethylpropion tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Moderate to severe obstructive sleep apnea (OSA) in adults with obesity
1. Patient’s current (within the past 4 weeks) weight (lbs):
2. Date of weight (MMDDYY):

3. Patient's current (within the past 4 weeks) BMI:
4. Date of BMI (MMDDYY):
5. Does the patient have a diagnosis of diabetes?
6. Is the patient taking another GLP-1 or GLP/GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?
7. Does the patient have a recent (within the last 12 months) ambulatory or in-lab polysomnogram? If yes, a copy of ambulatory or in-lab polysomnogram results must be attached/submitted with this request.
8. Has the patient failed other treatments for this indication? If yes, must list the treatment, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
9. Is there reasoning why alternative treatments (such as positive airway pressure (PAP) or weight loss pharmacotherapy) are not suitable for the patient? If yes, must list reasoning in the Provider Comment section below or attach applicable chart notes.

Renewal Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria]: Patients 12 years of age or older for weight loss; Moderate to severe obstructive sleep apnea (OSA) in adults with obesity

QUESTIONS BASED ON DIAGONSIS SELECTED:

Patients 12 years of age or older for weight loss

1. Patient's current (within the past 4 weeks) weight (lbs):
2. Date of weight (MMDDYY):

Moderate to severe obstructive sleep apnea (OSA) in adults with obesity

1. Has the patient experienced a decrease from the baseline apnea/hypoapnea index (AHI) since initiation of Qsymia?
2. Is the patient taking another GLP-1 or GLP/GIP receptor agonist (medications containing semaglutide, liraglutide, exenatide dulaglutide, tirzepatide)?

RATIONALE

- PAP remains the mainstay for OSA treatment. However, studies consistently demonstrate that weight loss significantly improves OSA control, with reductions in both the severity of symptoms and related comorbidities. Specifically, in individuals with OSA who are obese, weight loss interventions—ranging from lifestyle changes to pharmacotherapy and surgical options—are critical components of comprehensive care. While weight loss medications such as liraglutide and phentermine/topiramate (Qsymia) are primarily indicated for obesity management, there is clinical evidence supporting their role in improving OSA outcomes. Both drugs have been studied in clinical trials for their potential benefit in OSA patients, with findings indicating positive effects on OSA severity. A meta-analysis of 27 studies involving weight reduction interventions—such as pharmacotherapy, bariatric surgery, and lifestyle modifications—found that a 20% reduction in body mass index (BMI) was associated with a 57% reduction in OSA severity, as measured by the apnea-hypopnea index (AHI). Thus, while the evidence specifically linking pharmacotherapy to clinically meaningful outcomes in OSA—such as mortality and cardiovascular events—is limited, the weight loss achieved through medications like liraglutide and phentermine/topiramate has been shown to significantly improve OSA severity. These medications provide an important option for patients who are unable to achieve sufficient weight loss through lifestyle interventions alone, offering a more accessible and effective pathway to managing OSA in the context of obesity.

FDA APPROVED INDICATIONS

QSYMIA is a combination of phentermine, a sympathomimetic amine anorectic, and topiramate, indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:

- Adults with an initial body mass index (BMI) of:
  - 30 kg/m2 or greater (obese) or
  - 27 kg/m2 or greater (overweight) in the presence of at least one weight related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia
- Pediatric patients aged 12 years and older with BMI in the 95th percentile or greater standardized for age and sex.

REFERENCES

Phentermine (phentermine hydrochloride) [package insert]. Epic Pharma, LLC. Revised 11.2019
Diethylpropion (diethylpropion hydrochloride immediate release, diethylpropion hydrochloride controlled release) [package insert]. Ketlman Pharmaceuticals Inc. Revised 6.2010

Creation Date: 3/2020
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

JAK INHIBITORS - ABROCITINIB (CIBINQO)

Generic	Brand	Tablet Strength	HICL	GCN	Exception/Other
ABROCITINIB	CIBINQO	50 MG, 100 MG, 200 MG	47767	51825, 51827, 51828	NF- Comm, Hx, Fed; F- SF Specialty tier

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:

1. Patient is new to KPCO within the past 90 days and is stable on therapy.
2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
3. The patient has a diagnosis of atopic dermatitis and requested medication is prescribed by a CPMG or affiliated dermatologist.

If met, approve indefinitely at HICL, max 1 tablet per day.
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must meet all the following:

1. The patient has a diagnosis of moderate to severe atopic dermatitis.
2. Medication is prescribed by a dermatologist.
3. Medication is not being used in combination with another biologic or or advanced small molecule for the same indication.
4. Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Inadequate response (after at least 2 months) or intolerance to at least one topical corticosteroid or topical calcineurin inhibitor (pimecrolimus, tacrolimus), or the patient has been on biologic therapy within the past 4 months, making these therapies inappropriate
    b. Inadequate response (after at least 2 months) or intolerance to at least **one** or contraindication to at least **two** of the following therapies, or the patient has been on biologic therapy within the past 4 months, making these therapies inappropriate: Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy, azathioprine, cyclosporine, methotrexate, mycophenolate
    c. Inadequate response (after at least 2 months), intolerance, or relative contraindication to tralokinumab (Adbry) or dupilumab (Dupixent).

If criteria are met, approve indefinitely at HICL, max 1 tablet per day.
If criteria are not met, do not approve.

ePA Questions

1. Is the patient stable on therapy with abrocitinib (Cibinqo)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Will this medication be used in combination with a biologic or advanced small molecule for the same indication?

4. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (topical steroid; tacrolimus ointment; azathioprine tablets (50 mg); cyclosporine capsules (25 mg, 100 mg); methotrexate 2.5 mg tablets or 25mg/ml vials; mycophenolate mofetil 250 mg capsules or 500 mg tablets) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

RATIONALE:
Per Health Plan

FDA APPROVED INDICATIONS
Atopic dermatitis

REFERENCES
Per Health Plan.

Creation date: 03/2020
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2025

NON-PREFERRED JAK INHIBITORS
LITFULO

Generic	Brand	Tablet Strength	HICL	GCN	Exception/Other
RITLECITINIB	LITFULO	50 MG	49026	54429	Nonformulary Specialty tier

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on therapy.
2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
3. The patient has a diagnosis of severe alopecia areata (AA) and requested medication is prescribed by a dermatologist.

   If met, approve indefinitely at HICL, max 1 tablet daily.
   If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of severe alopecia areata with 50% or more scalp hair loss.
2. Medication is prescribed by a dermatologist.
3. Patient is 12 years of age or older.
4. Medication is not being used in combination with a biologic or advanced small molecule for the same indication.
5. Patient with inadequate response (after at least 4 months), intolerance, or contraindication to the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Methotrexate or oral tofacitinib (Xeljanz)

   If criteria are met, approve ritlecitinib (Litfulo) at HICL indefinitely, max 1 tablet per day.
   If criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with ritlecitinib (Litfulo)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. % scalp hair loss:
4. Will this medication be used in combination with a biologic or advanced small molecule for the same indication?
5. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
6. Is there reasoning why alternatives (methotrexate 2.5 mg tablets or 25mg/ml vials; Xeljanz 10 mg tablets) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

RATIONALE:
Per Health Plan

In alopecia areata, time to initial hair growth with JAK inhibitors does not appear for at least several months.

FDA APPROVED INDICATIONS
Treatment of severe alopecia areata in patients 12 years of age and older

REFERENCES
Per Health Plan.

Creation date: 03/2020
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2025

NON-PREFERRED JAK INHIBITORS
OLUMIANT

Generic	Brand	Tablet Strength	HICL	GCN	Exception/Other
BARICITINIB	OLUMIANT	1 MG 2 MG 4 MG	44296	47205, 43468, 43469	Nonformulary Specialty tier

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:

1. Patient is new to KPCO within the past 90 days and is stable on therapy
2. Medication is not being used in combination with a biologic or advanced small molecule for the same indication.
3. Patient has one of the following indications and medication is prescribed by the appropriate specialist as noted below:
    a. Patient has a diagnosis of rheumatoid arthritis (RA) and requested medication is prescribed by a rheumatologist.
    b. The patient has a diagnosis of severe alopecia areata (AA) and requested medication is prescribed by a dermatologist.

If met, approve indefinitely with a max of 1 tablet per day.
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria below:

A. Rheumatoid Arthritis
B. Alopecia Areata (severe)

A. Rheumatoid Arthritis:
    1. Patient has a diagnosis of RA.
    2. Medication is prescribed by a rheumatologist.
    3. Patient is 18 years of age or older.
    4. Medication is not being used in combination with a biologic or advanced small molecule for the same indication.
    5. Patient with failure or intolerance to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
        a. At least 2 of the following medications: methotrexate hydroxychloroquine, sulfasalazine, or leflunomide
        b. At least 1 TNFi (e.g., infliximab-dyyb-preferred [F], adalimumab-atto-preferred [F])
        c. tofacitinib (Xeljanz)

If criteria are met, approve at HICL indefinitely, max 1 per day.
If criteria are not met, do not approve.

B. Alopecia Areata:
   1. Patient has a diagnosis of severe alopecia areata with 50% or more scalp hair loss.
   2. Medication is prescribed by a dermatologist.
   3. Patient is 18 years of age or older.
   4. Medication is not being used in combination with a biologic or advanced small molecule for the same indication.
   5. Patient with inadequate response (after at least 4 months), intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Methotrexate or oral tofacitinib (Xeljanz)
      b. Ritlecitinib (Litfulo)

   If criteria are met, approve at HICL indefinitely, max 1 tablet per day.
   If criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with baricitinib (Olumiant)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Will this medication be used in combination with a biologic or advanced small molecule for the same indication?
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Rheumatoid Arthritis; Alopecia Areata (severe)]

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   Rheumatoid Arthritis
   1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
   2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); Xeljanz 10 mg tablets, adalimumab-atto (Amjevita)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

   Alopecia Areata (severe)
   1. % scalp hair loss:
   2. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
   3. Is there reasoning why alternatives (methotrexate 2.5 mg tablets or 25mg/ml vials; Xeljanz 10 mg tablets) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

RATIONALE:
Per Health Plan

In alopecia areata, time to initial hair growth with JAK inhibitors does not appear for at least several months.

FDA APPROVED INDICATIONS
Rheumatoid arthritis
Treatment of severe alopecia areata in patients 18 years of age and older

REFERENCES
Per Health Plan.

30-DAY QUANTITY LIMITS:

Brand Name	Dosage Form	Strength(s)	# units per day supply or dispense
Olumiant	Tablet	1 mg, 2 mg, 4 mg	1 per day

Creation date: 03/2020
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2025

NON-PREFERRED JAK INHIBITORS
RINVOQ TABLETS

Generic	Brand	HICL	GPID	Exception/Other
UPADACITINIB	RINVOQ 15 MG, 30 MG, 45 MG TABLETS	45955	46822, 51719, 52085	NF- Comm, Hx, Fed; F- SF; Specialty Tier

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
A. Patient is new to KPCO within the past 90 days and is currently stable on therapy.
B. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
C. Patient has one of the following indications and medication is prescribed by the appropriate specialist as noted below:
   1. Patient has a diagnosis of rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis, nonradiographic axial spondyloarthritis, or polyarticular juvenile idiopathic arthritis (JIA) and requested medication is prescribed by a rheumatologist.
   2. The patient has a diagnosis of ulcerative colitis, Crohn's disease, or inflammatory bowel disease-unspecified/indeterminate colitis (IBD-U) and requested medication is prescribed by a gastroenterologist.
   3. The patient has a diagnosis of atopic dermatitis and requested medication is prescribed by a dermatologist.

   If met, approve indefinitely at GPID, max 1 per day.
   If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria below:

A. Rheumatoid Arthritis
B. Psoriatic Arthritis (PsA)
C. Ankylosing Spondylitis, Nonradiographic Axial Spondyloarthritis
D. Polyarticular Juvenile Idiopathic Arthritis
E. Ulcerative Colitis (UC)
F. Crohn's Disease (CD) or Inflammatory Bowel Disease-Unspecified/Indeterminate Colitis (IBD-U)
G. Atopic Dermatitis

A. Rheumatoid Arthritis:
   1. Patient has a diagnosis of RA.
   2. Medication is prescribed by a rheumatologist.
   3. Patient is 18 years of age or older.
   4. Request must be for 15 mg strength.
   5. Medication is not being used in combination with a biologic for the same indication.
   6. Patient with failure or intolerance to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy,

diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. At least 2 of the following medications: methotrexate hydroxychloroquine, sulfasalazine, or leflunomide
   b. At least 1 TNFi (e.g., infliximab-dyyb-preferred [F], Amjevita-preferred [F])
   c. tofacitinib (Xeljanz)

If criteria are met, approve at GPID indefinitely, max 1 per day.
If criteria are not met, do not approve.

B. Psoriatic Arthritis (PsA):
   1. Patient has a diagnosis of PsA.
   2. Medication is prescribed by a rheumatologist or dermatologist.
   3. Patient is 2 years of age or older.
   4. Patient weighs at least 30 kg.
   5. Request must be for 15 mg strength.
   6. Medication is not being used in combination with a biologic for the same indication.
   7. Patient with failure or intolerance to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. At Least 2 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, leflunomide, sulfasalazine
      b. At least 1 TNFi (e.g., infliximab-dyyb-preferred [F], Amjevita-preferred [F])
      c. tofacitinib (Xeljanz) [required only for patients 18 years of age or older; not indicated for patients under 18 for PsA]

   If criteria are met, approve at GPID indefinitely, max 1 per day.
   If criteria are not met, do not approve.

C. Ankylosing Spondylitis or Nonradiographic Axial Spondyloarthritis:
   1. Patient has a diagnosis of either ankylosing spondylitis or nonradiographic axial spondyloarthritis.
   2. Medication is prescribed by a rheumatologist.
   3. Patient is 18 years of age or older.
   4. Request must be for 15 mg strength.
   5. Medication is not being used in combination with a biologic for the same indication.
   6. Patient with failure or intolerance to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

a. Methotrexate or sulfasalazine, or the patient has documented high disease activity in which these medications would not be suitable treatment
b. At least 1 TNFi (e.g., infliximab-dyyb-preferred [F], Amjevita-preferred [F])
c. tofacitinib (Xeljanz)

If criteria are met, approve at GPID indefinitely, max 1 per day.
If criteria are not met, do not approve.

D. Polyarticular Juvenile Idiopathic Arthritis (PJIA):
1. Patient has a diagnosis of PJIA.
2. Medication is prescribed by a rheumatologist.
3. Patient is 2 years of age or older.
4. Request must be for 15 mg strength.
5. Medication is not being used in combination with a biologic for the same indication.
6. Patient with failure or intolerance to at least one of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception
   a. Methotrexate
   b. Leflunomide
   c. Hydroxychloroquine
   d. Sulfasalazine

If criteria are met, approve at GPID indefinitely, max 1 per day.
If criteria are not met, do not approve.

E. Ulcerative Colitis (UC):
1. Patient has a diagnosis of UC.
2. Medication is prescribed by a gastroenterologist.
3. Patient is 18 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least 1 TNF inhibitor (ex: infliximab [F], Amjevita [F], golimumab [NF, PA] or certolizumab [NF, PA]), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

   If criteria are met, approve as follows:
   - FIRST APPROVAL: 45 mg tab at GPID x 6-months, max 1 per day, max # fills: 2, max 28 days' supply.

- SECOND APPROVAL: 15 mg tab at GPID indefinitely, max 1 per day.
- THIRD APPROVAL: 30 mg tab at GPID indefinitely, max 1 per day.

If criteria are not met, do not approve.

F. Crohn's Disease (CD) or Inflammatory Bowel Disease-Unspecified/Indeterminate Colitis (IBD-U):
1. Patient has a diagnosis of CD or IBD-U.
2. Medication is prescribed by a gastroenterologist.
3. Patient is 18 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least 1 TNF inhibitor (ex: infliximab [F], Amjevita [F], golimumab [NF, PA] or certolizumab [NF, PA]), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

   If criteria are met, approve as follows:
   - FIRST APPROVAL: 45 mg tab at GPID x 6-months, max 1 per day, max # fills: 3, max 28 days' supply.
   - SECOND APPROVAL: 15 mg tab at GPID indefinitely, max 1 per day.
   - THIRD APPROVAL: 30 mg tab at GPID indefinitely, max 1 per day.

   If criteria are not met, do not approve.

G. Atopic Dermatitis:
1. The patient has a diagnosis of moderate to severe atopic dermatitis.
2. Medication requested is prescribed by a dermatologist.
3. Patient is 12 years of age or older.
4. Medication is not being used in combination with a biologic or relevant immunosuppressive therapy for the same indication (methotrexate, mycophenolate, cyclosporine, JAK inhibitor).
5. Request must be for 15 mg or 30 mg strength.
6. Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Inadequate response (after at least 2 months) or intolerance to at least one topical corticosteroid or topical calcineurin inhibitor (pimecrolimus, tacrolimus), or the patient has been on biologic therapy within the past 4 months, making these therapies inappropriate.
   b. Inadequate response (after at least 2 months) or intolerance to at least **one** or contraindication to at least **two** of the following therapies, or the patient has been on biologic therapy within the past 4 months, making these therapies inappropriate: Phototherapy or

narrow-band short wave ultraviolet B (NB-UVB) light therapy, Azathioprine, Cyclosporine, Methotrexate, Mycophenolate

c. Inadequate response (after at least 2 months), intolerance, or relative contraindication to tralokinumab (Adbry) or dupilumab (Dupixent).

If criteria are met, approve indefinitely at GPID, max 1 tablet per day.
If criteria are not met, do not approve.

ESCALATION CRITERIA/QTY LIMIT OVERRIDES: Patient must meet New Member or Initial Criteria prior to review for Quantity Overrides. Escalation Criteria reviews only the strength/quantities authorized upon PA approval and is only eligible for the following indications:

A. Patient with Ulcerative Colitis for whom provider is requesting Rinvoq 45 mg beyond the initial 8-week approval:

1. Patient must have objective signs of persistent or worsening disease activity as demonstrated by at least one of the following:
    a. colonoscopy or imaging with persistent or worsening activity compared to baseline
    b. fecal calprotectin greater than 150 [only if patient had an elevated fecal calprotectin prior to medication initiation]
    c. C-reactive protein greater than 2 [only if patient had an elevated C-reactive protein prior to medication initiation]

If criteria are met, approve 45 mg tablet x8 weeks, max 1 per day.
If criteria are not met, do not approve. Retain approval limitations from Initial Review.

B. Patient with Crohn's Disease or Inflammatory Bowel Disease-Unspecified/Indeterminate Colitis (IBD-U) for whom provider is requesting Rinvoq 45 mg beyond the initial 12-week approval:

1. Patient must have objective signs of persistent or worsening disease activity as demonstrated by at least one of the following:
    a. colonoscopy or imaging with persistent or worsening activity compared to baseline
    b. fecal calprotectin greater than 150 [only if patient had an elevated fecal calprotectin prior to medication initiation]
    c. C-reactive protein greater than 2 [only if patient had an elevated C-reactive protein prior to medication initiation]

If criteria are met, approve 45 mg tablet x12 weeks, max 1 per day.
If criteria are not met, do not approve. Retain approval limitations from Initial Review.

ePA Questions

1. Is the patient stable on therapy with upadacitinib (Rinvoq)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Will this medication be used in combination with a biologic or advanced small molecule for the same indication?
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Rheumatoid Arthritis; Psoriatic Arthritis (PsA); Ankylosing Spondylitis or Nonradiographic Axial Spondyloarthritis; Polyarticular Juvenile Idiopathic Arthritis (PJIA); Ulcerative Colitis (UC); Crohn's Disease (CD), or Inflammatory Bowel Disease-Unspecified/Indeterminate Colitis (IBD-U); Atopic Dermatitis]
   QUESTIONS BASED ON DIAGNOSIS SELECTED
   Rheumatoid Arthritis

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); Xeljanz 10 mg tablets - half tablet twice daily; adalimumab-atto (Amjevita)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Psoriatic Arthritis (PsA)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); Xeljanz 10 mg tablets - half tablet twice daily; adalimumab-atto (Amjevita)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Ankylosing Spondylitis or Nonradiographic Axial Spondyloarthritis

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; Xeljanz 10 mg tablets - half tablet twice daily; adalimumab-atto (Amjevita)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Ulcerative Colitis (UC)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (infliximab (Inflectra), adalimumab-atto (Amjevita), etc.) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Crohn's Disease (CD), or Inflammatory Bowel Disease-Unspecified/Indeterminate Colitis (IBD-U)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (infliximab (Inflectra), adalimumab-atto (Amjevita), etc.) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Atopic Dermatitis

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (topical steroid; tacrolimus ointment; azathioprine tablets (50 mg); cyclosporine capsules (25 mg, 100 mg); methotrexate 2.5 mg tablets or 25mg/ml vials; mycophenolate mofetil 250 mg capsules or 500 mg tablets) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Health Plan

In alopecia areata, time to initial hair growth with JAK inhibitors does not appear for at least several months.

FDA APPROVED INDICATIONS
Ulcerative colitis
Crohn's disease
Rheumatoid arthritis
Psoriatic arthritis
Atopic dermatitis
Ankylosing Spondylitis
Nonradiographic axial spondyloarthritis

REFERENCES
Per Health Plan.

30-DAY QUANTITY LIMITS:

Brand Name	Dosage Form	Strength(s)	# units per day supply or dispense
Rinvoq	Tablet	15 mg, 30 mg, 45 mg	1 per day

Creation date: 03/2020
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2025

NON-PREFERRED JAK INHIBITORS
RINVOQ LIQUID

Generic	Brand	HICL	GPID	Exception/Other
UPADACITINIB	RINVOQ 1 MG/ML SOLUTION	45955	55651	NF, Specialty tier

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is currently stable on therapy.
2. Patient has a diagnosis of psoriatic arthritis (PsA) or polyarticular juvenile idiopathic arthritis (JIA) and medication is prescribed by a rheumatologist.
3. Patient is between 2-17 years of age.
4. Medication is not being used in combination with a biologic for the same indication.

If met, approve indefinitely at GPID, max 15 mg per day.
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria below:

A. Psoriatic Arthritis (PsA)
B. Polyarticular Juvenile Idiopathic Arthritis (PJIA)

A. Psoriatic Arthritis (PsA)
1. Patient has a diagnosis of PsA.
2. Medication is prescribed by a rheumatologist or dermatologist.
3. Patient is between 2-17 years of age.
4. Medication is not being used in combination with a biologic for the same indication.
5. Patient with failure or intolerance to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. At least 1 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate or sulfasalazine
   b. At least 1 TNFi (e.g. infliximab-dyyb-preferred [F], adalimumab-atto-preferred [F, PA])

   If criteria are met, approve at GPID indefinitely, max 15 mg per day.
   If criteria are not met, do not approve.

B. Polyarticular Juvenile Idiopathic Arthritis (PJIA)
1. Patient has a diagnosis of PJIA.
2. Medication is prescribed by a rheumatologist.
3. Patient is 2 years of age or older.
4. Medication is not being used in combination with a biologic for the same indication.
5. Patient with failure or intolerance to at least one of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required

drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
a. Methotrexate
b. Leflunomide
c. Hydroxychloroquine
d. Sulfasalazine

If criteria are met, approve at GPID indefinitely, max 15 mg per day.
If criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with upadacitinib (Rinvoq)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Will this medication be used in combination with a biologic for the same indication?
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Psoriatic Arthritis (PsA); Polyarticular Juvenile Idiopathic Arthritis]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Psoriatic Arthritis (PsA)
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; adalimumab-atto) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Polyarticular Juvenile Idiopathic Arthritis (JIA)
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg; hydroxychloroquine 200 mg tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Health Plan

In alopecia areata, time to initial hair growth with JAK inhibitors does not appear for at least several months.

FDA APPROVED INDICATIONS
Psoriatic arthritis
Polyarticular Juvenile Idiopathic Arthritis (JIA)

REFERENCES
Per Health Plan.

30-DAY QUANTITY LIMITS:

Brand Name	Dosage Form	Strength(s)	# units per day supply or dispense
Rinvoq	Tablet	15 mg, 30 mg, 45 mg	1 per day

Creation date: 09/2024
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: n/a

NON-PREFERRED JAK INHIBITORS
XELJANZ

Generic	Brand	Tablet Strength	HICL	GPID	Exception/Other
TOFACITINIB CITRATE	XELJANZ, XELJANZ XR	5 MG, 11 MG XR 22 MG XR 1 MG/ML		33617, 38086, 47546, 48684	Formulary with Criteria for all except Xeljanz 10mg tablets Formulary, Unrestricted and NOT Specialty tier

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:

1. Patient is new to KPCO within the past 90 days and is currently stable on therapy.
2. Medication is not being used in combination with a biologic for the same indication.
3. Patient has a diagnosis of Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Nonradiographic Axial Spondyloarthritis, Polyarticular Juvenile Idiopathic Arthritis, Ulcerative Colitis or Inflammatory Bowel Disease-Unspecified/Indeterminate Colitis
4. Requests for Xeljanz 5 mg, 11mg XR: Patient is unable to use the 10 mg tablets, one-half tablet 2 times a day, due to a clinical/physical/medical reason (i.e., dexterity or vision issues)

If criteria are met, approve indefinitely.
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria below:

A. Rheumatoid Arthritis
B. Psoriatic Arthritis (PsA)
C. Ankylosing Spondylitis, Nonradiographic Axial Spondyloarthritis
D. Polyarticular Juvenile Idiopathic Arthritis (PJIA)
E. Ulcerative Colitis (UC) or Inflammatory Bowel Disease-Unspecified/Indeterminate Colitis (IBD-U)

A. Rheumatoid Arthritis:
   1. Patient has a diagnosis of RA.
   2. Medication is prescribed by a rheumatologist.
   3. Patient is 18 years of age or older.
   4. Medication is not being used in combination with a biologic for the same indication.
   5. Patient with failure or intolerance to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. At least 2 of the following medications: methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide
      b. At least 1 TNFi (e.g., infliximab-dyyb-preferred [F], adalimumab-atto (Amjevita)-preferred [F])

c. Requests for Xeljanz 5 mg, 11 mg XR: Patient is unable to use the 10 mg tablets, one-half tablet 2 times a day, due to a clinical/physical/medical reason (i.e., dexterity or vision issues)

If criteria are met, approve indefinitely, max 2 per day for 5mg or 1 per day for the XR.
If criteria are not met, do not approve.

B. Psoriatic Arthritis (PsA):
1. Patient has a diagnosis of PsA.
2. Medication is prescribed by a rheumatologist.
3. Patient is 18 years of age or older.
4. Medication is not being used in combination with a biologic for the same indication.
5. Patient with failure or intolerance to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. At least 2 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, sulfasalazine, or leflunomide
   b. At least 1 TNFi (e.g., infliximab-dyyb-preferred [F], adalimumab-atto (Amjevita)-preferred [F])
   c. Requests for Xeljanz 5 mg, 11 mg XR: Patient is unable to use the 10 mg tablets, one-half tablet 2 times a day, due to a clinical/physical/medical reason (i.e., dexterity or vision issues)issues)

If criteria are met, approve indefinitely, max 2 per day for 5mg or 1 per day for the XR.
If criteria are not met, do not approve.

C. Ankylosing Spondylitis or Nonradiographic Axial Spondyloarthritis:
1. Patient has a diagnosis of ankylosing spondylitis or nonradiographic axial spondyloarthritis.
2. Medication is prescribed by a rheumatologist.
3. Patient is 18 years of age or older
4. Medication is not being used in combination with a biologic for the same indication.
5. Patient with failure or intolerance to all of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. methotrexate or sulfasalazine, or the patient has documented high disease activity in which these medications would not be suitable treatment
   b. at least 1 TNFi (e.g., infliximab-dyyb-preferred [F], adalimumab-atto (Amjevita)-preferred [F])
   c. Xeljanz 10 mg tablets, one-half 2 times a day

If criteria are met, approve indefinitely, max 2 per day for 5mg or 1 per day for the XR.
If criteria are not met, do not approve.

D. Polyarticular Juvenile Idiopathic Arthritis (PJIA):
   1. Patient has a diagnosis of JIA.
   2. Medication is prescribed by a rheumatologist.
   3. Patient is 2 years of age or older.
   4. Medication is not being used in combination with a biologic for the same indication.
   5. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Patient with failure or intolerance to at least 1 of the following medications: methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
      b. Patient with failure or intolerance to at least 1 TNFi (e.g. adalimumab-atto (Amjevita)-preferred [F], infliximab-dyyb (Inflectra)-preferred [F])
      c. Requests for Xeljanz 1 mg/ml solution: Patient body weight is less than 40 kg, or the patient is unable to swallow tablets
      d. Requests for Xeljanz 5 mg: Patient is unable to use the 10 mg tablets, one-half tablet 2 times a day, due to a clinical/physical/medical reason (i.e., dexterity or vision issues)

   If criteria are met, approve indefinitely.
   If criteria are not met, do not approve.

E. Ulcerative Colitis (UC) or Inflammatory Bowel Disease-Unspecified/Indeterminate Colitis (IBD-U):
   1. Patient has a diagnosis of UC or IBD-U.
   2. Medication is prescribed by a gastroenterologist.
   3. Patient is 18 years of age or older.
   4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   5. Medication requested is one of the following and all medication-specific criteria below are met, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Xeljanz 5 mg or 11 mg XR: Patient stepped down from 10 mg 2 times a day to 5 mg 2 times a day, and is unable to use 10 mg tablets, one-half tablet 2 times a day, due to a clinical/physical/medical reason (i.e., dexterity or vision issues)
      b. Xeljanz 22 mg XR: Patient is unable to use 10 mg tablets, one tablet 2 times a day, due to clinical/physical/medical reason (i.e., dexterity or vision issues)

   If criteria are met, approve indefinitely, max 2 per day for 5 mg or 1 per day for XR.
   If criteria are not met, do not approve.

ePA Questions

1. Is there reasoning why alternatives (Xeljanz 10 mg tablets – half tablet twice daily) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.
2. Will this medication be used in combination with a biologic or advanced small molecule for the same indication?
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Rheumatoid Arthritis; Psoriatic Arthritis (PsA); Ankylosing Spondylitis or Nonradiographic Axial Spondyloarthritis; Polyarticular Juvenile Idiopathic Arthritis (PJIA); Ulcerative Colitis (UC) or Inflammatory Bowel Disease-Unspecified/Indeterminate Colitis (IBD-U)]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Rheumatoid Arthritis

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); adalimumab-atto (Amjevita)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Psoriatic Arthritis (PsA)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); adalimumab-atto (Amjevita)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Ankylosing Spondylitis or Nonradiographic Axial Spondyloarthritis

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets, adalimumab-atto (Amjevita)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); adalimumab-atto (Amjevita)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Ulcerative Colitis or Inflammatory Bowel Disease –Unspecified/Indeterminate Colitis (IBD-U)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reasoning for discontinuation in the Provider Comment section below or attach applicable chart notes.

2. Is there reasoning why alternatives (such as Xeljanz 10 mg tablets) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

RATIONALE:
Per Health Plan

Note: A Health Plan cannot deny based on patients' ability to cut tablets, so if qualifies for the drug and cannot cut tablets, must approve the 5mg or 11mg strength as applicable. However, please inform the provider/patient that the 10mg strength is a formulary brand tier medication and the 5mg and 11mg strengths are specialty tier medications.

In alopecia areata, initial hair growth with JAK inhibitors does not appear for at least several months.

FDA APPROVED INDICATIONS
Ulcerative colitis
Rheumatoid arthritis
Psoriatic arthritis
Atopic dermatitis
Polyarticular course juvenile idiopathic arthritis
Alopecia Areata
Ankylosing spondylitis

REFERENCES
Per Health Plan.

30-DAY QUANTITY LIMITS:

Brand Name	Dosage Form	Strength(s)	# units per day supply or dispense
Xeljanz	Tablet	5 mg	2 per day
Xeljanz XR	Tablet	11 mg, 22 mg	1 per day
Xeljanz	Solution	1 mg/ml	Max 10 mg (10 ml) per day

Creation date: 03/2020
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2025

NPH INSULIN PENS

Generic	Brand	HICL	GPID	Exception/Other
INSULIN NPH HUMAN ISOPHANE	HUMULIN N KWIKPEN	00780	18488	

GUIDELINES FOR COVERAGE

Must meet the following:

1. If not currently on Humulin N vial*, patient must fail glargine U-100 due to adverse drug reaction/intolerance that is not expected to occur with the requested agent, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
2. Meets one of the following requirements for pen form:
   a. Prescription is written by an Endocrinology specialist.
   b. Patient is under 18 years of age.
   c. Patient is 18 years of age or older and is unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination.

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (glargine-yfgn vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

The use of insulin pens at KPCO is generally reserved for patients with physical and cognitive impairment.
Insulin glargine-yfgn is KPCO preferred basal insulin.

*Specifically Humulin N vial. If patient on Humulin N, there is no step therapy requirement; patient must only meet requirement for pen form.

Novolin N products are excluded for coverage.

FDA APPROVED INDICATIONS

Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation date: 5/4/2017
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

OBETICHOLIC ACID

Generic	Brand	HICL	GPID	Exception/Other
OBETICHOLIC ACID	OCALIVA	43438	41444, 41445	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of primary biliary cholangitis
2. Prescribed by a gastroenterologist or hepatologist
3. Patient is at least 18 years of age and older
4. Patient does not have cirrhosis OR has compensated cirrhosis with no evidence of portal hypertension
5. The requested agent will be used in combination with ursodeoxycholic acid (e.g., Ursodiol, Urso 250, Urso Forte) in adults with an inadequate response to ursodeoxycholic acid at a dosage of 13-15mg/kg/day for at least 1 year, OR as monotherapy in adults unable to tolerate ursodeoxycholic acid
6. Patient does not have complete biliary obstruction

If met, approve x1 year at HICL, max 1 per day .
If not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of primary biliary cholangitis
2. Patient's alkaline phosphatase levels are less than 1.67-times the upper limit of normal OR have decreased by at least 15% from baseline while on treatment with obeticholic acid
3. The patient has not developed complete biliary obstruction

If met, approve indefinitely at HICL max 1 per day.
If not met, do not approve.

ePA Questions
Initial Review Questions
1. Does the patient have cirrhosis?
2. Does the patient have compensated cirrhosis with no evidence of portal hypertension?
3. Does the patient have complete biliary obstruction?
4. Will the requested medication be used in combination with ursodeoxycholic acid (e.g., Ursodiol, Urso 250, Urso Forte)?
5. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
6. Alkaline phosphatase lab:
7. Date of Alkaline phosphatase lab (MMDDYY):

Renewal Review Questions
1. Alkaline phosphatase lab:
2. Date of Alkaline phosphatase lab (MMDDYY):
3. Does the patient have complete biliary obstruction?

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ocaliva.

FDA APPROVED INDICATIONS

Treatment of adults with primary biliary cholangitis without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, either in combination with ursodiol (ursodeoxycholic acid) in patients with an inadequate response to ursodiol, or as monotherapy in patients unable to tolerate ursodiol.

REFERENCES

Ocaliva [Prescribing Information]. New York, NY: Intercept Pharmaceuticals, Inc. May 2021.

Creation date: 07/2022
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2023

OCTREOTIDE ACETATE CAPSULES (MYCAPSSA)

Generic	Brand	HICL	GPID	Comments
OCTREOTIDE ACETATE	MYCAPSSA	02826	48334	Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Must be prescribed by an endocrinology specialist
2. Patient must be age 18 years or older
3. Patient must have a diagnosis of acromegaly
4. Patient has had inadequate response to surgery or radiation, or surgery or radiation are not medically appropriate per provider documentation
5. The patient is currently stable (defined as currently receiving a stable dose for at least the previous 3 months) on an injectable somatostatin analog therapy (e.g., octreotide, lanreotide, pasireotide)
6. Patient has experienced severe injection site pain or reaction using injectable somatostatin analog therapy for long-term maintenance treatment, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception. [Documentation of needle phobia or unwillingness to receive injections does not qualify as medical necessity or contraindication to injectable products.]

If initial criteria are met, approve x 6 months, max daily dose 4 capsules.
If criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following criteria:
1. Individual's condition responded while on therapy defined as meeting all the following criteria:
    a. Achieved and maintains both:
        i. GH levels are < 1 µg/L within 2-hours after 75 g of oral glucose
        ii. IGF-1 levels are less than or equal to the upper limit of normal for the patient's age and gender
    b. No evidence of disease progression

If criteria are met, approve x 12 months, max daily dose 4 capsules.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient stable (defined as currently receiving a stable dose for at least the previous 3 months) on an injectable somatostatin analog therapy (e.g., octreotide, lanreotide, pasireotide)?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (injectable somatostatin analogs) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
4. Regarding surgical/radiologic intervention, please check the box that most accurately describes this patient:

a. The patient is not a candidate for surgery or radiation. (Please provide details in Provider Comment section or attach applicable chart notes with rationale.)
b. The patient has inadequate response to surgery or radiation.

Renewal Review Questions

1. Is there evidence of disease progression in this patient since starting Mycapssa?
2. Current GH level drawn within 2-hours after 75 g of oral glucose (µg/L):
3. Date of GH after glucose lab (MMDDYY):
4. Current IGF-1 level:
5. Date of IGF-1 lab (MMDDYY):

FDA APPROVED INDICATIONS

Octreotide acetate capsules (Mycapssa) are indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

REFERENCES

Per Health Plan.
Preference is for continued use of injectable over oral formulation.

Creation Date: 01/05/2021
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

ODEVIXIBAT

Generic	Brand	HICL	GPID	Exception/Other
ODEVIXIBAT	BYLVAY	47501	49976, 49977, 49978, 49979	Specialty tier

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on therapy.
2. Patient has a diagnosis of cholestatic pruritus due to Alagille syndrome (ALGS) or cholestatic pruritus due to Progressive Familial Intrahepatic Cholestasis (PFIC).
3. Medication is prescribed by a gastroenterology specialist.

If met, approve indefinitely at HICL.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following diagnoses and meet all the diagnosis-specific criteria below:

A. Diagnosis of cholestatic pruritus due to Alagille syndrome (ALGS), a type of genetic disorder
B. Diagnosis of cholestatic pruritus due to progressive familial intrahepatic cholestasis (PFIC) without type 2 specific ABCB11 variants

A. Cholestatic pruritic due to ALGS: Must meet all the following:
1. Patient is at least 12 months of age or older.
2. Medication is prescribed by a gastroenterology specialist.
3. Patient has had an inadequate response to at least two other conventional treatments for the symptomatic relief of pruritus (cholestyramine or other bile acid sequestrant, naltrexone, rifampin, ursodeoxycholic acid), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

B. Cholestatic pruritus due to PFIC, type 1 or type 2 (without type 2 specific ABCB11 variants): Must meet all the following:
1. Patient is 3 months of age or older.
2. Medication is prescribed by a gastroenterology specialist.
3. Patient has had an inadequate response to at least two other conventional treatments for the symptomatic relief of pruritus (cholestyramine or other bile acid sequestrant, naltrexone, rifampin, ursodeoxycholic acid), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria met, approve indefinitely at HICL.
If criteria not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with the requested medication?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (ursodiol tablets, colesevelam tablets, cholestyramine powder, colestipol tablets, naltrexone 50 mg tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

REFERENCES
1. Ovchinsky N et al. Efficacy and safety of odevixibat in patients with Alagille syndrome (ASSERT): a phase 3, double-blind, randomized, placebo-controlled trial. The Lancet Gastroenterology and Hepatology. Volume 9, Issue 7, July 2024, Pages 632-645.
2. Thompson R. Interim results from an ongoing, open-label, single-arm trial of odevixibat in progressive familial intrahepatic cholestasis. JHEP Reports. Volume 5, Issue 8, August 2023, 100782
3. IDP analytics. Hepatology: Cholestatic Liver Disease (ipdanalytics.com).

Creation date: 09/2022
Effective date: 10/2024
Reviewed date: 09/2024
Revised date: 09/2024

OFATUMUMAB (KESIMPTA)

Generic	Brand	HICL	GPID	Exception/Other
OFATUMUMAB	KESIMPTA		48513	NF- Comm, Hx, Fed; F- SF Least preferred of anti-CD20 mABs

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Requesting provider is a CPMG or affiliated neurologist
2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include non-active secondary progressive MS or primary progressive MS.)
3. Patient has tried an infused rituximab product (brand or biosimilar) and with the infusion, experienced a severe Grade 3 or Grade 4 infusion reaction, or the provider submitted justification and supporting clinical documentation that states one of the following: i) provider attests that the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
    a. Severe Grade 3 infusion reaction:
        i. prolonged reaction that is NOT rapidly responsive to symptomatic medication and/or brief interruption of infusion, or
        ii. hospitalization for clinical sequelae directly related to infusion of medication, or
        iii. severe infusion reaction that does not improve with subsequent infusion despite highly effective home PO premedications in the days prior to the infusion, day of infusion IV premedications, and slow infusion rate
    b. Severe Grade 4 infusion reaction: life-threatening reaction requiring urgent intervention

If initial criteria are met, approve x 1 year at GPID.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following:
1. Requesting provider is a CPMG or affiliated neurologist
2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include non-active secondary progressive MS or primary progressive MS.)

If renewal criteria are met, approve x 2 years at GPID.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes: relapsing or active form of multiple sclerosis, non-active secondary-progressive MS, primary-progressive MS]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

3. Is there reasoning why alternatives (rituximab) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions

1. Diagnosis associated with this request: [check boxes: relapsing or active form of multiple sclerosis, non-active secondary-progressive MS, primary-progressive MS]

RATIONALE

Ofatumumab (Kesimpta) is the second anti-CD20 monoclonal antibody FDA-approved for the treatment of relapsing forms of MS, but the first that is self-administered via subcutaneous injection. Ocrelizumab (Ocrevus) was the first anti-CD20 approved, is given through intravenous (IV) infusion, and rituximab (Rituxan, Truxima, Ruxience), also IV, has long been used off-label for the treatment of MS.[1-3]

Although ofatumumab may have more clinical trial data to support its use, rituximab has more real-world experience at KP. The KP Interregional guideline recommends the use of rituximab as the preferred highly-effective disease modifying therapy (DMT), over both ocrelizumab and ofatumumab.[4] Long-term safety data with ofatumumab is also unknown.

Ofatumumab was studied compared to teriflunomide, a modestly-effective DMT, in the ASCLEPIOS I and II phase 3 clinical trials.[5] There are no head-to-head trials with ofatumumab and other highly-effective DMTs.

- Ocrelizumab, ofatumumab, rituximab and ublituximab are part of the Anti-CD20 monoclonal antibody class of drugs. For the most part these agents in the class are molecularly similar and mechanistically the same.
- Off-label, non-oncologic use of rituximab is supported by a CMS-approved Compendia resource.
    - Micromedex categorizes off-label use of rituximab for Multiple Sclerosis; Strength of recommendation, Adult, Class IIb. Strength of evidence, Adult, Category B
- Additional supporting national standard treatment guidelines, peer-reviewed medical literature and/or recognized standards of care includes the following:
    - In June 2019, a consensus paper was updated by the MS Coalition that discusses the use of disease-modifying therapies in MS. Rituximab is listed among various options, involving different mechanisms of action and modes of administration, which have shown benefits in patients with MS.
    - In 2018, the American Academy of Neurology has practice guidelines regarding disease modifying therapies for adults with MS. The guidelines mention rituximab for use in MS.
    - The recent 2021 update of the KP Inter-regional MS Treatment Practice Recommendations continues to recommend the utilization of our preferred drug in the Anti-CD20 mAB class, rituximab or its biosimilar.
    - There are no head-to-head evidence shows that either ocrelizumab or ublituximab are superior to rituximab products.
    - Use of rituximab products in MS is backed by real-world, published clinical experience at KP. Long-term ocrelizumab and ublituximab safety is less understood than that of rituximab
    - A network meta-analysis found that there was no significant difference between ocrelizumab and ofatumumab in terms of annualized relapse rate and time to confirmed disability worsening at three or six months.[6] Of note, rituximab was not included in this

meta-analysis. There is no data to show that ofatumumab is superior to rituximab for the treatment of MS.

Ofatumumab may be appropriate for patients who are unable to tolerate rituximab, rituximab-abbs, or ocrelizumab due to Grade 3 or Grade 4 infusion-related reactions despite aggressive pre-medication regimens. One example of an aggressive pre-medication regimen for an IV anti-CD20 is cetirizine/loratadine 10 mg twice daily + famotidine 20 mg twice daily +/- dexamethasone 4-8 mg daily for 3 days before each infusion.

FDA APPROVED INDICATIONS
Treatment of relapsing forms of multiple sclerosis.

[a]Disease Modifying Therapies

Class	Generic name	Brand or alternative name	Formulation	Preferred or Non-preferred per IR KP guidelines *Does NOT refer to formulary status)*
Synthetic Cytokines	Interferon-beta 1a	Avonex	IM injection	NP
	Interferon-beta 1a	Plegridy	SQ injection	NP
	Interferon-beta 1a	Rebif	SQ injection	NP
	Interferon-beta 1b	Extavia	SQ injection	P
		Betaseron	SQ Injection	NP
Synthetic Myelin Basic Protein	Glatiramer acetate	Brand: Copaxone;	SQ injection	NP
		Generic: Glatopa (Sandoz)	SQ injection	P
		Generic: Glatiramer acetate (Mylan)	SQ injection	NP
Reduced proliferation of activated T and B lymphocytes	Teriflunomide	Aubagio	Oral	NP
	Leflunomide[c] (pro-drug of teriflunomide)	Generic only (Brand: Arava)	Oral	P
Stimulator of Nrf2 pathway (aka Fumaric Acid Derivatives)	Dimethyl fumarate (pro-drug of MMF)	Tecfidera	Oral	Generic – P Brand – NP
	Diroximel fumarate (pro-drug of MMF)	Vumerity (bioequivalent to Tecfidera)	Oral	NP
	Monomethyl fumarate (active metabolite)	Bafiertam	Oral	NP
S1P Receptor Modulator	Fingolimod	Gilenya	Oral	P
	Ozanimod	Zeposia	Oral	NP
	Siponimod	Mayzent	Oral	NP
	Ponesimod	Ponvory	Oral	NP
T and B cell Depleting Small Molecule	Cladribine	Mavenclad	Oral	NP
T and B cell Depleting Antibody	Alemtuzumab	Lemtrada	Infusion	NP

Lymphocyte Anti-migration Antibody	Natalizumab	Tysabri	Infusion	P
B-cell Depleting Antibodies	Rituximab-abbs[c]	Biosimilar: Truxima	Infusion	NP
	Rituximab-arrx[c]	Biosimilar: Riabni	Infusion	P
	Rituximab[c]	Brand: Rituxan	Infusion	NP
	Ocrelizumab	Ocrevus	Infusion	NP
	Ofatumumab	Kesimpta	SQ injection	NP
	Ublituximab	Briumvi	Infusion	NP

[c]*Off-label as a disease modifying treatment for MS*

[b]**High risk features defined as meeting at least 1 of the following criteria** (MRI obtained within past 12months):

a. Incomplete recovery defined as an attack that lasts ≥ 30 days and has significant functional limitations with the exception of ongoing sensory symptoms
b. Relapse w sphincter dysfunction, including urinary urgency or hesitancy
c. Motor relapse
d. Cerebellar relapse
e. 3 or more relapses in the first 2 years after diagnosis
f. After at least 6 months of therapy, a relapse in the next 6 months
g. Annualized relapse rate of ≥1
h. After 1yr of therapy, ≥ 3 new or enlarging T2, gadolinium-enhancing lesions, or diffusion-weighted imaging lesions
i. ≥ 1 cord lesion on imaging

REFERENCES

1. Ineichen BV, Moridi T, Granberg T, Piehl F. Rituximab treatment for multiple sclerosis. Mult Scler. 2020 Feb;26(2):137-152.
2. Zecca C, Bovis F, Novi G, et al. Treatment of multiple sclerosis with rituximab: A multicentric Italian-Swiss experience. Mult Scler. 2020 Oct;26(12):1519-1531.
3. Torgauten HM, Myhr KM, Wergeland S, et al. Safety and efficacy of rituximab as first- and second line treatment in multiple sclerosis - A cohort study. Mult Scler J Exp Transl Clin. 2021 Jan 31;7(1):2055217320973049.
4. Kaiser Permanente Interregional MS Leaders Workgroup. The KP Interregional Treatment Algorithm: Disease Modifying Therapies (DMTs) for Relapsing Forms of Multiple Sclerosis. Last updated November 2021. Available at: Multiple Sclerosis (MS) Treatment Algorithm - Disease Modifying Therapies (DMTs) for Relapsing Forms: Inter-Regional Consensus | CO Clinical Library (kp.org)
5. Hauser SL, Bar-Or A, Cohen JA, et al. Ofatumumab versus Teriflunomide in Multiple Sclerosis. *N Engl J Med*. 2020 Aug 6;383(6):546-557.
6. Samjoo IA, Worthington E, Drudge C, et al. Comparison of ofatumumab and other disease-modifying therapies for relapsing multiple sclerosis: a network meta-analysis. J Comp Eff Res. 2020 Dec;9(18): 1255-1274.

Creation Date: 05/2022
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

OLAPARIB - QUANTITY LIMIT Restriction

Generic	Brand	HICL	GPID	Exception/Other
OLAPARIB 100 MG TABLETS	LYNPARZA	41642	43766	Max 4 tabs per day

Olaparib 100 mg QTY restriction rules:

- Prescriptions for olaparib 100mg tabs must be for quantity of 4 tabs per day or less.
- If patient requires a dose that exceeds 4 tablets per day:
  - Patient must use olaparib 2-150 mg tabs for 300 mg BID doses.
  - Two separate prescriptions must be used (one for each strength) to result in 250 mg BID.

RATIONALE

Olaparib comes in 100 mg and 150 mg tablet strengths.

Standard dosing and dose reduction recommendations:

Olaparib (Tablet) Dosage Reduction Levels

Dosage reduction levels	Recommended olaparib dosage and schedule
Initial (usual) dosage	300 mg twice daily
First dosage reduction	250 mg twice daily
Second dosage reduction	200 mg twice daily

Olaparib (Lynparza) 100 mg tabs is restricted to max 4 tabs per day (200 mg BID) based on cost of 2-150 mg tabs (300 mg) BID being more cost effective vs. 3-100 mg tabs (300mg) BID.

Creation Date: 07/2024
Effective Date: 08/2024
Reviewed Date:
Revised Date:

OMALIZUMAB (XOLAIR)

Generic	Brand	HICL	GPID	Comments
OMALIZUMAB SYRINGE	XOLAIR SYRINGE	25399		NF- Comm, Hx, Fed; F- SF COGS - labeled as self-injectable with MD discretion

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:

1. Patient is new to KPCO within the past 90 days and noted as stable on Xolair for the treatment of Chronic Idiopathic Urticaria (CIU), Asthma, and/or Chronic rhinosinusitis with nasal polyposis (CRSwNP).
2. Medication is prescribed by an Allergist, Pulmonologist, or ENT specialist.
3. Medication is not being used in combination with another biologic for the same indication.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following diagnoses and meet the diagnosis-specific criteria below:

A - Ages 18 and older with Chronic Idiopathic Urticaria (CIU)
B - Ages 12 through 17 with Chronic Idiopathic Urticaria (CIU)
C - Asthma
D - Chronic rhinosinusitis with nasal polyposis (CRSwNP)
E - IgE-mediated food allergy

A. Chronic idiopathic urticaria, ages 18 and older (CIU): Must meet all the following:
    1. Medication is prescribed by an Allergist.
    2. Medication is not being used in combination with another biologic for the same indication.
    3. Patient has received at least 2 doses within a healthcare setting and the provider attests to have performed a careful assessment of risk for anaphylaxis and mitigation strategies, including patient education.
    4. And trial and failure of at least one of the following combinations if KP Colorado did not approve the use of Xolair as a clinic-administered medication, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
        - second-generation antihistamine with first-generation H1 antihistamine
        - antihistamine with H2-antagonist
        - antihistamine with leukotriene modifier (montelukast or zafirlukast)

If initial criteria are met, approve at HICL indefinitely.
If initial criteria are not met, do not approve.

B. Chronic idiopathic urticaria, ages 12 through 17 (CIU): Must meet all the following:
   1. Medication is prescribed by an Allergist.
   2. Medication is not being used in combination with another biologic for the same indication.
   3. Patient has received at least 2 doses within a healthcare setting and the provider attests to have performed a careful assessment of risk for anaphylaxis and mitigation strategies, including patient education.
   4. And trial and failure of at least one of the following combinations if KP Colorado did not approve the use of Xolair as a clinic-administered medication, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      - antihistamine with H2-antagonist
      - antihistamine with leukotriene modifier (montelukast or zafirlukast)

If initial criteria are met, approve at HICL indefinitely.
If initial criteria are not met, do not approve.

C. Asthma: Must meet all the following:
   1. Patient is 6 years of age or older.
   2. Medication is prescribed by an Allergist or Pulmonologist.
   3. Medication is not being used in combination with another biologic for the same indication.
   4. Patient has received at least 2 doses within a healthcare setting and the provider attests to have performed a careful assessment of risk for anaphylaxis and mitigation strategies, including patient education.

   And all the following, if KP Colorado did not approve the use of Xolair as a clinic-administered medication:
   5. Determination of atopic asthma phenotype by prescribing physician.
   6. Patient has a diagnosis of moderate-to-severe persistent asthma as evidenced by spirometry (FEV1 is less than or equal to 80% of predicted and FEV1/forced vital capacity [FVC] reduced by 5% or greater from age-appropriate values).
   7. Patient has uncontrolled asthma as evidenced by ANY of the following:
      - Two or more asthma exacerbations requiring systemic corticosteroids (3 or more days each) in the past 12 months
      - one asthma-related hospitalization in the past 12 months
      - Asthma Control Test (ACT) consistently less than 20
   8. Patient is adherent (more than 75% proportion of days covered) to optimized triple drug therapy with high-dose ICS plus LABA plus tiotropium (Spiriva Respimat) in the previous 6 months, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve at HICL indefinitely.
If initial criteria are not met, do not approve.

D. Chronic rhinosinusitis with nasal polyposis (CRSwNP): Must meet all the following:
   1. Patient is 18 years of age or older.
   2. Medication is prescribed by an Allergist or an Ear, Nose & Throat specialist.
   3. Medication is not being used in combination with another biologic for the same indication.
   4. Patient has received at least 2 doses within a healthcare setting and the provider attests to have performed a careful assessment of risk for anaphylaxis and mitigation strategies, including patient education.

   And all the following, if KP Colorado did not approve the use of Xolair as a clinic-administered medication:
   5. Patient has persistent rhinosinusitis symptoms (lasting longer than 12 weeks) with severe nasal obstruction and rhinorrhea or reduced sense of smell.
   6. Patient has had sinus surgery.
   7. Patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      - At least one intranasal corticosteroid [e.g. fluticasone, mometasone, etc.]
      - At least one antileukotriene antagonists [e.g. montelukast, zafirlukast, zileuton]
      - Two or more courses of oral corticosteroids in the past year
      - Dupilumab [PA required]
      - Mepolizumab [PA required]

If initial criteria are met, approve at HICL indefinitely.
If initial criteria are not met, do not approve.

E. Ig-E mediated food allergy: **Provider must include documentation confirming** all the following:
   1. Patient is 1 year of age or older.
   2. Medication is prescribed by an Allergist or Immunologist.
   3. Diagnosis of Ig-E mediated food allergy to peanuts and at least two other foods (i.e. milk, egg, wheat, cashew, hazelnut) is confirmed by skin-prick testing and blood testing (i.e. IgE) to these foods, with positive test results and dates.
   4. Patient has signs and symptoms (e.g. hives, swelling, wheezing, hypotension and gastrointestinal symptoms) of a substantial systemic allergic reaction.
   5. Patient's previous allergic reactions occurred soon after ingestion of the food.
   6. In the physician's opinion, the food allergies are hard to avoid and unlikely to diminish with age (e.g. peanuts, tree nuts, seafood).
   7. Patient agrees to avoidance of food allergens as much as possible.
   8. IgE blood concentration of at least 30 IU/mL
   9. Patient weighs between 10 kg and 150 kg.
   10. Patient does NOT meet ANY of the following combination weight and IgE criteria:
      a. Weighs between 10 and 12kg AND has an IgE level above 1500IU/mL
      b. Weighs between 40 and 50kg AND has an IgE level above 1500IU/mL
      c. Weighs between 50 and 60kg AND has an IgE level above 1200IU/mL

d. Weighs between 60 and 70kg AND has an IgE level above 1000IU/mL
e. Weighs between 70 and 80kg AND has an IgE level above 900IU/mL
f. Weighs between 80 and 90kg AND has an IgE level above 800IU/mL
g. Weighs between 90 and 125kg AND has an IgE level above 600IU/mL
h. Weighs between 125 and 150kg AND has an IgE level above 500IU/mL

11. Patient has no history of severe anaphylaxis.
12. Patient does not have poorly controlled or severe asthma.
13. Patient has not previously received immunotherapy for the allergen being treated.
14. Patient has not received monoclonal antibody therapy in the past 6 months.
15. Patient has been prescribed an epinephrine auto-injector.
16. Patient has received at least 2 doses within a healthcare setting and the provider attests to have performed a careful assessment of risk for anaphylaxis and mitigation strategies, including patient education.

If initial criteria are met, approve at HICL x6 months.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Patient has had no episodes of severe anaphylaxis during therapy.
2. Patient has not developed poorly controlled or severe asthma during therapy.
3. Patient has noted improvement of treated condition.

If met, approve at HICL x6 months.
If not met, do not approve.

ePA Questions
1. Is the patient using another biologic for the same indication?
2. Is the patient stable on therapy with the requested medication?
3. For patients noted stable on therapy, start date of therapy (MMDDYY):
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Chronic Idiopathic Urticaria (CIU); Asthma; Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP); IgE-mediated food allergy]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Chronic Idiopathic Urticaria (CIU)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (oral antihistamines, H2RA, montelukast tablets) are not suitable? If yes, you must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Has the patient received at least 2 doses within a healthcare setting and the provider attests to have performed a careful assessment of risk for anaphylaxis and mitigation strategies, including patient education?

Asthma

1. Has the patient experienced any of the following (check any/all boxes that apply):
   a. Two or more asthma exacerbations requiring systemic corticosteroids (at least 3 days each) in the past 12 months
   b. one asthma-related hospitalization in the past 12 months
   c. Asthma Control Test (ACT) consistently less than 20

2. Has the patient received at least 2 doses within a healthcare setting and the provider attests to have performed a careful assessment of risk for anaphylaxis and mitigation strategies, including patient education?
3. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (triple drug therapy with high-dose ICS-LABA plus tiotropium (Spiriva Respimat)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

1. Has the patient received at least 2 doses within a healthcare setting and the provider attests to have performed a careful assessment of risk for anaphylaxis and mitigation strategies, including patient education?
2. Does the patient have persistent rhinosinusitis symptoms (lasting longer than 12 weeks) with severe nasal obstruction and rhinorrhea or reduced sense of smell?
3. Has the patient had sinus surgery?
4. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone, mometasone, etc.], antileukotriene antagonists [e.g., montelukast]) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.
6. How many courses of oral corticosteroids has the patient taken for this indication in the past year?

IgE-mediated food allergy

1. Does the patient have a diagnosis of Ig-E mediated food allergy to peanuts and at least two other foods (i.e. milk, egg, wheat, cashew, hazelnut) that is confirmed by skin-prick testing and blood testing (i.e. IgE) to these foods, with positive test results and dates. If yes, you must attach applicable chart notes with supporting documentation.
2. Does the patient have signs and symptoms (e.g. hives, swelling, wheezing, hypotension and gastrointestinal symptoms) of a substantial systemic allergic reaction? If yes, you must attach applicable chart notes with supporting documentation.
3. Did the patient's previous allergic reactions occur soon after ingestion of the food? If yes, you must attach applicable chart notes with supporting documentation.
4. In the physician's opinion, are the food allergies hard to avoid and unlikely to diminish with age (e.g. peanuts, tree nuts, seafood)?
5. Does the patient agree to avoidance of food allergens as much as possible?
6. IgE blood concentration (IU/mL):
7. Patient's current weight (lbs):
8. Date of patient weight (MMDDYY):
9. Does the patient have a history of severe anaphylaxis?
10. Does the patient have poorly controlled or severe asthma?
11. Has the patient previously received immunotherapy for the allergen being treated?
12. Has the patient received monoclonal antibody therapy in the past 6 months?
13. Has the patient been prescribed an epinephrine auto-injector?
14. Has the patient received at least 2 doses within a healthcare setting and the provider attests to have performed a careful assessment of risk for anaphylaxis and mitigation strategies, including patient education?

RATIONALE

The primary role of omalizumab is the treatment of refractory chronic idiopathic urticaria (CIU). Omalizumab is generally not as preferred for refractory asthma when compared to dupilumab or benralizumab as they cover more common asthma phenotypes and are generally easier and safer to use.

FDA APPROVED INDICATIONS

Asthma: Treatment of moderate to severe persistent asthma in adults and patients 6 years and older who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. (Limitations of use: Not indicated for acute bronchospasm or status asthmaticus.)

Rhinosinusitis (chronic) with nasal polyps: Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps in adults with inadequate response to nasal corticosteroids.

Urticaria (chronic spontaneous): Treatment of chronic spontaneous urticaria in adults and adolescents 12 years and older who remain symptomatic despite H1 antihistamine treatment. (Limitations of use: Not indicated for other allergic conditions or other forms of urticaria.)

IgE-mediated food allergy: Reduction of allergic reactions (type 1), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients ≥1 year of age with IgE-mediated food allergy; to be used in conjunction with food allergen avoidance.

REFERENCES

Table 1: Second-generation H1 antihistamines

Generic name	Standard dose	Higher dose
Cetirizine	10 mg orally once daily	20 mg orally twice daily
Desloratadine	5 mg orally once daily	10 mg orally twice daily
Fexofenadine	180 mg orally once daily	240 mg orally twice daily
Levocetirizine	5 mg orally once daily	10 mg orally twice daily
Loratadine	10 mg orally once daily	20 mg orally twice daily

Table 2: First-generation H1 antihistamines

Generic name
Brompheniramine
Chlorpheniramine
Diphenhydramine
Doxylamine
Triprolidine

Table 3: H2 antihistamines

Cimetidine
Famotidine
Nizatidine
Ranitidine

Table 4: High-dose ICS and High-dose ICS plus LABA combinations for Age above 12 years

fluticasone/salmeterol DPI (Advair Diskus) 500/50 mcg, 1 inh twice daily
fluticasone/salmeterol MDI (Advair HFA) 230/21 mcg, 2 puffs twice daily

mometasone/formoterol MDI (Dulera) 200/5 mcg, 2 puffs twice daily
ciclesonide MDI (Alvesco) 160 mcg, 2 puffs twice daily
fluticasone MDI (Flovent HFA) 220 mcg, 2 puffs twice daily
budesonide DPI (Pulmicort Flexhaler) 180 mcg, 4 inh twice daily
mometasone MDI (Asmanex HFA) 200 mcg, 2 puffs twice daily
mometasone DPI (Asmanex Twisthaler) 220 mcg, 2 inh twice daily

Creation Date:07/28/2021
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 11/2024

OMAVELOXOLONE (SKYCLARYS)

Generic	Brand	HICL	GPID	Exception/Other
OMAVELOXOLONE	SKYCLARYS	48741	53799	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient age is between 16 and 40 years.
2. Medication is prescribed by a CPMG or affiliated Neurologist or Geneticist.
3. Patient has genetically confirmed Friedreich's ataxia without pes cavus*.
4. Patient has a modified Friedreich's Ataxia Rating Scale (mFARS) score ≥20 and ≤80.
5. Patient is ambulatory without assistance.

If initial criteria are met, approve x6 months.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Documentation of improvement on the modified Friedreich's Ataxia Rating Scale (mFARS) score from baseline.

If renewal criteria are met, approve indefinitely.
If renewal criteria are not met, do not approve.

*Pes Cavus is a particular type of foot deformity. Clinical trial data did not show benefit of Omaveloxolone in patients with FA and this deformity.

ePA Questions
Initial Review Questions
1. Does the patient have genetically confirmed Friedreich's ataxia without pes cavus?
2. Patient's current modified Friedreich's Ataxia Rating Scale (mFARS) score:
3. Date of modified Friedreich's Ataxia Rating Scale (mFARS) score (MMDDYY):
4. Is the patient ambulatory without assistance?

Renewal Review Questions
1. Patient’s current modified Friedreich's Ataxia Rating Scale (mFARS) score:
2. Date of modified Friedreich's Ataxia Rating Scale (mFARS) score (MMDDYY):

RATIONALE
ETSP guidelines

FDA APPROVED INDICATIONS
Skyclarys is indicated for the treatment of Friedreich’s ataxia (FA) in adults and adolescents aged 16 years and older.

REFERENCES
Skyclarys Prescribing Information. Plano, TX: Reata Pharmaceuticals, Inc.; February 2023. https://www.skyclarys.com/docs/skyclarys_us_prescribing_information/

Creation Date: 07/2023
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

KAISER PERMANENTE

KAISER COLORADO HMO MR GUIDELINES

OPIOID CUMULATIVE DOSING OVERRIDE

Generic	Brand	HICL	GCN	Exception/Other
OPIOIDS	OPIOIDS			

GUIDELINES FOR USE

1. Is the request for an opioid product equal to or exceeding the soft-stop threshold (90 mg morphine equivalent dose [MED])?

   NOTE: Claims should stop for DUR_MAX_CUMUL_DOSE 2 edit with SOFT_DENY_LIMIT= 90 (i.e., Cumulative morphine equivalent dose of [patient's current MED] = / exceeds threshold of [90 mg MED per day]).

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient have one of the following conditions?
   - Diagnosis of cancer
   - Diagnosis of palliative care
   - Diagnosis of sickle cell disease
   - Patients enrolled in hospice
   - Patient is a resident of a long-term care facility or intermediate care for intellectually disabled

   If yes, **approve as follows:**
   - **Inform the pharmacist to place the appropriate HD (High Dose) DUR code into the claim {see below for listing of OCDP PPS codes}**

   If no, continue to #3.

3. Is the prescriber aware of multiple prescribers for opioid prescriptions?

   If yes, Inform pharmacist to make a clinical judgment about dispensing. Pharmacist may use applicable DUR codes to process the claim, if appropriate. {see below for listing of OCDP PPS codes}

   If no, Inform pharmacist to discuss with the prescribers and make a clinical judgment about dispensing. Pharmacist may use applicable DUR codes to process claim, if appropriate.

Reason for Service Code	Professional Service Code	Result of Service Code	Limits Overridden	Persistence Logic
HD (High Dose)	MO (Prescriber Consulted)	4C (Hospice)	Soft & Hard Limit	Class Persistent
HD (High Dose)	RO (RPh Consulted Other Source)	4C (Hospice)	Soft & Hard Limit	Class Persistent
HD (High Dose)	MO (Prescriber Consulted)	4B (Palliative Care)	Soft & Hard Limit	Class Persistent
HD (High Dose)	RO (RPh Consulted Other Source)	4B (Palliative Care)	Soft & Hard Limit	Class Persistent
HD (High Dose)	MO (Prescriber Consulted)	4D (Cancer)	Soft & Hard Limit	Class Persistent
HD (High Dose)	RO (RPh Consulted Other Source)	4D (Cancer)	Soft & Hard Limit	Class Persistent
HD (High Dose)	MR (Medication Review)	4D (Cancer)	Soft & Hard Limit	Class Persistent
HD (High Dose)	MO (Prescriber Consulted)	1G (Prescr Approval)	Soft Limit Only	Persistent

KAISER PERMANENTE

KAISER COLORADO HMO MR GUIDELINES

OPIOID CUMULATIVE DOSING OVERRIDE

RATIONALE

To align with opioid restrictions per CMS 2017 Call Letter. Prior authorization will be required for opioid prescriptions in excess of hard opioid edit. Soft opioid edit thresholds may be overridden by a dispensing pharmacist or provider/patient may request a coverage determination. MedImpact's standard soft opioid edit is set at ≥ 120 mg morphine equivalent dose (MED). MedImpact's standard hard opioid edit threshold is set at ≥ 200 mg MED. This requirement should not apply to patients with cancer, hospice patients, or patients approved by case management or retrospective DUR Programming. Additional payment determination is required for patients identified as hospice. Soft-thresholds may also be override by the pharmacy via DUR PPS codes or as part of coverage determination process. Hard-thresholds are only overridable as part of the coverage determination process. The cumulative opioid edit minimizes false positives by accounting for known exceptions: 1) patients on hospice, have certain cancer diagnosis 2) overlapping dispensing dates for Rx refills and new Rx orders for continuing fills 3) high-dose opioid usage previously determined to be medically necessary (approved PAs, previous coverage determinations, case management) 4) no consecutive high-MED days criterion as it would not prevent beneficiaries from reaching high opioid doses.

REFERENCES

- Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.
- Ballas SK. Pain Management of Sickle Cell Disease, 2005. Hematol Oncol Clin N Am 19 (2005) 785-802.
- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016; 65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.Available at http://www.cdc.gov/drugoverdose/prescribing/guideline.html. [Assessed August 11, 2016].
- Washington State Interagency Guideline on Prescribing Opioids for Pain. June 2015. Available at http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf [Accessed August 11, 2016].
- CMS Medicare Benefit Policy Manual Chapter 9 – Coverage of Hospice Services Under Hospital Insurance. Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c09.pdf [Accessed January 2, 2017].

Created: 12/18
Effective: 03/05/21 Client Approval: 02/26/21

ORAL CLADRIBINE (MAVENCLAD)

Generic	Brand	HICL	GCN	Exception/Other
CLADRIBINE	MAVENCLAD	07840	44338	Non-Formulary Oral formulation

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past year
2. Must have had at least one and no more than one treatment course (consisting of 2 treatment cycles) of cladribine, with last dose at least 43 weeks prior (if no prior treatment course, use initial criteria)

If above criteria are met, approve x1 year, max 2 fills, max qty 10 tablets.
If above criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: All the following must be met:
1. Medication is prescribed by a CPMG or affiliated neurologist
2. Patient is 18 years of age or older
3. Patient has a diagnosis of relapsing or active form of multiple sclerosis, and does not have a diagnosis of clinically isolated syndrome (CIS), non-active secondary-progressive MS, or primary-progressive MS
4. The patient must have high-risk features** for early progression to non-relapsing progressive MS, or any of these high-risk features while on disease modifying treatment
5. Patient has never taken more than two treatment courses (consisting of 2 treatment cycles each) of cladribine, and the patient has not taken cladribine within the past 43 weeks. [FDA states treatment beyond 2 years/courses may further increase the risk of malignancy.]
6. The patient has had a trial and inadequate response or intolerance to at least 2 alternative drugs indicated for the treatment of multiple sclerosis, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient Is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Rituximab or its biosimilar (Anti-CD20)
   b. Ocrelizumab (Anti-CD20)
   c. Ofatumumab (Anti-CD20)
   d. Ublituximab (Anti-CD20)
   e. Natalizumab (if JCV neg) - (alpha-4 integrin inhibitor)
   f. Fingolimod (S1P)
   g. Siponimod (S1P)
   h. Ozanimod (S1P)
   i. Ponesimod (S1P)

If above criteria are met, approve x1 year, max 2 fills, max qty 10 tablets.
If above criteria are not met, do not approve.

RENEWAL CRITERIA: All the following must be met:
1. Prescribed by a CPMG or affiliated neurologist
2. Patient has a diagnosis of relapsing or active form of multiple sclerosis, and does not have a diagnosis of clinically isolated syndrome (CIS), non-active secondary-progressive MS, or primary-progressive MS
3. Patient must have completed at least one treatment cycle within the past year, but no more than 3 treatment cycles in the course of their lifetime.

If above criteria are met, approve x1 year, max 2 fills, max qty 10 tablets.
If above criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes: relapsing or active form of multiple sclerosis, clinically isolated syndrome (CIS), non-active secondary-progressive MS, primary-progressive MS]
2. How many treatment courses of cladribine (consisting of 2 treatment cycles each) has the patient completed in their lifetime?
3. Does the patient have high-risk features for early progression to non-relapsing progressive MS, or any high-risk features while on disease modifying treatment? Please check all that apply:
    - Incomplete recovery defined as an attack that lasts at least 30 days with significant functional limitations with the exception of ongoing sensory symptoms
    - Relapse w sphincter dysfunction, including urinary urgency or hesitancy
    - Motor relapse
    - Cerebellar relapse
    - 3 or more relapses in the first 2 years after diagnosis
    - After at least 6 months of therapy, a relapse within 6 months
    - At least 1 relapse per year
    - After at least 1 year of therapy, 3 or more new or enlarging T2, gadolinium-enhancing lesions, or diffusion-weighted lesions on imaging
    - 1 or more cord lesion on imaging
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (rituximab, fingolimod 0.5 mg capsules) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

REFERENCES:
Treatment course 1:
Cycle 1: start day 0-5
Cycle 2: start on days 23-27 to finish on days 27-32

Wait at least 43 weeks after last dose of Course 1, Cycle 2

Treatment course 2:
Cycle 1: start day 0-5
Cycle 2: start on days 23-27 to finish on days 27-32

* Contraindications & Serious Precautions to Mavenclad:

1) patients with current malignancy
2) pregnant women, and women and men of reproductive potential who do not plan to use effective contraception during MAVENCLAD dosing and for 6 months after the last dose in each treatment course.
3) HIV infection.
4) active chronic infections (e.g., hepatitis or tuberculosis).
5) history of hypersensitivity to cladribine.
6) women intending to breastfeed on a MAVENCLAD treatment day and for 10 days after the last dose.
7) lymphopenia (grade 2) at baseline
8) liver function abnormality at baseline

** High risk features defined as meeting at least 1 of the following criteria (MRI obtained within past 12 months):

a. Incomplete recovery defined as an attack that lasts ≥ 30 days and has significant functional limitations with the exception of ongoing sensory symptoms
b. Relapse w sphincter dysfunction, including urinary urgency or hesitancy
c. Motor relapse
d. Cerebellar relapse
e. 3 or more relapses in the first 2 years after diagnosis
f. After at least 6 months of therapy, a relapse in the next 6 months
g. Annualized relapse rate of ≥1
h. After 1yr of therapy, ≥ 3 new or enlarging T2, gadolinium-enhancing lesions, or diffusion-weighted imaging lesions
i. ≥ 1 cord lesion on imaging

Disease Modifying Therapies

Class	Generic name	Brand or alternative name	Formulation	Preferred or Non-preferred per IR KP guidelines *(Does NOT refer to formulary status)*
Synthetic Cytokines	Interferon-beta 1a	Avonex	IM injection	NP
	Interferon-beta 1a	Plegidy	SQ injection	NP
	Interferon-beta 1a	Rebif	SQ injection	NP
	Interferon-beta 1b	Extavia	SQ injection	P
		Betaseron	SQ Injection	NP
Synthetic Myelin Basic Protein	Glatiramer acetate	Brand: Copaxone;	SQ injection	NP
		Generic: Glatopa (Sandoz)	SQ injection	P
		Generic: Glatiramer acetate (Mylan)	SQ injection	NP
Reduced proliferation of activated T and B lymphocytes	Teriflunomide	Aubagio	Oral	NP
	Leflunomide** (pro-drug of teriflunomide)	Generic only (Brand: Arava)	Oral	NP
Stimulator of Nrf2 pathway (aka Fumaric Acid Derivatives)	Dimethyl fumarate (pro-drug of MMF)	Tecfidera	Oral	Generic – P Brand – NP
	Diroximel fumarate (pro-drug of MMF)	Vumerity (bioequivalent to Tecfidera)	Oral	NP
	Monomethyl fumarate (active metabolite)	Bafiertam	Oral	NP
S1P Receptor Modulator	Fingolimod	Gilenya	Oral	P
	Ozanimod	Zeposia	Oral	NP

	Ponesimod	Ponvory	Oral	NP
	Siponimod	Mayzent	Oral	NP
T and B cell Depleting Small Molecule	Cladribine	Mavenclad	Oral	NP
T and B cell Depleting Antibody	Alemtuzumab	Lemtrada	Infusion	NP
Lymphocyte Anti-migration Antibody	Natalizumab	Tysabri	Infusion	NP
B-cell Depleting Antibodies	Rituximab-abbs**	Biosimilar: Truxima,	Infusion	P
	Rituximab-pvvr**	Biosimilar: Ruxience	Infusion	NP
	Rituximab**	Brand: Rituxan	Infusion	NP
	Ocrelizumab	Ocrevus	Infusion	NP
	Ofatumumab	Kesimpta	SQ injection	NP
	Ublituximab	Briumvi	Infusion	NP

Off-label disease modifying therapy for MS

Creation date: 5/2020
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2025

OSILODROSTAT (ISTURISA)

Generic	Brand	HICL	GPID	Comments
OSILODROSTAT	ISTURISA	46396	47793, 47794, 47795	Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

1. Patient must be 18 years of age or older
2. Prescriber must be an Endocrinologist
3. Documented diagnosis of Cushing's disease
4. Documentation of failed pituitary surgery or contraindication to pituitary surgery
5. Must meet diagnosis/drug specific criteria below:
   a. Treatment to inhibit cortisol synthesis (steroidogenesis inhibitors) in Cushings disease: Patient has failed, is intolerant to, or has a contraindication to, all of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      i. Oral ketoconazole
      ii. Oral metyrapone
   b. Treatment to reduce ACTH levels in Cushing's disease related to pituitary tumor: Patient has failed, is intolerant to, or has a contraindication to all of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      i. Oral ketoconazole
      ii. Oral cabergoline
      iii. Injectable pasireotide

      If initial criteria are met, approve at HICL x 6 months, max 6 tablets per day.
      If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:

1. Individual's condition responded while on therapy.
   Response is defined as: Achieved and maintains at least three of the following:
   - A urinary free cortisol (UFC) ≤ the upper limit of normal (ULN)
   - Cortisol levels is within normal limits
   - No symptoms consistent with Cushing's disease
   - No evidence or symptoms of hypercortisolism
   - No evidence of disease progression

If renewal criteria are met, approve at HICL x 1 year, max 6 tablets per day.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Has the patient experienced failed pituitary surgery, or does the patient have a contraindication to pituitary surgery? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
2. Indication associated with this request: [check boxes for all diagnoses listed in criteria: Treatment to inhibit cortisol synthesis (steroidogenesis inhibitors) in Cushing's disease; Treatment to reduce ACTH levels in Cushing's disease related to pituitary tumor]
   QUESTIONS BASED ON DIAGNOSIS SELECTED
   Treatment to inhibit cortisol synthesis (steroidogenesis inhibitors) in Cushing's disease
   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   2. Is there reasoning why alternatives (ketoconazole tablets, metyrapone tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

   Treatment to reduce ACTH levels in Cushing's disease related to pituitary tumor
   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   2. Is there reasoning why alternatives (ketoconazole tablets, cabergoline tablets, injectable pasireotide) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Does the patient have any of the following (check any/all applicable boxes): Symptoms associated with Cushing's disease; Evidence or symptoms of hypercortisolism; Evidence of disease progression
2. Current Urinary Free Cortisol (UFC) lab:
3. Date of UFC Lab (MMDDYY):
4. Current Cortisol level:
5. Date of Cortisol lab (MMDDYY):

RATIONALE
To ensure appropriate use of osilodrostat

FDA APPROVED INDICATIONS
Isturisa (osilodrostat) is a cortisol synthesis inhibitor indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. It inhibits 11beta-hydroxylase (CYP11B1), the enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland, thereby lowering cortisol levels.

REFERENCES
Per Health Plan

Tablet Strength	GPI	Quantity limit per day
1 mg tablet	30022060600320	8 tablets
5 mg tablet	30022060600330	6 tablets
10 mg tablet	30022060600340	6 tablets

Creation Date: 03/2021
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

OXYBATE SALTS (SODIUM, CALCIUM, MAG, POT) (XYWAV)

Generic	Brand	HICL	GPID	Exception/Other
OXYBATE SALTS (SODIUM, CALCIUM, MAG, POT)	XYWAV	46743	48419	Non-Formulary 4th preferred in narcolepsy class

GUIDELINES FOR COVERAGE

CRITERIA FOR ALL PATIENTS CURRENTLY TAKING THE REQUESTED MEDICATION: MUST MEET ALL THE FOLLOWING:

1. Medication is prescribed by a Neurology or a Board-Certified Sleep Medicine provider.
2. Medication is being prescribed for Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia; or Cataplexy (not excessive daytime sleepiness) due to narcolepsy.
3. Medication requested is not be used in combination with solriamfetol (Sunosi), pitolisant (Wakix) or any other oxybate product (i.e. Xyrem, Lumryz).
4. Patient must have tried and failed or have intolerance or contraindication to sodium oxybate (generic Xyrem) [Prior Authorization required], or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve indefinitely at GPID, max 18 mL/day.
If criteria are not met, do not approve.

CRITERIA FOR ANY PATIENT NOT CURRENTLY TAKING THE REQUESTED MEDICATION: MUST MEET ALL THE FOLLOWING:

A. Medication is prescribed by Neurology or a Board-Certified Sleep Medicine provider.
B. Medication requested is not be used in combination with solriamfetol (Sunosi), pitolisant (Wakix) or any other oxybate product (i.e. Xyrem, Lumryz).
C. Patient must have one of the following indications and meet all criteria pertaining to that indication:
    1. Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia: Must meet all the following, or the provider submitted justification and supporting clinical documentation that states one of the following: i) the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
        a. Patient must have tried and failed or have a contraindication to each of the following: amphetamines, methylphenidate, and either modafinil or armodafinil.
        b. Patient must have tried and failed or have a contraindication to Sunosi, Wakix, and sodium oxybate (generic Xyrem) [Prior Authorization required for all].

        If criteria are met, approve indefinitely at GPID, max 18 mL/day.
        If criteria are not met, do not approve.

2. Cataplexy (not excessive daytime sleepiness) due to narcolepsy: Must meet all the following, or the provider submitted justification and supporting clinical documentation that states one of the following: i) the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Patient must have tried and failed or have a contraindication to each of the following: a tricyclic antidepressant (TCA), a selective serotonin reuptake inhibitor (SSRI), and a selective serotonin-norepinephrine (SNRI).
    b. Patient must have tried and failed or have a contraindication to Wakix and sodium oxybate (generic Xyrem) [Prior Authorization required for all].

    If critieria are met, approve indefinitely at GPID, max 18 mL/day.
    If criteria are not met, do not approve.

ePA Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia; Cataplexy (not excessive daytime sleepiness) due to narcolepsy]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia

1. Is the patient stable on therapy with this medication?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Is the medication being used in combination with solriamfetol (Sunosi), pitolisant (Wakix) or any other oxybate product (i.e. Xyrem, Lumryz)?
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (amphetamines, methylphenidate, modafinil, armodafinil) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Cataplexy (not excessive daytime sleepiness) due to narcolepsy

1. Is the patient stable on therapy with this medication?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Is the medication being used in combination with solriamfetol (Sunosi), pitolisant (Wakix) or any other oxybate product (i.e. Xyrem, Lumryz)?
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (amitriptyline tablets, desipramine tablets, nortriptyline capsules; citalopram tablets/solution, escitalopram tablets, fluoxetine capsules/solution, paroxetine IR tablets, sertraline tablets/susp; venlafaxine ER capsules (37.5 mg, 75 mg, 150 mg), duloxetine capsules (20 mg, 30 mg, 60 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Lumryz, sodium oxybate oral solution. and Xywav have the same active ingredient (oxybate, a CNS depressant) and have not been studied for use in combination or as alternating treatments. Sunosi, a dopamine and norepinephrine reuptake inhibitor, is indicated to improve wakefulness in adults with excessive daytime sleepiness due to narcolepsy or obstructive sleep apnea. Wakix, an antagonist/inverse agonist of the histamine-3 receptor, is indicated for excessive daytime sleepiness and cataplexy in adults with narcolepsy. Currently, there are no published studies evaluating combination use of these medications.

FDA APPROVED INDICATIONS AND SUPPORTED OFF-LABEL INDICATIONS
Xyrem/Xywav/Lumryz = Cataplexy; Narcolepsy; Idiopathic hypersomnia
Sunosi = Narcolepsy; Idiopathic hypersomnia; Hypersomnia associated with Obstructive sleep apnea
Wakix = Cataplexy; Narcolepsy; Idiopathic hypersomnia

Creation date: 03/2020
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2025

PALOPEGTERIPARATIDE (YORVIPATH)

Generic	Brand	HICL	GPID	COMMENTS
PALOPEGTERIPARATIDE	YORVIPATH	49810		Non-Formulary, specialty tier

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

1. Patient must be 18 years of age or older.
2. Medication must be prescribed by an Endocrinologist.
3. Diagnosis of hypoparathyroidism confirmed by BOTH of the following:
    - Pretreatment low albumin-corrected serum calcium (i.e., ≤ 8.5 mg/dL) confirmed on at least two occasions separated by at least 2 weeks
    - Pretreatment undetectable or inappropriately low intact parathyroid (PTH) concentration (i.e., < 20 pg/mL), by second- or third-generation immunoassay, on at least two occasions
4. The patient's hypoparathyroidism is NOT due to impaired responsiveness to parathyroid hormone or a history of disease that affects calcium metabolism or calcium-phosphate homeostasis
5. Yorvipath is not being used to treat acute post-surgical hypoparathyroidism
6. Most recent (within past 30 days) albumin-corrected serum calcium 7.8–10.6 mg/dL
7. Most recent (within past 30 days) serum 25(OH) vitamin D 20–80 ng/mL
8. Patient has had a 12-week trial and failed*, or has an intolerance or contraindication to ALL of the following below, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    - Calcium supplements and active forms of vitamin D (e.g., calcitriol) up to maximally indicated doses^
    - Thiazide diuretic, if hypercalciuria is present [i.e. 24-hour urinary calcium ≥ 250 mg (6.25 mmol)]
    - Teriparatide (Forteo) up to twice or three times daily dosing

**Examples of a "failed" can include large swings in calcium levels, calcium phosphate product cannot be maintained within an acceptable range, high risk of renal complications due to hypercalciuria or calcium containing stones, evidence of renal complications such as nephrolithiasis or having a condition causing poor calcium and vitamin D absorption.*

^Maximum dose shown in table below:

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
calcitriol (Rocaltrol®)	0.25 mcg PO QD initially; dose may be increased at 2- to 4-wk intervals	2 mcg/day
calcium carbonate (Caltrate®, OsCal®, Tums®)	1-3 g PO QD in divided doses	3 g/day
calcium citrate (Cal-Citrate®, Cal-C-Caps®)	1-3 g PO QD in divided doses	3 g/day

If yes, approve all strengths for 6 months at HICL with a quantity limit as follows:

- 168 mcg/0.56 mL: #1.12 mL (max 2 pens) per 28 days.
- 294 mcg/0.98 mL: #1.96 mL (max 2 pens) per 28 days.
- 420 mcg/1.4 mL: #2.8 mL (max 2 pens) per 28 days.

If no, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Documentation of positive clinical response [e.g., albumin-corrected serum calcium level in normal range (approximately 8.3-10.6 mg/dL), independence from conventional therapy (e.g., requiring no active vitamin D, ≤ 600 mg/day of calcium)]

If yes, approve all strengths indefinitely at HICL with a quantity limit as follows:
- 168 mcg/0.56 mL: #1.12 mL (max 2 pens) per 28 days.
- 294 mcg/0.98 mL: #1.96 mL (max 2 pens) per 28 days.
- 420 mcg/1.4 mL: #2.8 mL (max 2 pens) per 28 days.

If not, do not approve.

RATIONALE
PTH-based therapies are an option for patients with chronic hypoparathyroidism who cannot maintain stable serum and urinary calcium levels with calcium and vitamin D treatment.
Palopegteriparatide is a long-acting prodrug of PTH (1-34) FDA approved for treatment of adults with hypoparathyroidism. Teriparatide (Forteo) (PTH [1-34]), the bioactive domain of PTH, is FDA approved for osteoporosis. However, teriparatide has been used extensively long-term, including data from randomized trials, demonstrating effectiveness for the treatment of hypoparathyroidism when compared to calcitriol or conventional therapy. When Natpara, recombinant human PTH (1-84), was recalled in 2019, teriparatide was recommended as an alternative in a joint guidance statement from the American Society for Bone and Mineral Research (ASBMR) and Endocrine Society. It is notable that if teriparatide is used in this clinical scenario, twice daily or even three times daily injections are usually needed.

The goal of PTH-based therapy treatment is to maintain serum calcium within the normal range without the need for active vitamin D (e.g., calcitriol) or therapeutic calcium doses (elemental calcium > 600 mg/day).

FDA APPROVED INDICATIONS
YORVIPATH (palopegteriparatide) is indicated for the treatment of hypoparathyroidism in adults.

YORVIPATH was not studied for acute post-surgical hypoparathyroidism. YORVIPATH's titration scheme was only evaluated in adults who first achieved an albumin-corrected serum calcium of ≥ 7.8 mg/dL using calcium and active vitamin D treatment.

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3. Khan AA, Rubin MR, Schwarz P, et al. Efficacy and Safety of Parathyroid Hormone Replacement With TransCon PTH in Hypoparathyroidism: 26-Week Results From the Phase 3 PaTHway Trial. J Bone Miner Res. 2023;38(1):14-25.

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Creation Date: 5/2025
Effective Date: 6/2025
Reviewed Date:
Revised Date:

PATIROMER (VELTASSA) - STEP THERAPY

Generic	Brand	HICL	GCN	Exception/Other
PATIROMER	VELTASSA	42767	40065, 40066, 40067	Nonformulary

Step Therapy Criteria
Must meet the criteria below or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed another drug in the same pharmacological class or with the same mechanism of action as the required drug and the drug was discontinued due to lack of efficacy, diminished effect, or adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Requesting provider is a CPMG or an affiliated network nephrologist.
2. Patient has tried and failed or has contraindications to sodium zirconium cyclosilicate (Lokelma).

If criteria are met, approve indefinitely at HICL.
If criteria are not met, do not approve.

RATIONALE
Per Health Plan
- Sodium zirconium cyclosilicate (Lokelma) is the first-line KPCO formulary therapy for hyperkalemia. Patiromer (Veltassa) is the second-line KPCO therapy for hyperkalemia and is non-formulary
- Both sodium zirconium cyclosilicate (Lokelma) and patiromer (Veltassa) have quantity limits
    - Lokelma - max of 3 per day to avoid medication overuse, and to account for initial titration.
    - Veltassa - max of 1 per day to avoid medication overuse and doubling of strengths.

REFERENCES

Creation date: 06/2022
Effective date: 06/2024
Reviewed date: 05/2024
Revised date: 05/2023

NON-PREFERRED PEGFILGRASTIM

Generic	Brand	HICL	GPID	Exception/Other
PEGFILGRASTIM 6MG/0.6ML	NEULASTA	23255	15666, 37706	Nonformulary
PEGFILGRASTIM-CBQV 6MG/0.6ML	UDENYCA	45445	45679, 53944, 55209	Nonformulary LATEX FREE
PEGFILGRASTIM-BMEZ 6MG/0.6ML	ZIEXTENZO	46183	47234	Nonformulary
PEGFILGRASTIM-APGF 6MG/0.6ML	NYVEPRIA	46612	48222	Nonformulary
PEGFILGRASTIM-PBBK 6MG/0.6ML	FYLNETRA	48035	52395	Nonformulary LATEX FREE
PEGFILGRASTIM-FPGK 6MG/0.6ML	STIMUFEND	48269	52848	Nonformulary

GUIDELINES FOR COVERAGE

Review based on patient age:

A. ADULT USE (ages 18 years and older): Must meet all the following criteria:
   1. Medication is prescribed by a Hematologist/Oncologist
   2. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Patient has experienced febrile neutropenia or neutropenia resulting in delay of chemotherapy despite 10 days of Granix [F] or other short-acting GCSF
      b. Patient has intolerance or contraindication to Fulphila

      If criteria are met, approve indefinitely at HICL.
      If criteria are not met, do not approve.

B. PEDIATRIC USE (ages 17 years and younger): Must meet all the following:
   1. Medication is prescribed by a Hematologist/Oncologist
   2. Must be using GCSF to prevent febrile neutropenia with chemotherapy
   3. Patient has intolerance or contraindication to Fulphila, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

      If criteria are met, approve indefinitely at HICL.
      If criteria are not met, do not approve.

ePA Questions

1. Patient age: [check boxes: Under 18 years of age; 18 years of age or older]
   QUESTIONS BASED ON PATIENT AGE
   Patient under 18 years of age

1. Is the medication being used to prevent febrile neutropenia with chemotherapy?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (Fulphila) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Patient 18 years of age or older

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Granix) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Adult Use: Fulphila is our preferred long-acting GCSF in adults; however, use of a short-acting GCSF is preferred over long-acting unless patient fails short-acting GCSF
Pediatric Use: Fulphila is our preferred GCSF for pediatric patients

FDA APPROVED INDICATIONS

See pegfilgrastim package insert

Creation Date:01/2020
Effective Date: 09/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

PREFERRED PEGFILGRASTIM - PEGFILGRASTIM-JMDB (FULPHILA)

Generic	Brand	HICL	GPID	Exception/Other
PEGFILGRASTIM-JMDB 6MG/0.6ML	FULPHILA	45010	44881	Nonformulary - LATEX FREE

GUIDELINES FOR COVERAGE

Review based on patient age:

A. ADULT USE (ages 18 years and older): Must meet all the following criteria:
   1. Medication is prescribed by a Hematologist/Oncologist
   2. Patient has experienced febrile neutropenia or neutropenia resulting in delay of chemotherapy despite 10 days of Granix [F] or other short-acting GCSF, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

      If criteria are met, approve indefinitely.
      If criteria are not met, do not approve.

B. PEDIATRIC USE (ages 17 years and younger): Must meet all the following:
   1. Medication is prescribed by a Hematologist/Oncologist
   2. Must be using GCSF to prevent febrile neutropenia with chemotherapy

      If criteria are met, approve indefinitely.
      If criteria are not met, do not approve.

ePA Questions

Patient age: [check boxes: Under 18 years of age; 18 years of age or older]

QUESTIONS BASED ON PATIENT AGE

Patient under 18 years of age

1. Is the medication being used to prevent febrile neutropenia with chemotherapy?

Patient 18 years of age or older

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Granix) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Adult Use: Fulphila is our preferred long-acting GCSF in adults; however, use of a short-acting GCSF is preferred over long-acting unless patient fails short-acting GCSF
Pediatric Use: Fulphila is our preferred GCSF for pediatric patients

FDA APPROVED INDICATIONS

See pegfilgrastim package insert

Creation Date:01/2020
Effective Date: 09/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

PEGVISOMANT (SOMAVERT)

Generic	Brand	HICL	GPID	Exception/Other
PEGVISOMANT	SOMAVERT	25062	19372, 19373, 19374, 37056, 37057	Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Medication is prescribed by an endocrinologist
2. Patient has a diagnosis of acromegaly
3. Patient is not a candidate for, or has had an inadequate response to surgery and/or radiotherapy
4. Failure of a somatostatin analog [octreotide (KP preferred) or lanreotide] at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

If initial criteria are met, approve at HICL x 12 months.
If criteria are not met, do not approve.

RENEWAL CRITERIA
1. Patient has had a positive clinical response to therapy (i.e., normalization of IGF-1 levels and/or improvement in symptoms)

If met, approve at HICL indefinitely.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (octreotide or lanreotide) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Regarding surgical/radiologic intervention, please check the box that most accurately describes this patient:
    a. The patient is not a candidate for surgery or radiotherapy. (Please provide details in Provider Comment section or attach applicable chart notes with rationale.)
    b. The patient has inadequate response to surgery or radiotherapy.

Renewal Review Questions
1. Has the patient had a positive clinical response to therapy?

RATIONALE
The Acromegaly Consensus Group suggests use of pegvisomant as a second-line therapy option in patients with persistent, significant disease despite surgical resection and minimal/no response to first-line therapy, either as monotherapy (in patients without concern for tumor growth) or in combination with a somatostatin analog (in patients with concern for tumor growth).

FDA APPROVED INDICATIONS
Somavert, a growth hormone receptor antagonist, is indicated for the treatment of acromegaly in patients who have had inadequate response to surgery and/or radiation therapy and/or other medical therapies, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum insulin-like growth factor-1 levels.

REFERENCES
Per Health Plan.

Creation Date: 03/2022
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 09/2023

FYCOMPA (PERAMPANEL)

Generic	Brand	HICL	GPID	Exception/Other
PERAMPANEL	FYCOMPA	39628	41309, 33271, 33272, 33273, 33274, 33275, 33276	

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on perampanel (Fycompa).
2. Patient has a diagnosis of Partial Onset or Primary Generalized Tonic-Clonic Seizures and is being managed by a CPMG or affiliated neurologist or epileptologist.

If New Member Criteria are met, approve x3 months at HICL.
If New Member Criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria below:

A. Partial Onset Seizures (also known as focal onset aware or impaired awareness)
B. Primary Generalized Tonic-Clonic Seizures (also known as generalized onset motor tonic-clonic)

A. To treat Partial Onset Seizures (also known as focal onset aware or impaired awareness): All the following must be met:
   1. Medication is prescribed by a CMPG or affiliated neurologist or epileptologist.
   2. Dose does not exceed 12 mg per day.
   3. The patient is stable on perampanel (Fycompa), or the patient has failed at least 2 of the following medications, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      - Brivaracetam [non-formulary]
      - Carbamazepine [preferred formulary]
      - Eslicarbazepine [non-formulary]
      - Felbamate [formulary]
      - Gabapentin [formulary]
      - Lacosamide [preferred formulary]
      - Lamotrigine [preferred formulary]
      - Levetiracetam [preferred formulary]
      - Oxcarbazepine [preferred formulary]
      - Phenobarbital [formulary]
      - Phenytoin [formulary]
      - Pregabalin [formulary]
      - Primidone [formulary]
      - Tiagabine [non-formulary]

- Topiramate [preferred formulary]
- Valproic acid derivative [formulary]
- Vigabatrin [non-formulary]
- Zonisamide [preferred formulary]

If initial criteria are met, approve indefinitely at HICL.
If initial criteria are not met, do not approve.

B. To treat Primary Generalized Tonic-Clonic Seizures (also known as generalized onset motor tonic-clonic): All the following must be met:
   1. Medication is prescribed by a CMPG or affiliated neurologist or epileptologist.
   2. This medication will be used as adjunctive therapy with at least one other anti-seizure drug.
   3. Dose does not exceed 12 mg per day.
   4. The patient is stable on perampanel (Fycompa), or patient has failed least 2 of the following medications, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      - clobazam [formulary]
      - felbamate [formulary]
      - lacosamide [preferred formulary]
      - lamotrigine [preferred formulary]
      - levetiracetam [preferred formulary]
      - rufinamide [non-formulary]
      - topiramate [preferred formulary]
      - valproic acid derivative [formulary]
      - zonisamide [preferred formulary]

If initial criteria are met, approve indefinitely at HICL.
If initial criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with the requested medication?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Partial Onset Seizures (also known as focal onset aware or impaired awareness); Primary Generalized Tonic-Clonic Seizures (also known as generalized onset motor tonic-clonic)]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Partial Onset Seizures
   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   2. Is there reasoning why alternatives (carbamazepine ER tablets (100 mg, 200 mg, 400 mg), carbamazepine IR tablets (200 mg), carbamazepine chewable tablets (100 mg); divalproex sodium DR (12 hr) or ER (24 hr) tablets, divalproex sodium sprinkle caps (125 mg), valproic

acid capsules (250 mg); lacosamide tablets; lamotrigine IR, ER, or chewable tablets; levetiracetam IR or ER tablets; oxcarbazepine tablets (150 mg, 300 mg, 600 mg); topiramate IR tablets or sprinkle capsules (25 mg); zonisamide capsules; felbamate tablets (400 mg, 600 mg) or suspension; gabapentin capsules (100 mg, 300 mg, 400 mg); pregabalin capsules; primidone tablets; Dilantin 30 mg capsules, phenytoin ER capsules (100 mg) or chewable tablets (50 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Primary Generalized Tonic-Clonic Seizures

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (clobazam tablets; divalproex sodium DR (12 hr) or ER (24 hr) tablets, divalproex sodium sprinkle caps (125 mg), valproic acid capsules (250 mg); lacosamide tablets; lamotrigine IR, ER, or chewable tablets; levetiracetam IR or ER tablets; topiramate IR tablets or sprinkle capsules (25 mg); zonisamide capsules; felbamate tablets (400 mg, 600 mg) or suspension) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

FDA APPROVED INDICATIONS

Fycompa is indicated:

- For the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 4 years of age and older.
- For adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older.

REFERENCES

1. Fycompa Prescribing Information. Woodcliff Lake, NJ: Eisai Inc.; April 2024
2. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment resistant epilepsy. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Epilepsy Curr. Jul-Aug 2018;18(4):269-78.

Creation Date: 07/2023
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

PHARMACY DISPENSED CONTINUOUS INSULIN DELIVERY DEVICE PA GUIDELINE
OMNIPOD

Generic	Brand	HICL	GPID	Comments
INSULIN PUMP CARTRIDGE	OMNIPOD DASH PODS (GEN 4)	33823		
INSULIN PUMP CONTROLLER	OMNIPOD DASH PDM KIT (GEN 4)	40278		
INSULIN PUMP CARTRIDGE	OMNIPOD 5 DEXG7G6 PODS (GEN 5)	47736		
INSULIN PUMP CART & CONTROLLER	OMNIPOD 5 DEXG7G6 INTRO (GEN 5)	47922		
INSULIN PUMP CART & CONTROLLER	OMNIPOD 5 INTRO (G6/LIBRE2PLUS)	49847		
INSULIN PUMP CARTRIDGE	OMNIPOD 5 DEXG7G6 PODS (GEN 5)	49386		
INSULIN PUMP CARTRIDGE	OMNIPOD 5 (G6/LIBRE2PLUS)	49846		
INSULIN PUMP CART & CONTROLLER	OMNIPOD DASH INTRO KIT (GEN 4)	47923		
INSULIN PUMP CART 10 U/DAY INSULIN PUMP CART 15 U/DAY INSULIN PUMP CART 20 U/DAY INSULIN PUMP CART 25 U/DAY INSULIN PUMP CART 30 U/DAY INSULIN PUMP CART 35 U/DAY INSULIN PUMP CART 40 U/DAY	OMNIPOD GO PODS	48902, 48904, 48905, 48906, 48907, 48908, 48909		

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following based on type of diabetes:

A – Type 1 Diabetes, Not Currently Using an Insulin Pump
B – Type 1 Diabetes, Currently Using an Insulin Pump
C – Type 2 Diabetes, Not Currently Using an Insulin Pump
D – Gestational Diabetes
E – Type 2 Diabetes, Currently Using an Insulin Pump

A. Type 1 Diabetes, Not Currently Using an Insulin Pump: Must meet all the following:
   1. Patient must have diagnosis of Type 1 Diabetes
   2. The prescriber must be an Endocrinology or Diabetes specialist
   3. Request must be for Omnipod DASH or Omnipod 5
   4. Patient has completed a comprehensive diabetes education program
   5. Patient has been on a program of at least 3 daily injections of insulin with frequent self-adjustments of dose for at least 1 to 2 months prior to this request
   6. Patient has documented frequency of glucose self-testing of at least 3 times per day for 1 to 2 months prior to this request
   7. Meets one or more of the following, while on the multiple injection regimen:
      a. Glycosylated hemoglobin level (HbA1C) greater than 6%
      b. History of recurring hypoglycemia
      c. Wide fluctuations in blood glucose before mealtime

d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
e. History of severe glycemic excursions

If initial criteria are met, approve the PDM kit at HICL x 1 fill only and the DASH or 5 pods at HICL indefinitely.
If initial criteria are not met, do not approve. The patient does not qualify for a continuous insulin delivery device at this time and may continue other means of insulin administration.

B. Type 1 Diabetes, Currently Using an Insulin Pump: Must meet all the following:
1. Patient must have diagnosis of Type 1 Diabetes
2. The prescriber must be an Endocrinology or Diabetes specialist
3. Request must be for Omnipod DASH or Omnipod 5

If initial criteria are met, approve the PDM kit at HICL x 1 fill only and the DASH or 5 pods at HICL indefinitely.
If initial criteria are not met, do not approve. The patient does not qualify for a continuous insulin delivery device at this time and may continue other means of insulin administration.

C. Type 2 Diabetes, Not Currently Using an Insulin Pump: Must meet the following based on product requested:
I. Omnipod DASH: Must meet all the following:
1. Patient must have diagnosis of Type 2 Diabetes
2. Prescriber must be an Endocrinology or Diabetes specialist
3. Patient has completed a comprehensive diabetes education program
4. Patient monitors blood glucose at least 3-4 times per 24 hours
5. Patient is currently using at least 3-4 insulin injections per 24 hours
6. Meets one or more of the following, while on the multiple injection regimen:
a. Glycosylated hemoglobin level (HbA1C) greater than 6%
b. History of recurring hypoglycemia
c. Wide fluctuations in blood glucose before mealtime
d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
e. History of severe glycemic excursions
7. Patient has worked with a Diabetes Care Specialist for at least 6 months on insulin adjustments and the following continue to occur:
a. At least 2 or more nocturnal hypoglycemia episodes (blood glucose <65mg/dL) in the past month
b. Use of glucagon in the past 12 months
8. Patient has been on a program of at least 3 daily injections of insulin with frequent self-adjustments of dose for at least 1 to 2 months prior to this request
9. Patient has documented frequency of glucose self-testing of at least 3 times per day for 1 to 2 months prior to this request

If initial criteria are met, approve the PDM kit at HICL x 1 fill only and the DASH or 5 pods at HICL indefinitely.
If initial criteria are not met, do not approve. The patient does not qualify for a continuous insulin delivery device at this time and may continue other means of insulin administration.

D. Gestational Diabetes: Must meet all the following:
1. Request must be for Omnipod DASH
2. Patient must be pregnant and at high risk of developing pregnancy-related complications

3. Prescriber must be an Endocrinology or Maternal Fetal Medicine provider

   If initial criteria are met, approve the PDM kit at HICL x 1 fill only and the DASH pods at HICL x 1 year.
   If initial criteria are not met, do not approve.

E. Type 2 Diabetes, Currently Using an Insulin Pump: Must meet the following based on product requested:
   I. Omnipod DASH: Must meet all the following:
      1. Patient must have diagnosis of Type 2 Diabetes
      2. The prescriber must be an Endocrinology or Diabetes specialist
      3. Request must be for Omnipod DASH

   If initial criteria are met, approve the PDM kit at HICL x 1 fill only and the DASH pods at HICL indefinitely.
   If initial criteria are not met, do not approve. The patient does not qualify for a continuous insulin delivery device at this time and may continue other means of insulin administration

RATIONALE
KPCO Insulin pump guidelines are included to ensure just and fair reviews between the DME benefit and the Pharmacy benefit.
CMS designated these products as 'disposable insulin delivery devices similar to syringes' therefore are not durable medical equipment and are covered under Part D. KP is following this guidance for the Commercial lines of business as well as Medicare lines.

NOTE: The Freestyle Libre and the Dexcom products are reviewed and approved through the DME process and dispensed through the DME vendor

FDA APPROVED INDICATIONS
Type 1 and Type 2 Diabetes with multiple daily insulin injections - Omnipod Dash
Type 1 Diabetes with multiple daily insulin injections - Omnipod 5 G6
Type 2 Diabetes with multiple daily insulin injections - V-Go

REFERENCES
KPCO Insulin Pump Guidelines 4.8.19
KPCO Endocrinology Dept
Omnipod DASH Insulin Management System with interoperable technology. 2019
https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191679.pdf

Creation date: 10/2019
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 11/2023

PHARMACY DISPENSED CONTINUOUS INSULIN DELIVERY DEVICE PA GUIDELINE
V-GO

Generic	Brand	HICL	GPID	Exception/Other
SUBCUTANEOUS INSULIN DEVICE 20 UNITS	V-GO 20	38483		
SUBCUTANEOUS INSULIN DEVICE 30 UNITS	V-GO 30	38484		
SUBCUTANEOUS INSULIN DEVICE 40 UNITS	V-GO 40	38486		

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following based on type of diabetes:

A – Type 2 Diabetes, Not Currently Using an Insulin Pump
B – Type 2 Diabetes, Currently Using an Insulin Pump

A. Type 2 Diabetes, Not Currently Using an Insulin Pump: Must meet the following based on product requested:
    B. V-Go: Must meet all the following:
        1. Patient must have diagnosis of Type 2 Diabetes
        2. Prescriber must be an Endocrinology or Diabetes specialist
        3. Patient has completed a comprehensive diabetes education program
        4. Patient monitors blood glucose at least 3-4 times per 24 hrs
        5. Patient is currently using at least 3-4 insulin injections per 24 hrs
        6. Patient is using 40 units or less of basal insulin per day
        7. Meets one or more of the following, while on the multiple injection regimen:
            a. Glycosylated hemoglobin level (HbA1C) greater than 6 %
            b. History of recurring hypoglycemia
            c. Wide fluctuations in blood glucose before mealtime
            d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
            e. History of severe glycemic excursions
        8. Patient has worked with a Diabetes Care Specialist for at least 6 months on insulin adjustments and the following continue to occur:
            a. At least 2 or more nocturnal hypoglycemia episodes (blood glucose <65mg/dL) in the past month
            b. Use of glucagon in the past 12 months
        9. Patient has been on a program of at least 3 daily injections of insulin with frequent self-adjustments of dose for at least 1 to 2 months prior to this request
        10. Patient has documented frequency of glucose self-testing of at least 3 times per day for 1 to 2 months prior to this request

    If initial criteria are met, approve at HICL indefinitely.
    If initial criteria are not met, do not approve. The patient does not qualify for a continuous insulin delivery device at this time and may continue self-administering insulin.

B. Type 2 Diabetes, Currently Using an Insulin Pump: Must meet the following based on product requested:
    I. V-Go: Must meet all the following:
        1. Patient must have diagnosis of Type 2 Diabetes

2. Prescriber must be an Endocrinology or Diabetes specialist
3. Patient is using 40 units or less of basal insulin per day

If initial criteria are met, approve at HICL indefinitely.
If initial criteria are not met, do not approve. The patient does not qualify for a continuous insulin delivery device at this time and may continue other means of insulin administration.

RATIONALE
KPCO Insulin pump guidelines are included to ensure just and fair reviews between the DME benefit and the Pharmacy benefit.
CMS designated these products as 'disposable insulin delivery devices similar to syringes' therefore are not durable medical equipment and are covered under Part D. KP is following this guidance for the Commercial lines of business as well as Medicare lines.

NOTE: The Freestyle Libre and the Dexcom products are reviewed and approved through the DME process and dispensed through the DME vendor

FDA APPROVED INDICATIONS
Type 1 and Type 2 Diabetes with multiple daily insulin injections - Omnipod Dash
Type 1 Diabetes with multiple daily insulin injections - Omnipod 5 G6
Type 2 Diabetes with multiple daily insulin injections - V-Go

REFERENCES
KPCO Insulin Pump Guidelines 4.8.19
KPCO Endocrinology Dept
Omnipod DASH Insulin Management System with interoperable technology. 2019
https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191679.pdf

Creation date: 10/2019
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 11/2023

PITOLISANT (WAKIX)

Generic	Brand	HICL	GPID	Exception/Other
PITOLISANT HCL	WAKIX	45575	45948, 45949	Non-Formulary 2nd preferred (after Sunosi)

GUIDELINES FOR COVERAGE

CRITERIA FOR ALL PATIENTS CURRENTLY TAKING THE REQUESTED MEDICATION: MUST MEET ALL THE FOLLOWING:

1. Medication is prescribed by a Neurology or a Board-Certified Sleep Medicine provider.
2. Medication is being prescribed for Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia; or Cataplexy (not excessive daytime sleepiness) due to narcolepsy.
3. Medication requested is not be used in combination with solriamfetol (Sunosi) or any oxybate product (i.e. Xyrem, Xywav, Lumryz).

If criteria are met, approve at HICL indefinitely, max 2 tablets/day.
If criteria are not met, do not approve.

CRITERIA FOR ANY PATIENT NOT CURRENTLY TAKING THE REQUESTED MEDICATION: MUST MEET ALL THE FOLLOWING:

A. Medication is prescribed by Neurology or a Board-Certified Sleep Medicine provider.
B. Medication requested is not be used in combination with solriamfetol (Sunosi) or any oxybate product (i.e. Xyrem, Xywav, Lumryz).
C. Patient must have one of the following indications and meet all criteria pertaining to that indication:
    1. Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia: Must meet all the following, or the provider submitted justification and supporting clinical documentation that states one of the following: i) the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
        a. Patient must have tried and failed or have a contraindication to each of the following: amphetamines, methylphenidate, and either modafinil or armodafinil.
        b. Patient must have tried and failed or have a contraindication to Sunosi [Prior Authorization required].

        If criteria are met, approve at HICL indefinitely, max 2 tablets/day.
        If criteria are not met, do not approve.

    2. Cataplexy (not excessive daytime sleepiness) due to narcolepsy: Patient must have tried and failed or have a contraindication to each of the following, or the provider submitted justification and supporting clinical documentation that states one of the following: i) the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy

exception: a tricyclic antidepressant (TCA), a selective serotonin reuptake inhibitor (SSRI), and a selective serotonin-norepinephrine (SNRI).

If critieria are met, approve at HICL indefinitely, max 2 tablets/day.
If criteria are not met, do not approve.

ePA Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia; Cataplexy (not excessive daytime sleepiness) due to narcolepsy]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia

1. Is the patient stable on therapy with this medication?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Is the medication being used in combination with solriamfetol (Sunosi) or any other oxybate product (i.e. Xywav, Xyrem, Lumryz)?
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (amphetamines, methylphenidate, modafinil, armodafinil) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Cataplexy (not excessive daytime sleepiness) due to narcolepsy

1. Is the patient stable on therapy with this medication?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Is the medication being used in combination with solriamfetol (Sunosi) or any other oxybate product (i.e. Xywav, Xyrem, Lumryz)?
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (amitriptyline tablets, desipramine tablets, nortriptyline capsules; citalopram tablets/solution, escitalopram tablets, fluoxetine capsules/solution, paroxetine IR tablets, sertraline tablets/susp; venlafaxine ER capsules (37.5 mg, 75 mg, 150 mg), duloxetine capsules (20 mg, 30 mg, 60 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Lumryz, sodium oxybate oral solution. and Xywav have the same active ingredient (oxybate, a CNS depressant) and have not been studied for use in combination or as alternating treatments. Sunosi, a dopamine and norepinephrine reuptake inhibitor, is indicated to improve wakefulness in adults with excessive daytime sleepiness due to narcolepsy or obstructive sleep apnea. Wakix, an antagonist/inverse agonist of the histamine-3 receptor, is indicated for excessive daytime sleepiness and cataplexy in adults with narcolepsy. Currently, there are no published studies evaluating combination use of these medications.

FDA APPROVED INDICATIONS AND SUPPORTED OFF-LABEL INDICATIONS
Xyrem/Xywav/Lumryz = Cataplexy; Narcolepsy; Idiopathic hypersomnia
Sunosi = Narcolepsy; Idiopathic hypersomnia; Hypersomnia associated with Obstructive sleep apnea
Wakix = Cataplexy; Narcolepsy; Idiopathic hypersomnia

Creation date: 03/2020
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2025

PLECANATIDE (TRULANCE)

Generic	Brand	HICL	GPID	Exception/Other
PLECANATIDE	TRULANCE	44054	42925	Formulary

GUIDELINES FOR COVERAGE

Must meet all the following:

1. The patient is 18 years of age or older with a diagnosis of IBS-C or CIC
2. The patient has tried and failed all of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. at least one bulk-forming laxative (a bulk forming laxative contains psyllium, methylcellulose, or polycarbophil and examples may include Metamucil, Citrucel, FiberCon)
    b. at least one osmotic laxative (an osmotic laxative contains magnesium hydroxide, polyethylene glycol, lactulose, magnesium citrate, or glycerin and examples may include milk of magnesia or Miralax)
    c. lubiprostone

If criteria are met, approve indefinitely at HICL, max 1 tablet per day.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (bulk-forming laxative, osmotic laxative, or others) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Per Plan.

REFERENCES

Per Plan.

Creation date: 3/15/2017
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2025

POSACONAZOLE (NOXAFIL)

Generic	Brand	HICL	GPID	Exception/Other
POSACONAZOLE	NOXAFIL	33461	35649, 26502, 49744	Formulary

GUIDELINES FOR COVERAGE

NEW MEMBER/INITIAL CRITERIA: Must meet ALL the following:

1. Prescriber specializes in Hematology, Oncology, Hematopoietic Stem Cell Transplantation, Solid Organ Transplant or Infectious Disease
2. Patient is at least 13 years of age, OR is at least 2 years of age AND weighs at least 40kg (88 pounds)
3. Posaconazole is being used as treatment or prophylaxis in patients with ONE of the following conditions:
   a. Acute leukemia or myelodysplastic syndrome (MDS) and receiving systemic chemotherapy
   b. Patient is s/p allogeneic hematopoietic stem cell transplant (HCT) and meets ONE of the following conditions:
      i. history of invasive fungal infection
      ii. is 30+days s/p transplant AND ANC remains <1,500
      iii. is 14+days s/p transplant AND ANC remains <500
   c. Graft versus host disease (GVHD) and currently being treated with systemic immunosuppressive therapy
   d. Invasive fungal infection with organism known to be resistant to voriconazole and fluconazole
   e. Invasive fungal infection with documented failure, intolerance or contraindication to fluconazole and/or voriconazole (as appropriate), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
4. If request is for posaconazole suspension, patient must have documented intolerance or contraindication, or inability to swallow to posaconazole tablets.

If initial criteria are met, approve x6 months at HICL.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet ONE OF the following:

1. If initial approval was for invasive fungal infection, patient has shown improvement of symptoms since starting on the drug.
2. If initial approval was for acute leukemia or MDS, patient continues to receive systemic chemotherapy for their diagnosis.
3. If initial approval was for s/p allogeneic HSCT, patient must continue to be neutropenic.
4. If initial approval was for GVHD, patient must be receiving either high dose corticosteroids OR other systemic anti-GVHD therapies (e.g., tacrolimus, sirolimus, ruxolitinib, ibrutinib, belumosudil, others).

If renewal criteria are met, approve x6 months at HICL.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Acute leukemia or myelodysplastic syndrome (MDS) and receiving systemic chemotherapy; s/p allogeneic hematopoietic stem cell transplant (HCT); Graft versus host disease (GVHD) and currently being treated with systemic immunosuppressive therapy; Invasive fungal infection]

   QUESTIONS BASED ON DIAGNOSIS SELECTED
   S/P allogeneic hematopoietic stem cell transplant (HCT)
   1. Does the patient have history of invasive fungal infection?
   2. Is the patient 30+days s/p transplant AND ANC remains <1,500?
   3. Is the patient 14+days s/p transplant AND ANC remains <500?

   Invasive fungal infection
   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   2. Is there reasoning why alternatives (fluconazole tablets, voriconazole tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Acute leukemia or myelodysplastic syndrome (MDS) and receiving systemic chemotherapy; s/p allogeneic hematopoietic stem cell transplant (HCT); Graft versus host disease (GVHD) and currently being treated with systemic immunosuppressive therapy; Invasive fungal infection]

QUESTIONS BASED ON DIAGNOSIS SELECTED
Acute leukemia or myelodysplastic syndrome (MDS)
1. Is the patient still receiving systemic chemotherapy?

S/P allogeneic hematopoietic stem cell transplant (HCT)
1. Is the patient still neutropenic?

Graft versus host disease (GVHD)
1. Is the patient receiving either high dose corticosteroids OR other systemic anti-GVHD therapies (e.g., tacrolimus, sirolimus, ruxolitinib, ibrutinib, belumosudil)?

Invasive fungal infection
1. Has the patient has shown improvement of symptoms since starting on the drug?

RATIONALE
To promote cost-effective, evidence-based use of posaconazole.

FDA APPROVED INDICATIONS
Treatment of fungal infections in adults and children 13 years of age and older
Prevention of fungal infections in adults and children 2 years of age and older who weigh greater than 88 lbs (40kg)

REFERENCES
1. NCCN Guidelines on Prevention and Treatment of Cancer-Related Infections. V.1.2024. www.nccn.org
2. Noxafil Prescribing Information. Merck & Co, Inc. Rahway NJ. Revised 09/2022.

Creation Date: 09/2023
Effective Date: 10/2024
Reviewed Date: 09/2024
Revised Date: 09/2024

POTASSIUM CHLORIDE (KCL) SOLUTION - AGE RESTRICTION

Generic	Brand	HICL	GPID	Exception/Other
POTASSIUM CHLORIDE LIQUID 20mEq/15mL			3443	Non-formulary
POTASSIUM CHLORIDE LIQUID 40mEq/15mL			3442	Non-formulary
POTASSIUM CHLORIDE 10 mEq POWDER PACKETS			54758	Non-formulary
POTASSIUM CHLORIDE 20mEq POWDER PACKETS			3404	

GUIDELINES FOR COVERAGE

INITIAL AND RENEWAL CRITERIA: ONE of the following must be met:

1. Patient is less than or equal to 10 years old
2. Current dosage is greater than 40mEq twice daily
3. Patient is using an alternative administration route, such as a gastrostomy tube
4. Patient has failed therapy using Klor-Con M tablets dissolved in water, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If coverage criteria are met at criterion 1, approve until patient turns 11 years of age.
If coverage criteria are met at criterion 2, 3, or 4, approve indefinitely.
If no criteria are met, do not approve.

Note:
The preferred alternative for patients who do not meet coverage criteria is to disperse the Klor-Con M tablets in water and swallow the slurry per the instructions below.

- Klor-Con M tablet slurry instructions:
  - Dissolve 1 tablet (20mEq) in 120 mL of water over 2 minutes
  - Stir for approximately 30 seconds and consume immediately
  - Add an additional 30mL of water to the container and consume immediately

ePA Questions

1. Is the patient using an alternative administration route, such as a gastrostomy tube? If yes, must attach applicable chart notes.
2. Is the patient unable to swallow tablets whole, halved, or dissolved in water? If yes, must attach applicable chart notes.

RATIONALE

Per KPCO UM Team

REFERENCES

Per Health Plan

Creation date: 5/2019
Effective date: 10/2024
Revised date: 09/2024
Reviewed date: 09/2024

PRUCALOPRIDE (MOTEGRITY)

Generic	Brand	HICL	GPID	Exception/Other
PRUCALOPRIDE	MOTEGRITY	36920	28445, 28446	Non-Formulary

GUIDELINES FOR COVERAGE

Must meet all the following:

A. The patient is 18 years of age or older with a diagnosis of Chronic Idiopathic Constipation (CIC)
B. The patient is 18 years of age or older with a diagnosis of CIC AND gastroparesis

A. The patient is 18 years of age or older with a diagnosis of Chronic Idiopathic Constipation (CIC)
   1. The patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. at least one bulk-forming laxative (a bulk forming laxative contains psyllium, methylcellulose, or polycarbophil and examples may include Metamucil, Citrucel, FiberCon)
      b. at least one osmotic laxative (an osmotic laxative contains magnesium hydroxide, polyethylene glycol, lactulose, magnesium citrate, or glycerin and examples may include milk of magnesia or Miralax)
      c. lubiprostone
      d. Trulance

If criteria are met, approve indefinitely at HICL, max 1 tablet per day.
If criteria are not met, do not approve.

B. The patient is 18 years of age or older with a diagnosis of CIC AND gastroparesis
   1. The patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. at least one bulk-forming laxative (a bulk forming laxative contains psyllium, methylcellulose, or polycarbophil and examples may include Metamucil, Citrucel, FiberCon)
      b. at least one osmotic laxative (an osmotic laxative contains magnesium hydroxide, polyethylene glycol, lactulose, magnesium citrate, or glycerin and examples may include milk of magnesia or Miralax)

If criteria are met, approve indefinitely at HICL, max 1 tablet per day.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (bulk-forming laxative, osmotic laxative, or others) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Does the patient have a diagnosis of Gastroparesis?

RATIONALE

Per Plan.

Prucalopride is a selective, high affinity 5-HT_4 receptor agonist whose action at the receptor site promotes cholinergic and nonadrenergic, noncholinergic neurotransmission by enteric neurons leading to stimulation of the peristaltic reflex, intestinal secretions, and gastrointestinal motility.

There are limited options for gastroparesis. Motegrity has off-label use with supporting evidence for gastroparesis. Patients with CIC and gastroparesis are not required to trial Amitiza and Trulance, as these medications do not aid in gastrointestinal motility. This allows for improved treatment options based on this dual indication.

REFERENCES

Per Plan.

Andrews CN, Woo M, Buresi M, et al. Prucalopride in diabetic and connective tissue disease-related gastroparesis: randomized placebo-controlled crossover pilot trial. *Neurogastroenterol Motil*. 2021;33(1):e13958. doi:10.1111/nmo.13958[PubMed 32743954]

Carbone F, Van den Houte K, Clevers E, et al. Prucalopride in gastroparesis: a randomized placebo-controlled crossover study. *Am J Gastroenterol*. 2019;114(8):1265-1274. doi:10.14309/ajg.0000000000000304[PubMed 31295161]

Creation date: 3/15/2017
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2025

RAMELTEON (ROZEREM)

Generic	Brand	HICL	GPID	Exception/Other
RAMELTEON	ROZEREM	33126	25202	Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient has insomnia characterized by difficulty with sleep onset.
2. Patient has tried and failed oral melatonin or has a contraindication to melatonin, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

   If the above criteria are met, approve generic ramelteon at HICL x 6 months.
   If the above criteria are not met, do not approve.

RENEWAL CRITERIA:
1. Documentation of a positive clinical response

   If met, approve indefinitely, maximum #1 tablet per day.
   If not met, do not approve.

ePA Questions
Initial Review Questions
1. Does the patient have insomnia characterized by difficulty with sleep onset?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (melatonin) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Has the patient had a positive clinical response to therapy?

Creation date: 05/2018
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2025

RAPID-ACTING INSULIN PENS - ASPART

Generic	Brand	HICL	GPID	Exception/Other
INSULIN ASPART PENS	NOVOLOG FLEXPEN, NOVOLOG RELION FLEXPEN	20769	92336	BRAND EXCLUDED
INSULIN ASPART CARTRIDGES	NOVOLOG PENFILL CARTRIDGE	20769	92886	BRAND EXCLUDED For use with NovoPen Echo device for ½ unit dosing

GUIDELINES FOR COVERAGE

Must meet the following:

1. Patient has failed* insulin Lispro (Humalog), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
2. Meets one of the following requirements for pen/cartridge form:
   a. Prescription is written by an Endocrinology specialist.
   b. Patient is under 18 years of age.
   c. Patient is 18 years of age or older and is unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination.

   If criteria are met, approve at HICL indefinitely.
   If criteria are not met, do not approve.
   [NOTE: Brand Novolog products are excluded from coverage. Kaiser Permanente will dispense unbranded insulin aspart.]

*NOTE: Failure can be defined as an adverse drug reaction or intolerance that is not expected to occur with the requested agent.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Humalog vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Unbranded insulin aspart is the unbranded biologic form of Novolog. An unbranded biologic is the same product as the branded biologic without the brand name on the packaging.

Step through Humulin R is not required for patients requesting aspart pens, only those seeking coverage for aspart vials. Humulin R is only available in vials, so patients requiring pen form for insulin administration would not be able to attempt therapy with Humulin R.

There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. Insulin Lispro (Humalog Kwikpen) is preferred based on its efficacy and safety profile, as well as its competitive cost advantage for patients and KPCO. The use of insulin pens at KPCO is reserved for children and adults with physical and/or cognitive impairment.

Certain insulin products offer ½ unit dosing such as Lispro (Humalog Junior KwikPen, Humalog Cartridge), Aspart (Novolog Cartridge), and Lispro aabc (Lyumjev Junior KwikPen). Humalog Junior KwikPen or Humalog Cartridge are preferred based on this insulin's efficacy and safety profile, as well as its competitive cost advantage for patients and KPCO.

Two rapid-acting insulin pens are available in a higher concentration such as Lispro (Humalog KwikPen U-200) and Lispro aabc (Lyumjev KwikPen U-200). Humalog KwikPen U-200 is KPCO preferred option for patients requiring insulin doses between 100 and 200 units/day.

Two insulin products are considered ultra-rapid acting insulins due to additives and their ability to speed up absorption by 5-10 minutes. These insulins are Lispro aabc and Aspart with niacinamide. Lispro aabc (Lyumjev) is the first insulin approved as a biologic. It has no clinical advantage over Fiasp but offeres a cost advantage and therefore is the preferred product. All insulins will be approved as biologics from now on.

Tempo pens are personalized diabetes management platform that combines the Tempo prefilled insulin pen, diabetes management devices, and app-driven support to deliver personalized guidance for people with diabetes.

FDA APPROVED INDICATIONS
Diabetes type 1 and type 2 treatment

Creation date: 5/4/2017
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

RAPID-ACTING INSULIN PENS
ASPART NIACINAMIDE

Generic	Brand	HICL	GPID	Exception/Other
INSULIN ASPART (NIACINAMIDE)	FIASP FLEXTOUCH PEN FIASP PENFILL CARTRIDGE	44099	43053, 43049	Ultra rapid

GUIDELINES FOR COVERAGE

Must meet the following:

1. Patient has failed insulin lispro (Humalog) due to difficulties with timing of mealtime doses, late hypoglycemia, or due to an adverse drug reaction/intolerance that is not expected to occur with the requested agent, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
2. Meets one of the following requirements for pen/cartridge form:
   a. Prescription is written by an Endocrinology specialist.
   b. Patient is under 18 years of age.
   c. Patient is 18 years of age or older and is unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

*NOTE: Failure can be defined as an adverse drug reaction or intolerance that is not expected to occur with the requested agent.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Humalog vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. Insulin Lispro (Humalog Kwikpen) is preferred based on its efficacy and safety profile, as well as its competitive cost advantage for patients and KPCO. The use of insulin pens at KPCO is generally reserved for children and adults with physical and/or cognitive impairment.

Certain insulin products offer ½ unit dosing such as Lispro (Humalog Junior KwikPen, Humalog Cartridge), Aspart (Novolog Cartridge), and Lispro aabc (Lyumjev Junior KwikPen). Humalog Junior KwikPen or Humalog Cartridge are preferred based on this insulin's efficacy and safety profile, as well as its competitive cost advantage for patients and KPCO.

Two rapid-acting insulin pens are available in a higher concentration such as Lispro (Humalog KwikPen U-200) and Lispro aabc (Lyumjev KwikPen U-200). Humalog KwikPen U-200 is KPCO preferred option for patients requiring insulin doses between 100 and 200 units/day.

Two insulin products are considered ultra-rapid acting insulins due to additives and their ability to speed up absorption by 5-10 minutes. These insulins are Lispro aabc and Aspart with niacinamide. Lispro aabc (Lyumjev) is the first insulin approved as a biologic. It has no clinical advantage over Fiasp but offeres a cost advantage and therefore is the preferred product. All insulins will be approved as biologics from now on.

Tempo pens are personalized diabetes management platform that combines the Tempo prefilled insulin pen, diabetes management devices, and app-driven support to deliver personalized guidance for people with diabetes.

FDA APPROVED INDICATIONS
Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation date: 5/4/2017
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

RAPID-ACTING INSULIN PENS - GLULISINE

Generic	Brand	HICL	GPID	Exception/Other
INSULIN GLULISINE	APIDRA SOLOSTAR	33152	26508	

GUIDELINES FOR COVERAGE

Must meet the following:

1. Patient has failed* insulin lispro (Humalog), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
2. Meets one of the following requirements for pen form:
   a. Prescription is written by an Endocrinology specialist.
   b. Patient is under 18 years of age.
   c. Patient is 18 years of age or older and is unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

*NOTE: Failure can be defined as an adverse drug reaction or intolerance that is not expected to occur with the requested agent.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Humalog vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. Insulin Lispro (Humalog Kwikpen) is preferred based on its efficacy and safety profile, as well as its competitive cost advantage for patients and KPCO. The use of insulin pens at KPCO is reserved for children and adults with physical and/or cognitive impairment.

Certain insulin products offer ½ unit dosing such as Lispro (Humalog Junior KwikPen, Humalog Cartridge), Aspart (Novolog Cartridge), and Lispro aabc (Lyumjev Junior KwikPen). Humalog Junior KwikPen or Humalog Cartridge are preferred based on this insulin's efficacy and safety profile, as well as its competitive cost advantage for patients and KPCO.

Two rapid-acting insulin pens are available in a higher concentration such as Lispro (Humalog KwikPen U-200) and Lispro aabc (Lyumjev KwikPen U-200). Humalog KwikPen U-200 is KPCO preferred option for patients requiring insulin doses between 100 and 200 units/day.

Two insulin products are considered ultra-rapid acting insulins due to additives and their ability to speed up absorption by 5-10 minutes. These insulins are Lispro aabc and Aspart with niacinamide. Lispro aabc (Lyumjev) is the first insulin approved as a biologic. It has no clinical advantage over Fiasp but offeres a cost advantage and therefore is the preferred product. All insulins will be approved as biologics from now on.

Tempo pens are personalized diabetes management platform that combines the Tempo prefilled insulin pen, diabetes management devices, and app-driven support to deliver personalized guidance for people with diabetes.

FDA APPROVED INDICATIONS
Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation date: 5/4/2017
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

RAPID-ACTING INSULIN PENS/CARTRIDGES - LISPRO U-100

Generic	Brand	HICL	GPID	Exception/Other
INSULIN LISPRO	ADMELOG SOLOSTAR, HUMALOG TEMPO PEN	11528	96719	GSN = 34731 Humalog KwikPen - preferred product
INSULIN LISPRO	HUMALOG CARTRIDGE	11528	5678	For use with HumaPen Luxura for ½ unit dosing (device no longer made)
INSULIN LISPRO	HUMALOG JUNIOR KWIKPEN	11528	43753	Preferred product for ½ unit dosing

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
Patient is new to KPCO within the past 90 days and is currently using Humalog Cartridge or Humalog Jr. Kwikpen.

If New Member Criteria are met, approve indefinitely at GPID.
If New Member Criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet ONE of the following:
1. Prescription is written by an Endocrinology specialist.
2. Patient is under 18 years of age.
3. Patient is 18 years of age or older and is unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination.

If met, approve indefinitely at GPID.
If above criteria are not met, do not approve.
[Note: Biosimilars of Humalog are non-preferred. Kaiser Permanente will dispense brand Humalog.]

ePA Questions
1. Is the patient stable on therapy with the requested product?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. Insulin Lispro (Humalog Kwikpen) is preferred based on its efficacy and safety profile, as well as its competitive cost advantage for patients and KPCO. The use of insulin pens at KPCO is generally reserved for children and adults with physical and/or cognitive impairment.

Certain insulin products offer ½ unit dosing such as Lispro (Humalog Junior KwikPen, Humalog Cartridge), Aspart (Novolog Cartridge), and Lispro aabc (Lyumjev Junior KwikPen). Humalog Junior

KwikPen or Humalog Cartridge are preferred based on this insulin's efficacy and safety profile, as well as its competitive cost advantage for patients and KPCO.

Two rapid-acting insulin pens are available in a higher concentration such as Lispro (Humalog KwikPen U-200) and Lispro aabc (Lyumjev KwikPen U-200). Humalog KwikPen U-200 is KPCO preferred option for patients requiring insulin doses between 100 and 200 units/day.

Two insulin products are considered ultra-rapid acting insulins due to additives and their ability to speed up absorption by 5-10 minutes. These insulins are Lispro aabc and Aspart with niacinamide. Lispro aabc (Lyumjev) is the first insulin approved as a biologic. It has no clinical advantage over Fiasp but offeres a cost advantage and therefore is the preferred product. All insulins will be approved as biologics from now on.

Tempo pens are personalized diabetes management platform that combines the Tempo prefilled insulin pen, diabetes management devices, and app-driven support to deliver personalized guidance for people with diabetes.

FDA APPROVED INDICATIONS
Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation date: 5/4/2017
Effective date: 06/2025
Reviewed date: 07/2024
Revised date: 05/2025

RAPID-ACTING INSULIN PENS - LISPRO U-200

Generic	Brand	HICL	GPID	Exception/Other
INSULIN LISPRO	HUMALOG KWIKPEN U-200	11528	37798	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet the following:
Patient's short-acting insulin dose is 100 units per day or more (including Regular) but their total daily insulin dose (basal + bolus) is less than 200 units/day or 2 units/kg/day.

If criteria are met, approve at GPID x2 years.
If criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following:
Patient's short-acting insulin dose exceeds 100 units/day but their total daily dose of insulin (basal + bolus) does NOT exceed 200 units/day or 2 units/kg/day.

If renewal criteria are met, approve at GPID x2 years.
If renewal criteria are not met, do not approve.

ePA Questions
1. Patient's long-acting insulin dose (units/day):
2. Patient's total daily dose of insulin (units/day):
3. Patient weight (kg):

RATIONALE
There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. Insulin Lispro (Humalog Kwikpen) is preferred based on its efficacy and safety profile, as well as its competitive cost advantage for patients and KPCO. The use of insulin pens at KPCO is generally reserved for children and adults with physical and/or cognitive impairment.

Two rapid-acting insulin pens are available in a higher concentration such as Lispro (Humalog KwikPen U-200) and Lispro aabc (Lyumjev KwikPen U-200). Humalog KwikPen U-200 is KPCO preferred option for patients requiring insulin doses between 100 and 200 units/day.

FDA APPROVED INDICATIONS
Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation date: 5/4/2017
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

RAPID-ACTING INSULIN PENS - LISPRO AABC

Generic	Brand	HICL	GPID	Exception/Other
INSULIN LISPRO-AABC	LYUMJEV U-100 KWIKPEN, LYUMJEV U-100 TEMPO PEN	46616	48229	1st insulin approved as a biologic Ultra rapid

GUIDELINES FOR COVERAGE

Must meet the following:

1. Patient has failed insulin lispro (Humalog) due to difficulties with timing of mealtime doses, late hypoglycemia, or due to an adverse drug reaction/intolerance that is not expected to occur with the requested agent, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception
2. Meets one of the following requirements for pen form:
   a. Prescription is written by an Endocrinology specialist.
   b. Patient is under 18 years of age.
   c. Patient is 18 years of age or older and is unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Humalog vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient unable to use insulin vials and syringes due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection technique, or compromised fine-motor coordination? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. Insulin Lispro (Humalog Kwikpen) is preferred based on its efficacy and safety profile, as well as its competitive cost advantage for patients and KPCO. The use of insulin pens at KPCO is generally reserved for children and adults with physical and/or cognitive impairment.

Certain insulin products offer ½ unit dosing such as Lispro (Humalog Junior KwikPen, Humalog Cartridge), Aspart (Novolog Cartridge), and Lispro aabc (Lyumjev Junior KwikPen). Humalog Junior

KwikPen or Humalog Cartridge are preferred based on this insulin's efficacy and safety profile, as well as its competitive cost advantage for patients and KPCO.

Two rapid-acting insulin pens are available in a higher concentration such as Lispro (Humalog KwikPen U-200) and Lispro aabc (Lyumjev KwikPen U-200). Humalog KwikPen U-200 is KPCO preferred option for patients requiring insulin doses between 100 and 200 units/day.

Two insulin products are considered ultra-rapid acting insulins due to additives and their ability to speed up absorption by 5-10 minutes. These insulins are Lispro aabc and Aspart with niacinamide. Lispro aabc (Lyumjev) is the first insulin approved as a biologic. It has no clinical advantage over Fiasp but offeres a cost advantage and therefore is the preferred product. All insulins will be approved as biologics from now on.

Tempo pens are personalized diabetes management platform that combines the Tempo prefilled insulin pen, diabetes management devices, and app-driven support to deliver personalized guidance for people with diabetes.

FDA APPROVED INDICATIONS
Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation date: 5/4/2017
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

RAPID-ACTING INSULIN PENS - LISPRO AABC

Generic	Brand	HICL	GPID	Exception/Other
INSULIN LISPRO-AABC	LYUMJEV U-200 KWIKPEN	46616	48231	1st insulin approved as a biologic Ultra rapid

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient's short-acting insulin dose is 100 units per day or more (including Regular), but the total daily insulin dose (basal + bolus) is less than 200 units/day or 2 units/kg/day.
2. Patient has failed insulin Lispro U-200 (Humalog KwikPen U-200) due to difficulties with timing of mealtime doses, late hypoglycemia, or due to an adverse drug reaction/intolerance that is not expected to occur with the requested agent, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at GPID x2 years.
If criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following:
Patient's short-acting insulin dose exceeds 100 units/day, but the total daily dose of insulin (basal + bolus) does NOT exceed 200 units/day or 2 units/kg/day.

If criteria are met, approve at GPID x2 years.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Patient's long-acting insulin dose (units/day):
3. Patient's total daily dose of insulin (units/day):
4. Patient weight (kg):

Renewal Review Questions
1. Patient's long-acting insulin dose (units/day):
2. Patient's total daily dose of insulin (units/day):
3. Patient weight (kg):

RATIONALE
There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. Insulin Lispro (Humalog Kwikpen) is preferred based on its efficacy and safety profile, as

well as its competitive cost advantage for patients and KPCO. The use of insulin pens at KPCO is generally reserved for children and adults with physical and/or cognitive impairment.

Two rapid-acting insulin pens are available in a higher concentration such as Lispro (Humalog KwikPen U-200) and Lispro aabc (Lyumjev KwikPen U-200). Humalog KwikPen U-200 is KPCO preferred option for patients requiring insulin doses between 100 and 200 units/day.

Two insulin products are considered ultra-rapid acting insulins due to additives and their ability to speed up absorption by 5-10 minutes. These insulins are Lispro aabc and Aspart with niacinamide. Lispro aabc (Lyumjev) is the first insulin approved as a biologic. It has no clinical advantage over Fiasp but offeres a cost advantage and therefore is the preferred product. All insulins will be approved as biologics from now on.

FDA APPROVED INDICATIONS
Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation date: 5/4/2017
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

RAPID-ACTING INSULIN VIALS - ASPART

Generic	Brand	HICL	GPID	Exception/Other
INSULIN ASPART	NOVOLOG VIAL	20769	92326	BRAND EXCLUDED

GUIDELINES FOR COVERAGE

Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has failed insulin lispro (Humalog) due to an adverse drug reaction/intolerance that is not expected to occur with the requested agent.
2. If DM2, patient has failed regular insulin (Humulin R) due to difficulties with timing of mealtime doses, late hypoglycemia, or due to an adverse drug reaction/intolerance that is not expected to occur with the requested agent.

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

[NOTE: Brand Novolog products are excluded from coverage. Kaiser Permanente will dispense unbranded insulin aspart.]

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Humalog vials, Humulin R vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Unbranded insulin aspart is the unbranded biologic form of Novolog. An unbranded biologic is the same product as the branded biologic without the brand name on the packaging.

Step through Humulin R is not required for patients requesting aspart pens, only those seeking coverage for aspart vials. Humulin R is only available in vials, so patients requiring pen form for insulin administration would not be able to attempt therapy with Humulin R.

There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. Regular insulin (Humulin R) and insulin lispro (Humalog) are KPCO preferred bolus insulin options based on their competitive cost advantage for patients and KPCO.

FDA APPROVED INDICATIONS

Diabetes type 1 and type 2 treatment

REFERENCES

Per Plan

Creation date: 07/2022
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

RAPID-ACTING INSULIN VIALS - ASPART NIACINAMIDE

Generic	Brand	HICL	GPID	Exception/Other
INSULIN ASPART (NIACINAMIDE)	FIASP VIAL	44099	43054	Ultra rapid

GUIDELINES FOR COVERAGE

Must meet the following:

1. Patient has failed insulin lispro (Humalog) due to difficulties with timing of mealtime doses, late hypoglycemia, or due to an adverse drug reaction/intolerance that is not expected to occur with the requested agent, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Humalog vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. Regular insulin (Humulin R) and insulin lispro (Humalog) are KPCO preferred bolus insulin options based on their competitive cost advantage for patients and KPCO.

FDA APPROVED INDICATIONS

Diabetes type 1 and type 2 treatment

REFERENCES

Per Plan

Creation date: 07/2022
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

RAPID-ACTING INSULIN VIALS - GLULISINE

Generic	Brand	HICL	GPID	Exception/Other
INSULIN GLULISINE	APIDRA VIAL	33152	25936	

GUIDELINES FOR COVERAGE

Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Patient has failed insulin lispro (Humalog) due to an adverse drug reaction/intolerance that is not expected to occur with the requested agent.
2. If DM2, patient has failed regular insulin (Humulin R) due to difficulties with timing of mealtime doses, late hypoglycemia, or due to an adverse drug reaction/intolerance that is not expected to occur with the requested agent.

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Humalog vials, Humulin R vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. Regular insulin (Humulin R) and insulin lispro (Humalog) are KPCO preferred bolus insulin options based on their competitive cost advantage for patients and KPCO.

FDA APPROVED INDICATIONS

Diabetes type 1 and type 2 treatment

REFERENCES

Per Plan

Creation date: 07/2022
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

RAPID-ACTING INSULIN VIALS - LISPRO AABC

Generic	Brand	HICL	GPID	Exception/Other
INSULIN LISPRO-AABC	LYUMJEV VIAL	46616	48226	1st insulin approved as a biologic Ultra rapid

GUIDELINES FOR COVERAGE
Must meet the following:
1. Patient has failed insulin lispro (Humalog) due to difficulties with timing of mealtime doses, late hypoglycemia, or due to an adverse drug reaction/intolerance that is not expected to occur with the requested agent, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Humalog vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
There is evidence to say that all insulin products are equally efficacious and safe if used appropriately. Insulin choice depends on insulin pharmacokinetics and patients' ability to safely handle various dosage forms. Regular insulin (Humulin R) and insulin lispro (Humalog) are KPCO preferred bolus insulin options based on their competitive cost advantage for patients and KPCO.

FDA APPROVED INDICATIONS
Diabetes type 1 and type 2 treatment

REFERENCES
Per Plan

Creation date: 07/2022
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

MYFEMBREE

Generic	Brand	HICL	GPID	Comments
RELUGOLIX, ESTRADIOL, NORETHINDRONE ACETATE	MYFEMBREE	47392	49699	Specialty tier

****Length of approval applies to Federal Group**

GUIDELINES FOR COVERAGE

Must have one of the following indications and meet indication specific criteria as follows:

A. **Premenopausal, fibroid induced, heavy menstrual bleeding [INITIAL CRITERIA, RENEWAL CRITERIA]**
B. **Premenopausal endometriosis with moderate to severe pain [INITIAL CRITERIA, RENEWAL CRITERIA]**

A. To treat premenopausal, fibroid induced, heavy menstrual bleeding
INITIAL CRITERIA: Must meet all the following criteria:

1. Patient is a female at least 18 years of age
2. Medication is prescribed by an OB/GYN (with an appropriate referral, if required)
3. Patient is premenopausal with a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
4. Patient has tried and failed, has an intolerance to, or has a contraindication to each of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Combined Hormonal Contraceptives (pill, patch or vaginal ring) - Note: cannot take concurrently with Myfembree
   b. Levonorgestrel-releasing intrauterine device (LNG IUD), Depot Medroxyprogesterone or Nora-Be
   c. GnRH (leuprolide)
5. Patient must not have previously completed 24 months of treatment with elagolix +E2/NETA (Oriahnn), relugolix +E2NETA (Myfembree), or elagolix monotherapy (Orilissa)
6. Patient must not be on an organic anion transporting polypeptide (OATP)1B1 inhibitor[b] (most common: cyclosporine, gemfibrozil; see comprehensive list in footnote)

   If initial criteria are met, then approve at GPID for up to 6 months, but no more than maximum of 24 total months of therapy [**Use for FEDERAL Group].
   If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the following:

1. Patient has not been on relugolix +E2NETA (Myfembree) for 24 months or more
2. Patient meets one of the following:
   a. Patient is currently taking relugolix +E2NETA (Myfembree) and has a history of blood transfusion to treat heavy menstrual bleeding

b. Patient has experienced a clinically significant improvement in fibroid-induced heavy menstrual bleeding, defined as at least 50% reduction in menstrual blood loss from baseline to the final month (6 months) of treatment with relugolix +E2NETA (Myfembree)

If met, then approve at GPID for the number of months to meet the maximum of 24 total months of therapy. [**Use for Federal Group].
If not met, do not approve.

B. To treat moderate to severe pain associated with endometriosis in premenopausal patients:
INITIAL CRITERIA: Must meet all of the following:

1. Patient is a female and at least 18 years of age
2. Medication is prescribed by an OB/GYN (with an appropriate referral, if required)
3. Patient is premenopausal with a diagnosis of moderate to severe pain associated with endometriosis
4. Patient has tried and failed, has an intolerance to, or has a contraindication to each of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. At least one NSAID
   b. At least one estrogen-progestin combination contraceptives (pills, patch, or ring) taken in a continuous fashion (skipping placebo tablets) - Note: cannot take concurrent with Myfembree
   c. Norethindrone acetate oral, Depot medroxyprogesterone acetate injection, medroxyprogesterone acetate oral, levonorgestrel intrauterine device, or etonorgestrel implant
   d. GnRH (nafarelin, leuprolide, goserelin or triptorelin) with add-back hormonal therapy (norethindrone [to counteract estrogen suppression effect of GnRH agonist])
5. Patient must not have previously completed 24 months of treatment with elagolix +E2/NETA (Oriahnn), relugolix +E2NETA (Myfembree), or elagolix monotherapy (Orilissa)
6. Patient must not be on organic anion transporting polypeptide (OATP)1B1 inhibitor [b] (most common: cyclosporine, gemfibrozil; see comprehensive list in footnote)

If initial criteria are met, then approve at GPID up to 6 months, but no more than maximum of 24 total months of therapy [**Use for FEDERAL Group].
If initial criteria are met, do not approve.

RENEWAL CRITERIA: Must meet the following:

1. Has not been on relugolix +E2NETA (Myfembree) for 24 months or more
2. Patient has experienced a 50% improvement in pain since starting treatment with relugolix +E2NETA (Myfembree)

If met, approve at GPID for the number of months to meet the maximum of 24 total months of therapy. [**Use for Federal Group].
If not met, do not approve.

RATIONALE- per OB/GYN

FDA APPROVED INDICATIONS
Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women and management of moderate to severe pain associated with endometriosis in premenopausal patients.

REFERENCES
package insert
[a](including women >35 years of age who smoke, current or history of deep vein thrombosis or pulmonary embolism, vascular disease (e.g., cerebrovascular disease, coronary artery disease, peripheral vascular disease), thrombogenic valvular or thrombogenic rhythm diseases of the heart (e.g., subacute bacterial endocarditis with valvular disease, atrial fibrillation), inherited or acquired hypercoagulopathies, uncontrolled hypertension, or headaches with focal neurological symptoms or have migraine headaches with aura if >35 years of age.)
[b](atazanavir, clarithromycin, cobicistat, cyclosporine, daclatasvir, darolutamide, elbasvir, eltrombopag, eluxadoline, gemfibrozil, grazoprevir, ledipasvir, leflunomide, letermovir, lopinavir, simeprevir, teriflunomide, velpatasvir, voxilaprevir. Additional category X interactions are those with CYP3A4 metabolism (fusidic acid, idelalisib), and drugs reliant on PGP. The concentrations of these may be increased to toxic levels if administered with PGP inhibitor elagolix: pazopanib, IV topotecan, vincristine (liposomal).)

Management of Symptomatic Uterine Leiomyomas VOL. 137, NO. 6, JUNE 2021 OBSTETRICS & GYNECOLOGY
Myfembree PACKAGE INESERT

Creation Date: 12/2020
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

RESMETIROM (REZDIFFRA)

Generic	Brand	HICL	GPID	Exception/Other
RESMETIROM	REZDIFFRA	49451		Non-formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days.
2. Patient is 18 years of age or older.
3. Medication is being prescribed by a gastroenterologist/hepatologist or other metabolic syndrome management specialist.
4. Patient has a diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) [formerly termed nonalcoholic steatohepatitis (NASH)] and has demonstrated response to the medication.

If met, approve x 1 year at HICL, max 1 tablet per day.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Patient must be 18 years of age or older.
2. Medication must be prescribed by a gastroenterologist/hepatologist or other metabolic syndrome management specialist.
3. Patient has a diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) [formerly termed nonalcoholic steatohepatitis (NASH)].
4. Patient has fibrosis stage F2 or F3 as determined by transient elastography (i.e., fibroscan) and/or liver biopsy.
5. Patient has disease progression refractory to lifestyle changes (e.g., healthy lifestyle/weight loss programs, 6-month trial of medications for weight loss with a goal of 7 to 10% weight loss). Additionally, patient understands to continue lifestyle interventions during resmetirom therapy.
6. Patient does NOT have a history of significant alcohol consumption as determined by the provider.
7. If patient has diabetes, it has been reasonably well-controlled with A1c less than 9%.
8. Medications that can cause or exacerbate metabolic dysfunction-associated steatotic liver disease (MASLD) (such as amiodarone, methotrexate, systemic glucocorticoids at greater than 5 mg/day, tamoxifen, estrogens at doses greater than those used for hormone replacement or contraception, anabolic steroids [except testosterone replacement], valproic acid, etc.) have been changed to alternative agents as applicable and clinically appropriate.

If initial criteria are met, approve x 1 year at HICL, max 1 tablet per day.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Patient has had follow up transient elastography (i.e., fibroscan) and/or liver biopsy demonstrating no worsening of liver fibrosis and/or ≥1-stage improvement in liver fibrosis since initiation of therapy.
2. Provider attests that patient has been adherent to the medication, recommended diet and lifestyle measures, abstinence of alcohol, and follow-up labs and assessments.

If met, approve x 1 year at HICL, max 1 tablet per day.
If not met, do not approve.

ePA Questions

Initial Review Questions

1. Is the patient stable on therapy with resmetirom?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Patient's fibrosis stage determined by transient elastography (i.e., fibroscan) and/or liver biopsy:
4. Date of fibroscan or liver biopsy (MMDDYY):
5. Does the patient have history of significant alcohol consumption?
6. Has the patient experienced disease progression refractory to lifestyle changes (e.g., healthy lifestyle/weight loss programs, 6-month trial of medications for weight loss with a goal of 7 to 10% weight loss)?
7. Does the patient understand to continue lifestyle interventions during resmetirom therapy?
8. Does the patient have diabetes?
9. Current A1c lab:
10. Date of A1c lab (MMDDYY):
11. Have medications that can cause or exacerbate metabolic dysfunction-associated steatotic liver disease been changed to alternative agents as applicable and clinically appropriate?

Renewal Review Questions

1. Patient's fibrosis stage determined by transient elastography (i.e., fibroscan) and/or liver biopsy:
2. Date of fibroscan or liver biopsy (MMDDYY):
3. Has the patient's liver fibrosis worsened since the start of resmetirom therapy?
4. Provider attests the patient has been adherent to the medication, recommended diet and lifestyle measures, abstinence of alcohol, and follow-up labs and assessments.

RATIONALE

Resmetirom is approved for the treatment of adults with NASH/MASH with moderate to advanced liver fibrosis (stages F2-F3), in conjunction with diet and exercise. Prior authorization is recommended to manage the costs and utilization of resmetirom. The proposed criteria are consistent with inclusion and exclusion criteria developed by the Kaiser Permanente Interregional Clinical Workgroup for resmetirom. It is proposed that the medication is prescribed by or in consultation with a gastroenterologist/hepatologist to ensure accurate diagnosis of noncirrhotic MASH with F2 or F3 fibrosis. Fibrosis stage can be evaluated by transient elastography (i.e., fibroscan) or liver biopsy. Patients should have disease progression refractory to lifestyle changes and understand the need to continue lifestyle interventions during resmetirom therapy. If the patient has diabetes, it should be reasonably well-controlled with A1c < 9%. Patients should not have a history of significant alcohol consumption as determined by the provider, since alcohol use is a significant contributor to liver disease progression and AASLD guidelines state that patients with ≥F2 fibrosis should abstain from alcohol use. Medications that can cause or exacerbate MASH should be changed to alternative agents as applicable and clinically appropriate.

FDA APPROVED INDICATIONS

Treatment of noncirrhotic metabolic dysfunction–associated steatohepatitis (MASH) [formerly termed nonalcoholic steatohepatitis (NASH)] with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis), in conjunction with diet and exercise, in adults.

REFERENCES

1. IPD Analytics. New Drug Review: Rezdiffra (resmetirom). March 2024.
2. MedImpact. Standard Commercial Drug Formulary Prior Authorization Guidelines: Resmetirom.
3. Rezdiffra [Prescribing Information]. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc. May 2024.

4. Kaiser Permanente Interregional Practice Recommendations. Rezdiffra (resmetirom) oral tablets. 03/29/2024.

Creation Date: 07/2024
Effective Date: 08/2024
Reviewed Date:
Revised Date:

RIFAXIMIN (XIFAXAN)

Generic	Brand	HICL	GPID	Exception/Other
RIFAXIMIN	XIFAXAN	20401	93749, 28530	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following diagnoses and meet all associated criteria:

A. Irritable Bowel Syndrome with Diarrhea (IBS-D)
B. Hepatic Encephalopathy (HE)
C. Small Intestinal Bacterial Overgrowth (SIBO)
D. Intestinal Methanogen Overgrowth (IMO)
E. Clostridium difficile infection (CDI)
F. Traveler's Diarrhea

A. Irritable Bowel Syndrome with Diarrhea (IBS-D): The following must be met: 1-5 below:
   1. Patient is at least 18 years of age
   2. Prescribed by a Gastroenterologist
   3. Failure of dietary modification (low FODMAP)
   4. Failure, contraindication, or intolerance to all of the following: at least one bile acid sequestrant for 2-week trial, at least one antispasmodic (dicyclomine) [if patient less than 65 years of age] for 2-week trial; at least one tricyclic antidepressant [if patient less than 65 years of age] for 6-week trial, and at least one antidiarrheal (loperamide or diphenoxylate-atropine) for 2-week trial, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
   5. Request is for 550 mg tablet

      If above criteria are met, then approve 1 fill, max 14-day supply, max 3 tablets daily.
      If above criteria are not met, then do not approve.

B. Hepatic Encephalopathy (HE): The following must be met: 1-4, or 1,2 and 5 below:
   1. Patient is at least 18 years of age
   2. Request is for 550 mg tablet
   3. Prescribed by a Gastroenterologist
   4. Failure, contraindication, or intolerance to lactulose, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
   5. Initiated during inpatient admission with diagnosis of hepatic encephalopathy

If above criteria are met, then approve indefinitely, max 2 tablets daily.
If above criteria are not met, then do not approve.

C. Small Intestinal Bacterial Overgrowth (SIBO): The following must be met: 1-4 below:
   1. Prescribed by a Gastroenterologist
   2. Failure of dietary modification (low FODMAP)
   3. Failure, contraindication, or intolerance to at least two of the following antibiotics: amoxicillin-clavulanate, ciprofloxacin, metronidazole, neomycin, doxycycline or tetracycline, or sulfamethoxazole-trimethoprim DS, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
   4. Request is for 550 mg tablet

   If above criteria are met, then approve 1 fill, max 14-day supply, max 3 tablets daily.
   If above criteria are not met, then do not approve.

D. Intestinal Methanogen Overgrowth (IMO): The following must be met: 1-4 below:
   1. Prescribed by a Gastroenterologist
   2. A breath test was performed demonstrating a methane concentration of at least 10 ppm at any point during the test
   3. Failure, contraindication, or intolerance to neomycin, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception
   4. Request is for 550 mg tablet

   If above criteria are met, then approve 1 fill, max 14-day supply, max 3 tablets daily.
   If above criteria are not met, then do not approve.

E. Clostridium difficile infection (CDI): The following must be met: 1-3 below:
   1. Patient is at least 18 years of age
   2. Prescribed by a Gastroenterologist or Infectious Disease specialist
   3. Patient is being treated for a second or subsequent recurrence of CDI after completion of 2 full prior treatment courses (unless documented intolerance resulting in early discontinuation)

   If above criteria are met, then approve 1 fill.
   If above criteria are not met, then do not approve.

F. Traveler's Diarrhea: The following must be met: 1-3 below:
   1. Patient is at least 12 years of age

2. Failure, contraindication, or intolerance to azithromycin and either ciprofloxacin or levofloxacin, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
3. Request is for 200 mg tablet

   If above criteria are met, then approve 1 fill, max 3-day supply, max 3 tablets daily.
   If above criteria are not met, then do not approve.

RENEWAL CRITERIA: Must have one of the following diagnoses and meet all associated criteria:

A. Irritable Bowel Syndrome with Diarrhea (IBS-D)
B. Small Intestinal Bacterial Overgrowth (SIBO)
C. Intestinal Methanogen Overgrowth (IMO)

A. Irritable Bowel Syndrome with Diarrhea (IBS-D): The following must be met: 1-3 below:
   1. Patient has recurrence of symptoms after documentation of positive clinical response to prior course(s).
   2. Patient has not received more than 2 prior treatment courses with rifaximin.
   3. Request is for 550 mg tablet

      If above criteria are met, then approve 1 fill, max 14-day supply, max 3 tablets daily. Up to 3 total treatment courses may be approved.
      If above criteria are not met, then do not approve.

B. Small Intestinal Bacterial Overgrowth (SIBO): The following must be met: 1-3 below:
   1. Patient has recurrence of symptoms after documentation of positive clinical response to prior course(s).
   2. Patient has not received more than 1 other treatment course with rifaximin in the past year.
   3. Request is for 550 mg tablet

      If above criteria are met, then approve 1 fill, max 14-day supply, max 3 tablets daily. Up to 2 treatment courses may be approved per year.
      If above criteria are not met, then do not approve.

C. Intestinal Methanogen Overgrowth (IMO): The following must be met: 1-3 below:
   1. Patient has recurrence of symptoms after documentation of positive clinical response to prior course(s).
   2. Patient has not received more than 1 other treatment course with rifaximin in the past year.
   3. Request is for 550 mg tablet

      If above criteria are met, then approve 1 fill, max 14-day supply, max 3 tablets daily. Up to 2 treatment courses may be approved per year.
      If above criteria are not met, then do not approve.

ePA Questions
Initial Review Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Irritable Bowel Syndrome with Diarrhea (IBS-D); Hepatic Encephalopathy (HE); Small Intestinal Bacterial Overgrowth (SIBO); Intestinal Methanogen Overgrowth (IMO); Clostridium difficile infection (CDI); Traveler's Diarrhea]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Irritable Bowel Syndrome with Diarrhea (IBS-D)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Low FODMAP diet; OTC loperamide, probiotics; colesevelam tablets, cholestyramine powder, colestipol tablets; dicyclomine 20 mg tablets; amitriptyline tablets, desipramine tablets, nortriptyline capsules; clidinium and chlordiazepoxide (generic Librax); diphenoxylate and atropine (generic Lomotil)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Hepatic Encephalopathy (HE)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Lactulose syrup: 10 g/15 mL) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Small Intestinal Bacterial Overgrowth (SIBO)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (amoxicillin-potassium clavulanate tablets (875-125 mg), ciprofloxacin tablets, doxycycline, metronidazole tablets, neomycin tablets, tetracycline, or sulfamethoxazole/trimethoprim DS) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Intestinal Methanogen Overgrowth (IMO)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (neomycin tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Breath test results: Methane concentration (ppm):

Clostridium difficile infection (CDI)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

Traveler's Diarrhea

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (azithromycin, ciprofloxacin, levofloxacin) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Irritable Bowel Syndrome with Diarrhea (IBS-D); Small Intestinal Bacterial Overgrowth (SIBO); Intestinal Methanogen Overgrowth (IMO)]
2. Has the patient experienced recurrence of symptoms after documentation of positive clinical response to prior course(s)?
3. Number of courses of rifaximin the patient has received for this indication in the past year:

Created: 02/2022
Effective: 12/2024
Reviewed: 11/2024
Revised: 11/2024

ARCALYST (RILONACEPT)

Generic	Brand	HICL	GPID	Exception/Other
RILONACEPT	ARCALYST	35438	99473	Nonformulary Specialty tier

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet the following:
1. Patient is new to KPCO within the past 90 days and is currently stable on Arcalyst.

If met, approve at HICL indefinitely.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following diagnoses and must meet all diagnosis-specific criteria below:

A. Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS)
B. Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
C. Recurrent pericarditis

A. For the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS)
   1. Medication is prescribed by a rheumatologist, geneticist, allergist/immunologist, or dermatologist.
   2. Patient is 12 years of age or older.

   If initial criteria are met, approve at HICL indefinitely.
   If initial criteria are not met, do not approve.

B. For the maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
   1. Medication is prescribed by a rheumatologist, geneticist, allergist/immunologist, or dermatologist.
   2. Patient's weight is greater than or equal to 10 kg.
   3. Genetic testing has confirmed mutation in the ILRN1 gene.

   If initial criteria are met, approve at HICL indefinitely.
   If initial criteria are not met, do not approve.

C. For the treatment of recurrent pericarditis (RP) and reduction in risk of recurrence
   1. Medication is prescribed by a cardiologist or rheumatologist.
   2. Patient is 12 years of age or older.
   3. Patient has experienced at least 3 episodes of pericarditis (current episode can count as 1 of the 3 if patient is currently having an episode) with at least 1 of them occurring despite the use of NSAIDs and colchicine (or contraindication or documented intolerance to these agents).
   4. CRP level greater than or equal to 1.0 mg/dL.

   If initial criteria are met, approve at HICL indefinitely.
   If initial criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with rilonacept (Arcalyst)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS); Deficiency of Interleukin-1 Receptor Antagonist (DIRA); Recurrent pericarditis]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
1. Patient's current weight (lbs):
2. Date of weight measurement (MMDDYY):
3. Does the patient have a mutation in the ILRN1 gene confirmed by genetic testing? If yes, must attach applicable chart notes with supporting documentation.

Recurrent pericarditis
1. Number of episodes of pericarditis the patient has experienced:
2. CRP level (mg/dL):
3. Date of CRP (MMDDYY):
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (NSAIDs, colchicine tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

REFERENCES
Per Health Plan

Creation date: 7/2/2021
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2024

RIMEGEPANT (NURTEC ODT)

Generic	Brand	HICL	GPID	Comments
RIMEGEPANT	NURTEC ODT	46383	47762	Oral CGRP antagonist; "Gepant" for acute and preventive tx

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following diagnoses and meet all diagnosis-specific criteria as follows:

A. Acute Migraine Treatment
B. Preventive Migraine Treatment

A. Acute Migraine Treatment: Must meet all the following:
   1. Prescribed for acute treatment of migraine with or without aura
   2. Patient must be age 18 or older
   3. Patient has failed (after at least one month of therapy), or the patient has intolerance or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. at least one triptan
      b. ubrogepant (Ubrelvy), or the patient has significant nausea or vomiting with migraine attacks that requires an orally disintegrating tablet (ODT)

If criteria are met, approve indefinitely at HICL, max 8 tablets per 30 days [MDD 0.27].
If criteria are not met, do not approve.

B. Preventive Migraine Treatment: Must meet all the following:
   1. Request is for rimegepant (Nurtec) every other day for the preventive treatment of migraine
   2. Patient must be age 18 or older
   3. Patient is not taking another CGRP-directed medication for migraine prevention
   4. Patient meets the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Patient with failure of (after at least 6-8 weeks at maximally tolerated dose), intolerance to, or contraindication to, at least two medications from different migraine preventive classes:
         i. Anticonvulsants: divalproex, valproate, topiramate
         ii. Beta blockers: atenolol, metoprolol, nadolol, propranolol, timolol
         iii. Antidepressants: amitriptyline, nortriptyline, venlafaxine, duloxetine

b. Patient with failure of (after at least two monthly doses), intolerance to, or contraindication to, at least 1 CGRP-mAb [erenumab (Aimovig), eptinezumab (Vyepti), fremanezumab (Ajovy), galcanezumab (Emgality)] for migraine prevention
c. Patient with failure of, intolerance to, or contraindication to Qulipta

If criteria are met, approve x6 months at HICL, maximum 1 tablet every other day [MDD 0.54].
If criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Request is for rimegepant (Nurtec) every other day for the preventive treatment of migraine
2. Patient is not taking another CGRP-directed medication for migraine prevention
3. Patient has experienced at least one of the following:
   a. Fewer migraines or headache attacks by at least 2 days per month with Nurtec therapy
   b. Lessening in migraine severity with Nurtec therapy
   c. Lessening in migraine duration with Nurtec therapy

If criteria are met, approve indefinitely at HICL, maximum 1 tablet every other day [MDD 0.54].
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Acute Migraine Treatment; Preventive Migraine Treatment]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Acute Migraine Treatment
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (sumatriptan tablets, rizatriptan tablets, rizatriptan ODT, eletriptan tablets, naratriptan tablets, sumatriptan nasal spray (5 mg/act, 20 mg/act), sumatriptan succinate injectable 6 mg/0.5 mL) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Preventive Migraine Treatment
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (Ajovy prefilled syringes or auto-injector; divalproex sodium DR or ER tablets, valproic acid capsules (250 mg), topiramate IR tablets; atenolol, metoprolol IR or ER, propranolol IR or ER; amitriptyline, nortriptyline, venlafaxine ER capsules, duloxetine capsules) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is the patient taking another CGRP-directed medication for migraine prevention?

Renewal Review Questions
1. Is the patient taking another CGRP-directed medication for migraine prevention?
2. Has the patient experienced fewer migraines or headache attacks by at least 2 days per month with Nurtec therapy?
3. Has the patient experienced lessening in migraine duration and/or severity with Nurtec therapy?

Available triptan/ergotamine options:

Generic	Brand	Formulations available

Almotriptan	Axert	Tablet
Eletriptan	Relpax	Tablet
Frovatriptan	Frova	Tablet
Naratriptan	Amerge	Tablet
Rizatriptan	Maxalt/Maxalt MLT	Tablet, ODT
Sumatriptan	Imitrex, Sumavel, Onzetra, Zembrace	Tablet, nasal spray, injection
Zolmitriptan	Zomig/Zomig ZMT	Tablet, ODT, nasal spray
Ergotamine	Ergomar	Sublingual
Ergotamine/caffeine	Cafergot	Tablet, suppository
Dihydroergotamine	Migranal, Trudhesa D.H.E.	Nasal spray, injection

ODT=orally disintegrating tablet

True contraindications to triptan class
- Ischemic coronary artery disease including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina)
- History of stroke or transient ischemic attack
- Peripheral vascular disease
- Ischemic bowel disease
- Uncontrolled hypertension
- Hemiplegic or basilar migraine
- Wolff-Parkinson-White syndrome

Quantity Limits for Novel Oral Migraine Treatment

Medication	Dosage Strength	Maximum quantity limit for 30 days	Notes
Acute migraine indication			
Ubrogepant (Ubrelvy)	50 mg, 100 mg	10	Tablet splitting of the 100 mg tablet has been approved and should be recommended for all patients prescribed to take a dose of 50 mg at onset of migraine
Rimegepant (Nurtec ODT)	75 mg	8	Tablet splitting n/a
Zavegepant (Zavzpret)	10 mg	6	Available as a ready-to-use, unit-dose disposable nasal spray device that contains 10 mg of zavegepant. Each carton contains 6 nasal spray units.
Lasmiditan (Reyvow)	50 mg, 100 mg	8	Tablet splitting NOT approved Approved doses to take at onset of migraine are 50 mg, 100 mg, or 200 mg, however, only 50 mg and 100 mg tablet strengths are available

Preventive migraine indication			
Atogepant (Qulipta)	10 mg, 30 mg, 60 mg	30	Tablet splitting of the 60 mg tablet has been approved and should be recommended for all patients prescribed 30 mg daily
Rimegepant (Nurtec ODT)	75 mg	16	Tablet splitting n/a

CGRP-Directed Migraine Medications

Generic (Brand)	Route CGRP "class"	Acute Migraine Approval	Preventive Migraine Approval
Eptinezumab (Vyepti)	IV, CGRP-mAb	X	100 mg or 300 mg Q 3 mo
Erenumab (Aimovig)	SC, CGRP-mAb	X	70 mg or 140 mg Q mo
Fremanezumab (Ajovy)	SC, CGRP-mAb	X	225 mg Q 609yary, OR 675 mg Q 3 mo
Galcanezumab (Emgality)	SC, CGRP-mAb	X	240 mg loading dose, then 120 mg Q mo
Atogepant (Qulipta)	Oral, CGRP antagonist "gepant"	X	10 mg, 30 mg or 60 mg daily
Rimegepant (Nurtec ODT)	Orally disintegrating tablet, CGRP antagonist "gepant"	75 mg at onset do NOT repeat dose	75 mg every OTHER day
Ubrogepant (Ubrelvy)	Oral, CGRP antagonist "gepant"	50 mg or 100 mg at onset, may repeat in 2 hours	X
Zavegepant (Zavzpret)	Intranasal, CGRP antagonist "gepant"	10 mg at onset do NOT repeat dose	X

RATIONALE

Acute migraine indication

At this time, there is a lack of compelling data for ubrogepant, rimegepant, or lasmiditan to replace triptans as the gold standard for acute migraine treatment, considering cost and familiarity [1]. The 2019 AHS update briefly mentions role of emerging acute therapies as these options were not approved until about one year after its publication AHS [2]. Reiterated is the role for these novel treatment options, which do not result in constriction of blood vessels, for patients with vascular-related contraindications to triptans. Also acknowledged is the higher cost of these new agents compared to the generic availability of oral triptans and recommendation for ubrogepant, rimegepant, or lasmiditan to be used only in patients who have contraindications to triptans or who have failed to respond or tolerate at least two oral triptans. Patients should treat at least 2 migraine attacks before a provider makes a determination on efficacy and tolerability.

A comparative analysis of ubrogepant, lasmiditan, and rimegepant was performed by the Institute of Clinical and Economic Review (ICER) to assess the effectiveness and safety of these medications. [3] In comparison to placebo, ubrogepant [odds ratio (OR) 2.12], rimegepant [OR 2.11], and lasmiditan [OR 3.01] showed higher odds of achieving pain freedom at 2 hours. The analysis did not demonstrate statistically significant differences among the medications in pain freedom at two hours, absence of the

most bothersome symptoms at two hours, and no disability at two hours in comparison to one another. On the other hand, in comparing triptans and ubrogepant, sumatriptan [OR 4.09] and eletriptan [OR 5.6] have shown to have higher odds of pain freedom at two hours than ubrogepant.

With regards to safety, nausea was the most common adverse effect seen with the use of ubrogepant. For single migraine attacks, ubrogepant and rimegepant had similar odds of experiencing any adverse event compared to triptans and placebo, but ubrogepant [OR 5.10] had lower odds for treatment-emergent adverse events compared to lasmiditan. Also, the risk of medication overuse headaches, which is present with triptans, is unknown with repeated use of ubrogepant and rimegepant.

In terms of cost per quality-adjusted life year (QALY) gained threshold, ubrogepant is considered cost effective at $40,000 per QALY gained. Ubrogepant has similar QALY values compared to rimegepant. Comparing ubrogepant and triptans, the cost of ubrogepant is substantially greater than triptans and has less QALYs than sumatriptan and eletriptan.

If choosing a one of these new acute medication options, pharmacokinetics and characteristics of a patient's migraine attacks should be kept in mind. Lasmiditan has pharmacokinetic characteristic similar to faster-acting triptans and most closely similar to almotriptan and eletriptan in regard to onset of action, time to maximum concentration, and half-life. Ubrogepant and rimegepant have slower onsets of action but longer half-lives which may be helpful for patients experiencing migraine recurrence. Dosing recommendations should also be considered when using these new medications including if a dose can be repeated in 2 hours, dose adjustments with other disease states, and potential for drug interactions (Table 1).

As the only gepant medication supplied in a non-oral formulation, zavegepant 10 mg nasal spray could be particularly useful in patients with characteristics associated with guideline-based recommendations for non-oral therapies, including headache attacks with severe nausea or vomiting or rapidly escalating headache pain, as well as for patients in whom oral forms are associated with inadequate response, slow onset of action, or poor tolerability. Additional trials are needed to provide evidence for the long-term safety and consistency of effect over time.

Using triptans as part of a combination therapy regimen can be useful (although possibly underutilized in clinical practice) and careful selection of agents to combine can achieve synergistic pharmacokinetic effects. For example, in patients needing a quick onset of action to relieve the migraine pain but also a longer duration to avoid migraine recurrence, a fast acting triptan (e.g. nasal spray, injectable, or faster-acting oral) can be combined with a long-acting NSAID. Effectiveness and safety of combining gepants or lasmiditan with other acute therapies is less defined. Pertaining to other acute migraine medications that could be utilized, study protocols for phase 3 clinical trials differed slightly, but all included specific recommendations for what patients could or could not take within 24 hours or 48 hours after the initial dose of the study medication. Due to the potential for duplicating mechanisms, it appears logical to avoid the combination of lasmiditan with a triptan, but there may be a role for combining lasmiditan with an analgesic and/or antiemetic if needed. While gepants and triptans do not appear to directly have overlapping mechanisms, they do both target the trigeminovascular system, and thus the utility in combining a gepant with a triptan remains unclear. Given the slower onset of gepants, there may be clinical situations where combining a gepant with a faster acting NSAID could be beneficial. Overall, more data is needed.

More real-world utilization and long-term safety and efficacy data is needed for these new acute medication options, but the development of these therapy options fills a long-standing gap in therapy for patients with multiple trials and failures of triptans or those with contraindications to this class.

Preventive migraine indication
Rimegepant was the first oral gepant approved for preventive treatment of migraine and this expanded indication came after rimegepant had already been approved for acute treatment of migraine. Atogepant is the second oral gepant approved for the preventive treatment of migraine and this is the only indication for which it is approved for (unlike rimegepant, atogepant does not have an indication for acute migraine treatment).

Preventive indication approvals for both rimegepant and atogepant came after injectable/infused CGRP-mAbs (erenumab, eptinezumab, fremanezumab, galcanezumab). There are no head-to-head clinical trials comparing oral and injectable/infused CGRP directed medications.

In a 2024 Position Statement update from the American Headache Society, CGRP-directed medications are listed as a first-line treatment option for migraine prevention along with older oral migraine preventives and onabotulinumtoxinA (for chronic migraine only).

FDA APPROVED INDICATIONS
Rimegepant: Acute treatment of migraine with or without aura in adults AND preventive treatment for episodic migraine

REFERENCES
1. Moreno-Ajona D, Pérez-Rodríguez A, Goadsby PJ. Gepants, calcitonin-gene-related peptide receptor antagonists: what could be their role in migraine treatment? Curr Opin Neurol. 2020;33(3):309-315.
2. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache. 2019;59(1):1-18.
3. Atlas S, Touchette D, Agboola F, et al. Acute Treatments for Migraine: Effectiveness and Value. Institute for Clinical and Economic Review. February 25, 2020. Available at: icer-review.org/wp-content/uploads/2019/06/ICER_Acute-Migraine_Final-Evidence-Report_updated_030320.pdf. Accessed August 27, 2020.
4. Ashina M. Migraine. N Engl J Med 2020;383:1866-76.
5. Yang CP, Liang CS, Chang CM, et al. Comparison of new pharmacologic agents with triptans for treatment of migraine: a systematic review and meta-analysis. JAMA Netw Open. 2021;4(10):e2128544.
6. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. 2024 Apr;64(4):333-341.

Creation Date: 08/2020
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

ADEMPAS (RIOCIGUAT)

Generic	Brand	HICL	GCN	Other
RIOCIGUAT	ADEMPAS	40644		

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet the following:
1. Patient is new to KPCO within the past 90 days and is currently stable on Adempas

If met, approve indefinitely at HICL.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following diagnoses and meet all the diagnosis-specific criteria below:

A. Pulmonary Arterial Hypertension (PAH) (WHO Group 1)
B. Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4)

A. Pulmonary Arterial Hypertension (PAH) (WHO Group 1): Must meet all the following:
1. Prescriber must be a cardiologist or a pulmonologist
2. Patient has a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) verified by right heart catheterization
3. Patient currently has WHO Functional Class II, III or IV symptoms
4. Patient has tried and failed or has an intolerance to or a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. One phosphodiesterase type 5 (PDE5) inhibitor: sildenafil (Revatio®) or tadalafil (Adcirca®)
   b. One endothelin receptor antagonist (ERA): Bosentan (Tracleer®), Ambrisentan (Letairis®), or macitentan (Opsumit®)

If criteria are met, approve indefinitely at HICL.
If criteria are not met, do not approve.

B. Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4): Must meet all the following:
1. Prescriber must be a pulmonologist or a cardiologist
2. Patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) verified by right heart catheterization
3. Patient is either not a candidate for pulmonary endarterectomy or the patient has persistent recurrent CTEPH after pulmonary endarterectomy

If criteria are met, approve indefinitely at HICL.
If criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with Adempas?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Pulmonary Arterial Hypertension (PAH, WHO Group 1) verified by right heart catheterization; Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) verified by right heart catheterization]

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   Pulmonary Arterial Hypertension (PAH, WHO Group 1) verified by right heart catheterization
   1. Patient's current WHO Functional Class:
   2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   3. Is there reasoning why alternatives (sildenafil tablets or suspension, tadalafil tablets or suspension, bosentan tablets, ambrisentan tablets, macitentan tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

   Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) verified by right heart catheterization
   1. Is the patient a candidate for pulmonary endarterectomy?
   2. Does the patient have persistent recurrent CTEPH after pulmonary endarterectomy?

RATIONALE
Ensure appropriate use consistent with FDA indication.

FDA APPROVED INDICATIONS
- Treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to reduce risks of disease progression and hospitalization
- Treatment of chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class in adults

REFERENCES
1. Adempas (riociguat) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; January 2018.
2. Adempas (riociguat) [product monograph]. Mississauga, Ontario, Canada: Bayer Inc: March 2020.

Creation Date: 8/18/2020
Effective Date: 06/2024
Reviewed Date: 05/2024
Revised Date: 05/2024

RISANKIZUMAB-RZZA (SKYRIZI)

Generic	Brand	HICL	GPID	Size	Notes
RISANKIZUMAB-RZZA	SKYRIZI 150 MG/ML SYRINGE	45699	49617	1	NF
RISANKIZUMAB-RZZA	SKYRIZI 150 MG/ML PEN INJCTR	45699	49591	1	NF
RISANKIZUMAB-RZZA	SKYRIZI ON-BODY 180 MG/1.2	45699	53397	1.2	NF
RISANKIZUMAB-RZZA	SKYRIZI ON-BODY 360 MG/1.2	45699	52475	2.4	NF

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:

2. Patient is new to KPCO within the past 90 days and is stable on therapy.
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
4. Patient has one of the following indications and medication is prescribed by the appropriate specialist as noted:
   a. Patient has a diagnosis of psoriatic arthritis (PsA) and requested medication is prescribed by a CPMG or affiliated rheumatologist.
   b. Patient has a diagnosis of psoriasis and requested medication is prescribed by a CPMG or affiliated dermatologist.
   c. Patient has a diagnosis of Crohn's Disease, ulcerative colitis, or inflammatory bowel disease-unclassified (IBD-U) and requested medication is prescribed by a CPMG or affiliated gastroenterologist.

   If met, approve indefinitely, with the following quantity limits based on indication:
   - PsA or Psoriasis: 1 pen/syringe per 84 days [max qty: 1, min ds: 84]
   - Crohn's Disease, ulcerative colitis, or inflammatory bowel disease-unclassified (IBD-U): 1 single-dose prefilled cartridge per 56 days [max qty: 2.4 mL, min ds: 56]

   If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria:

A. Psoriatic Arthritis (PsA)
B. Psoriasis
C. Crohn's Disease
D. Ulcerative colitis, or inflammatory bowel disease-unclassified (IBD-U)

A. Psoriatic Arthritis: All the following must be met:
   1. Patient has a diagnosis of psoriatic arthritis.
   2. Medication is prescribed by a rheumatologist.
   3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   4. Patient has experienced an inadequate response, intolerance, or has a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is

stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
a. at least 2 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, leflunomide, sulfasalazine
b. at least 1 TNF inhibitor (e.g., adalimumab-atto (Amjevita)-preferred [F], infliximab-dyyb (Inflectra)-preferred [F])
c. at least 1 IL-17 inhibitor (secukinumab (Cosentyx [F, PA])
d. IL-12/23 inhibitor (ustekinumab-kfce (Yesintek)-preferred [F, PA]) unless documented high disease activity
e. At least 1 IL-23 inhibitor (guselkumab (Tremfya)-preferred [NF, PA])

If criteria are met, approve at HICL x 1 month, max 1 syringe per 28 days (loading dose) [max qty: 1, min ds: 28], then 1 syringe per 84 days (maintenance dose) indefinitely [max qty: 1, min ds: 84]. If criteria are not met, do not approve.

B. Psoriasis: All the following must be met:
1. Patient has a diagnosis of moderate to severe psoriasis.
2. Medication is prescribed by a dermatologist.
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Patient has experienced an inadequate response, intolerance, or has a contraindication to a topical corticosteroid or topical calcineurin inhibitor (pimecrolimus, tacrolimus), or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate
   b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one** or contraindication to at least **two** of the following therapies, or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate: Acitretin, Cyclosporine, Methotrexate, Apremilast (Otezla), Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
   c. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one TNF inhibitor (adalimumab (Amjevita) - preferred [F], infliximab (Inflectra) - preferred [F]) - unless the patient has failed an IL-17 inhibitor
   d. Patient has experienced an inadequate response, intolerance, or has a contraindication to one IL12-23 inhibitor (ustekinumab-kfce (Yesintek) - preferred [F, PA])
   e. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one IL-17 inhibitor (secukinumab (Cosentyx) - preferred [F, PA])

If criteria are met, approve at HICL, x 1 month (loading dose) max 1 pen/syringe per 28 days [max qty: 1, min ds: 28], then 1 pen/syringe per 84 days (maintenance dose) indefinitely [max qty: 1, min ds: 84].
If criteria are not met, do not approve.

C. Crohn's Disease: Must meet the following #1-4 OR #1-3 and 5:
   1. Patient has a diagnosis of Crohn's Disease.
   2. Medication is prescribed by a gastroenterologist.
   3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication
   4. Has received, or is scheduled to receive, 3 IV induction doses that were authorized by the prior authorization or utilization management teams.
   5. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least 1 TNF inhibitor (ex: infliximab [F], adalimumab [F], or certolizumab [NF, PA]), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

   If criteria are met, approve indefinitely at HICL, max 1 single-dose prefilled cartridge [Skyrizi On-Body] per 56 days [max qty: 2.4 mL, min ds: 56].
   If criteria are not met, do not approve.

D. Ulcerative colitis or inflammatory bowel disease-unclassified (IBD-U): Must meet the following #1-4 OR #1-3 and 5:
   1. Patient has a diagnosis of ulcerative colitis or inflammatory bowel disease-unclassified (IBD-U)
   2. Medication is prescribed by a gastroenterologist.
   3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   4. Has received, or is scheduled to receive, 3 IV induction doses that were authorized by the prior authorization or utilization management teams.
   5. Patient has experienced an inadequate response, intolerance, or has a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      - at least 1 anti-TNF (ex: infliximab [F], adalimumab [F] or certolizumab [NF, PA])
      - at least 1 JAKi (ex: tofacitinib [F] or upadacitinib [NF, PA])
      - IL-12/23 inhibitor (ustekinumab-kfce (Yesintek)-preferred [F, PA])

   If criteria are met, approve indefinitely at HICL, max 1 single-dose prefilled cartridge [Skyrizi On-Body] per 56 days [max qty: 2.4 mL, min ds: 56].

If criteria are not met, do not approve.

ESCALATION CRITERIA/QTY LIMIT OVERRIDES: Patient must meet New Member or Initial Criteria prior to review for Quantity Overrides. Escalation Criteria reviews only the quantities authorized upon PA approval.

A. Patient with Crohn's disease, ulcerative colitis, or inflammatory bowel disease-unclassified (IBD-U):

1. For requests to start on escalated frequencies (1 single-dose prefilled cartridge [Skyrizi On-Body] per less than 56 days): Patient must have objective signs of persistent or worsening disease activity as demonstrated by at least one of the following:
   a. colonoscopy or imaging with persistent or worsening activity compared to baseline
   b. fecal calprotectin greater than 150 [only if patient had an elevated fecal calprotectin prior to medication initiation]
   c. C-reactive protein greater than 2 [only if patient had an elevated C-reactive protein prior to medication initiation]

   If met, approve at HICL x1 year, max 1 single-dose prefilled cartridge [Skyrizi On-Body] per 28 days [max qty: 2.4 mL, min ds: 28].
   If not met, deny and offer maximum 1 single-dose prefilled cartridge [Skyrizi On-Body] per 56 days indefinitely [max qty: 1, min ds: 56].

2. For requests to continue escalated frequencies (1 single-dose prefilled cartridge [Skyrizi On-Body] per less than 56 days): Patient must have been assessed by a gastroenterologist in the last 1 year, and the gastroenterologist evaluated if the frequency can be de-escalated and determined that the escalated frequency continues to be medically necessary.

   If met, approve at HICL x2 years, max 1 single-dose prefilled cartridge [Skyrizi On-Body] per 28 days [max qty: 2.4 mL, min ds: 28].
   If not met, deny and offer max 1 single-dose prefilled cartridge [Skyrizi On-Body] per 56 days indefinitely [max qty: 2.4 mL, min ds: 56].

ePA Questions
Initial Review Questions
1. Is the patient stable on therapy with risankizumab?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Psoriatic Arthritis (PsA), Psoriasis, Crohn's Disease; Ulcerative colitis or inflammatory bowel disease-unclassified (IBD-U)]

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   Psoriatic Arthritis (PsA)
   1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
   2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
   3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

Psoriasis
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (tacrolimus ointment, acitretin capsules (10 mg, 25 mg), cyclosporine capsules (25 mg, 100 mg), methotrexate tablets (2.5 mg) or injection (25 mg/mL), Otezla tablets, Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy, adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?
4. Current BSA (%):
5. Date of BSA assessment (MMDDYY):

Crohn's Disease
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (infliximab, adalimumab-atto (Amjevita), etc.) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?
4. Has the patient received, or is scheduled to receive, 3 IV induction doses of Risankizumab (Skyrizi)?

Ulcerative colitis or inflammatory bowel disease-unclassified (IBD-U)
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (infliximab, adalimumab-atto (Amjevita), tofacitinib (Xeljanz) 10 mg tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?
4. Has the patient received, or is scheduled to receive, 3 IV induction doses of Risankizumab (Skyrizi)?

RATIONALE
Ensure appropriate use is consistent with FDA indication.

Trial and failure of 2 DMARDs is required, as the DMARD classification is not representative of a specific pharmacological class and these medications are pharmacologically unrelated in terms of mechanism of action.

REFERENCES
“Stable on therapy,” means patient is tolerating well, appears to be effective, and provider wishes to continue.

Treatment	Relative Contraindications for Psoriasis
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses (ex: systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for psoriasis.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities, active malignancy, and hypersensitivity*
Acitretin	*Women of child potential (cannot consider pregnancy up to 3 years after completion of treatment), pregnancy, lactation, severe hepatic or renal dysfunction, chronically abnormal elevated lipid values, and hypersensitivity*

FDA APPROVED INDICATIONS

Plaque Psoriasis
Psoriatic Arthritis
Crohn's Disease
Ulcerative colitis

Creation Date: 11/2019
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

RISDIPLAM (EVRYSDI)

Generic	Brand	HICL	GPID	Exception/Other
RISDIPLAM	EVRYSDI	46765	48456	Non-Formulary Survival motor neuron 2 (SMN2)- directed RNA splicing modifier

GUIDELINES FOR COVERAGE

CRITERIA FOR ALL PATIENTS CURRENTLY TAKING THE REQUESTED MEDICATION: MUST MEET ALL THE FOLLOWING

1. Must be prescribed by a Neurologist
2. Patient is not, and will not be using this medication with nusinersen (Spinraza)
3. Patient does not require/have permanent invasive ventilation or tracheostomy
4. Patient is not dependent on invasive or non-invasive ventilation during waking hours to control hypercarbia, nor does patient have hypercarbia without ventilatory support
5. Patient has not experienced loss of function or progressive weakness (physical and/or pulmonary) since starting this medication
6. Patient has no prior or planned treatment with onasemnogene abeparvovec or other gene therapy for SMA

If all criteria above are met, approve at HICL (override PA Res and Formulary) x1 year.
If criteria are not met, do not approve.

CRITERIA FOR ANY PATIENT NOT CURRENTLY TAKING THE REQUESTED MEDICATION: MUST MEET ALL THE FOLLOWING:

1. Patient must be 25 years of age or younger
2. Medication must be prescribed by a Neurologist
3. Patient has a confirmed diagnosis of 5q-autosomal recessive SMA (biallelic deletions or mutations in the SMN1 gene)
4. Patient has 2-4 copies of SMN2 gene
5. Patient has no prior or planned treatment with onasemnogene abeparvovec or other gene therapy for SMA
6. Patient will not be using this medication with nusinersen (Spinraza)
7. Patient does not require/have permanent invasive ventilation or tracheostomy
8. Patient is not dependent on invasive or non-invasive ventilation during waking hours to control hypercarbia, nor does patient have hypercarbia without ventilatory support

If criteria are met, approve at HICL (override PA Res and Formulary) x1 year
If criteria are not met, do not approve. For patients less than 6 months of age, recommend onasemnogene abeparvovec-xioi (Zolgensma).

ePA Questions

1. Please select the box that most accurately describes this patient:
   a. Patient is currently taking risdiplam
   b. Patient is not currently taking risdiplam

   PATIENTS CURRENTLY TAKING RISDIPLAM

   1. Will the patient be using this medication with nusinersen (Spinraza)?
   2. Does the patient require/have permanent invasive ventilation or tracheostomy?

3. Is the patient dependent on invasive or non-invasive ventilation during waking hours to control hypercarbia?
4. Does the patient have hypercarbia without ventilatory support?
5. Has the patient experienced loss of function or progressive weakness (physical and/or pulmonary) since starting risdiplam?
6. Has the patient been, or is the patient planning to be treated with onasemnogene abeparvovec or other gene therapy for SMA?

PATIENTS NOT CURRENTLY TAKING RISDIPLAM

1. Does the patient have a confirmed diagnosis of 5q-autosomal recessive SMA (biallelic deletions or mutations in the SMN1 gene)?
2. Does the patient have 2-4 copies of SMN2 gene?
3. Has the patient been, or is the patient planning to be treated with onasemnogene abeparvovec or other gene therapy for SMA?
4. Will the patient be using this medication with nusinersen (Spinraza)?
5. Does the patient require/have permanent invasive ventilation or tracheostomy?
6. Is the patient dependent on invasive or non-invasive ventilation during waking hours to control hypercarbia?
7. Does the patient have hypercarbia without ventilatory support?

RATIONALE

Risdiplam, a survival motor neuron 2 (SMN2)-directed RNA splicing modifier, is the first oral therapy to be FDA approved for spinal muscular atrophy (SMA). It was approved in 2020 for the treatment of SMA in patients 2 months of age and older. FDA approval was based on data from two unpublished studies. One study, a Phase 2/3 open-label trial in symptomatic infants aged 1 to 7 months, demonstrated motor function ability after 12 months of treatment and 81% survival without permanent ventilation after at least 23 months of treatment, both of which are not expected with typical untreated disease progression. The second study is a Phase 2/3 randomized, placebo-controlled study in patients aged 2 to 25 years with later-onset SMA that showed motor function improvement or stabilization with risdiplam compared to motor function decline with placebo after one year. Data are promising but given the very limited data and lack of long-term safety data, exceedingly judicious prescribing and monitoring of therapy are warranted.

In May 2022, after interim results were published from the RAINBOWFISH trial that enrolled pre-symptomatic infants aged from birth to 6 weeks of age, the FDA updated its indication for risdiplam to include all pediatric patients with SMA.

Per Kaiser Permanente's Emerging Therapeutics Strategy Program guideline, for patients age < 6 months, based on the strength of current available data of onasemnogene abeparvovec-xioi (Zolgensma), KP consensus recommendation is to use onasemnogene abeparvovec-xioi as the preferred product for these patients.

Alternating treatments: There are no data supporting the efficacy and safety of alternating between risdiplam and nusinersen therapy; thus, alternating drug therapy is not recommended.

FDA APPROVED INDICATIONS

Treatment of spinal muscular atrophy (SMA) in pediatric and adult patients

REFERENCES

1. Baranello G, Servais L, Day JW, et al. FIREFISH Part 1: 16-month safety and exploratory outcomes of risdiplam (RG7916) treatment in infants with Type 1 spinal muscular atrophy (SMA). 24th International Annual Congress of the World Muscle Society. Oct 2019.
2. Chiriboga CA, Mercuri E, Fischer D, et al. JEWELFISH: Safety and pharmacodynamic data in patients with spinal muscular atrophy (SMA) receiving treatment with risdiplam (RG7916) that have previously been treated with nusinersen. 24th International Annual Congress of the World Muscle Society. Oct 2019.
3. NCT02913482. Investigate Safety, Tolerability, PK, PD and Efficacy of Risdiplam (RO7034067) in Infants WithType1 Spinal Muscular Atrophy (FIREFISH). https://clinicaltrials.gov/ct2/show/NCT02913482?term=risdiplam&draw=2&rank=4
4. NCT02908685. A Study to Investigate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Efficacy of Risdiplam (RO7034067) in Type 2 and 3 Spinal Muscular Atrophy (SMA) Participants (SUNFISH). https://clinicaltrials.gov/ct2/show/NCT02908685?term=risdiplam&draw=2&rank=8
5. NCT03032172. A Study of Risdiplam (RO7034067) in Adult and Pediatric Participants With Spinal Muscular Atrophy (Jewelfish). https://clinicaltrials.gov/ct2/show/NCT03032172?term=risdiplam&draw=2&rank=6
6. NCT03779334. A Study of Risdiplam in Infants With Genetically Diagnosed and Presymptomatic Spinal Muscular Atrophy (Rainbowfish). https://clinicaltrials.gov/ct2/show/NCT03779334?term=risdiplam&draw=2&rank=38.
7. MercuriE, et al. SUNFISH Part 2: Efficacy and Safety of Risdiplam (RG7916) in Patients with Type 2 or Non-Ambulant Type 3 Spinal Muscular Atrophy (SMA). Presented at: 2nd International Scientific and Clinical Congress on Spinal Muscular Atrophy; February 5-7 2020; Evry, France.
8. Servais L, et al. FIREFISH Part 2: Efficacy and safety of risdiplam (RG7916) in infants with Type 1 spinal muscular atrophy (SMA). Presented at the 2020 Cure SMA Research and Clinical Care Virtual Meeting. June 12, 2020
9. Finkel RS, Farrar MA, Vlodavets D, et al. RAINBOWFISH: Preliminary Efficacy and Safety Data in Risdiplam-Treated Infants with Presymptomatic SMA (P17-5.003). Neurology. 2022;98(18 Supplement):1636.

Creation Date: 3/2021
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

RISEDRONATE 35MG TABLET - STEP THERAPY

Generic	Brand	HICL	GCN	Exception/Other
RISEDRONATE SODIUM 35MG TABLET (generic only)	ACTONEL		17378 (generic only)	

Step Therapy Criteria: Must meet ONE of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. The request is for generic risedronate 35 mg tablets and the patient has tried and failed or had an intolerance/allergy to alendronate.
2. The request is for brand Actonel, the patient has tried and failed or had an intolerance/allergy to alendronate, and Brand When Generic is Available nonformulary guidance is met as noted in a-d below:
    a. An authorized generic is not available.
    b. Patient has a documented allergic reaction to an inactive ingredient in the generic product (example: dye) not present in the brand name product and other generic equivalents to the brand are not available without the inactive ingredient which caused the allergic reaction.
    c. Patient has treatment failure, intolerance, or contraindication to at least three other formulary, therapeutic alternatives (Note: In cases where no other alternatives are available, only the generic equivalent needs to have been tried).
    d. Patient meets requirements for coverage for generic equivalent, when/if applicable.

If met, approve indefinitely based on product requested and step met:
- generic risedronate sodium 35mg tablets at GPID-G.
- brand Actonel 35 mg tablets at GPID.

If not met, do not approve.

Note: This step therapy does not include Atelvia or its generic DR tablet.

STEP THERAPY RULES
- Coding looks back at claims from the past 365 days.
- If there is a paid claim for the required drug(s) [Alendronate] or the requested drug in the past 365 days, claims for the requested drug will pay without review.
- Coding overrides any non-formulary rejection when Step Therapy is met.

RATIONALE
Alendronate is the preferred, formulary oral bisphosphonate. Risedronate (Actonel) is a second line, non-formulary oral bisphosphonate for patients unable to take alendronate. For example, people with a history of gastrointestinal (GI) side effects to alendronate (but without esophageal disorders), risedronate can be substituted as some patients *may* have fewer GI side effects. Patients must try and fail alendronate prior to receiving nonformulary risedronate for benefit.

Regarding BWGA guidance noted: The Step regulation, CO 10-16-145, does not prohibit an organization from requiring a person to try a generic equivalent, a biosimilar drug, or an

interchangeable biologic product UNLESS THE PATIENT OR PRESCRIBER REQUESTED A STEP THERAPY EXCEPTION AND THEY MEET ONE OF THE REQUIREMENTS.

Creation Date: 11/2023
Effective Date: 12/2024
Reviewed Date: 11/2024
Revised Date:

RUXOLITINIB TOPICAL

Generic	Brand	HICL	GPID	Exception/Other
RUXOLITINIB PHOSPHATE	OPZELURA	38202	51172	Non-Formulary ROUTE ≠ ORAL

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and currently stable on ruxolitinib cream for atopic dermatitis or vitiligo.
2. Medication is not being used in combination with another biologic advanced small molecule for the same indication.
3. Prescribed by a CPMG or affiliated dermatology or allergy provider.
4. The patient is 12 years of age or older.

For atopic dermatitis: If met, approve x 1 year; Rx count 6; max 60 grams per 28 days [max qty: 60, min ds: 28].
For vitiligo: If met, approve indefinitely, max 60 grams per 28 days [max qty: 60, min ds: 28].
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria below:

A. MILD TO MODERATE ATOPIC DERMATITIS
B. VITILIGO

A. DIAGNOSIS OF MILD TO MODERATE ATOPIC DERMATITIS: Must meet all the following:
1. Prescribed by a CPMG or affiliated dermatology or allergy provider.
2. The patient is 12 years of age or older.
3. Medication is not being used in combination with another biologic advanced small molecule for the same indication.
4. Patient with inadequate response (after 6 weeks), intolerance, or contraindication to at least three of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) provider attests that the required drug(s) is/(are) contraindicated or likely will cause an adverse reaction or harm; ii) based on supporting clinical documentation provided, the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and a received step therapy exception:
   - 1 moderate potency or higher topical corticosteroid
   - 1 topical calcineurin inhibitor
   - Crisaborole (Eucrisa) 2% ointment (non-formulary)
   - Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy

If met, approve x 1 year; Rx count 6; max 60 grams per 28 days [max qty: 60, min ds: 28].
If not met, do not approve.

B. DIAGNOSIS OF VITILIGO: Must meet all the following:

1. Prescribed by a CPMG or affiliated dermatology provider.
2. Treatment area is ≤ 10% BSA.
3. The patient is 12 years of age or older.
4. Medication is not being used in combination with another biologic advanced small molecule for the same indication.
5. Patient with inadequate response after 6 months, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) provider attests that the required drug(s) is/(are) contraindicated or likely will cause an adverse reaction or harm; ii) based on supporting clinical documentation provided, the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and a received step therapy exception:
   - Topical corticosteroid, topical calcineurin inhibitor, or a mix of either
   - Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy

If met, approve indefinitely, max 60 grams per 28 days [max qty: 60, min ds: 28].
If not met, do not approve.

RENEWAL CRITERIA FOR ATOPIC DERMATITIS: Must meet all the following:
1. Patient's atopic dermatitis has been assessed by a dermatology or allergy provider in the past year.
2. The patient has experienced or maintained improvement in pruritus and/or relapsing-remitting dermatitis.

If met, approve x 1 year; Rx count 6; max 60 grams per 28 days [max qty: 60, min ds: 28].
If not met, do not approve.

ESCALATION CRITERIA: Must meet indication specific criteria as follows:
1. ATOPIC DERMATITIS: Patient's atopic dermatitis is assessed to be > 10% but < 20% body surface area by a dermatology or allergy provider in the past year.

If met, approve x 1 year; Rx count 6; max 120 grams per 28 days [max qty: 120, min ds: 28].
If not met, do not approve.

2. VITILIGO: Patient's vitiligo treatment area is > 3% but ≤ 10% body surface area by a dermatology provider in the past year.

If met, approve indefinitely, max 180 grams per 28 days [max qty: 180, min ds: 28].
If not met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient using another biologic or advanced small molecule for the same indication?
2. Is the patient stable on therapy with the requested medication?
3. For patients noted stable on therapy, start date of therapy (MMDDYY):
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Mild to Moderate Atopic Dermatitis; Vitiligo]
   QUESTIONS BASED ON DIAGNOSIS SELECTED

Mild to Moderate Atopic Dermatitis

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (topical steroid, tacrolimus ointment, phototherapy, or narrow-band short wave ultraviolet B (NB-UVB) light therapy) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.
3. Percent body surface area (BSA) impacted:

Vitiligo

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (topical steroid, tacrolimus ointment, phototherapy, or narrow-band short wave ultraviolet B (NB-UVB) light therapy) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.
3. Percent body surface area (BSA) impacted:

Renewal Review Questions

1. Has the patient's atopic dermatitis been assessed by a dermatology or allergy provider in the past year?
2. Has the patient experienced or maintained improvement in pruritus and/or relapsing-remitting dermatitis?

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opzelura.

Ruxolitinib (Opzelura) cream is indicated for:

1. Short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older. Opzelura clinical trials looked at up to 8 weeks of continuous use. Application area should not exceed 20% BSA. Consider alternative therapies for quantities beyond escalation criteria.
2. Treatment of nonsegmental vitiligo in non-immunocompromised patients 12 years of age and older. Application area should not exceed 10% BSA

REFERENCES

- Opzelura [Prescribing Information]. Wilmington, DE: Incyte, Corp., August 2024.
- Rosmarin D, Passeron T, Pandya AG, Grimes P, Harris JE, Desai SR, Lebwohl M, Ruer-Mulard M, Seneschal J, Wolkerstorfer A, Kornacki D, Sun K, Butler K, Ezzedine K; TruE-V Study Group. Two Phase 3, Randomized, Controlled Trials of Ruxolitinib Cream for Vitiligo. N Engl J Med. 2022 Oct 20;387(16):1445-1455. Doi: 10.1056/NEJMoa2118828. PMID: 36260792.

Creation date: 07/2022
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2025

S1P - FINGOLIMOD ODT (TASCENSO ODT)

Generic	Brand	HICL	GCN	Exception/Other
FINGOLIMOD ODT (0.25MG, 0.5MG)	TASCENSO ODT	48165	52637, 53376	Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. The requesting provider is a CPMG or affiliated neurologist.
2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include non-active Secondary-Progressive MS or Primary-Progressive MS.)
3. The patient is 10 years of age or older.
4. The patient is unable to swallow fingolimod capsules (0.5 mg [F] or 0.25 mg [NF]), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve at HICL x1 year.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. The requesting provider is a CPMG or affiliated neurologist.
2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include *non-active* Secondary-Progressive MS or Primary-Progressive MS.)

If renewal criteria are met, approve x1 year.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: relapsing or active form of multiple sclerosis, non-active Secondary-Progressive MS, Primary-Progressive MS]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (fingolimod capsules (0.5 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Relapsing or active form of multiple sclerosis, Non-active Secondary-Progressive MS, Primary-Progressive MS]

RATIONALE
Per Plan.

This guideline replaces the 2019 Gilenya PA guideline (retire Gilenya PA guideline once the S1P rec modulator guideline becomes effective)

FDA APPROVED INDICATIONS

Treatment of patients with relapsing forms of multiple sclerosis

Disease Modifying Therapies

Class	Generic name	Brand or alternative name	Formulation	Preferred or Non-preferred per IR KP guidelines *(Does NOT refer to formulary status)*
Synthetic Cytokines	Interferon-beta 1a	Avonex	IM injection	NP
	Interferon-beta 1a	Plegridy	SQ injection	NP
	Interferon-beta 1a	Rebif	SQ injection	NP
	Interferon-beta 1b	Extavia	SQ injection	P
		Betaseron	SQ Injection	NP
Synthetic Myelin Basic Protein	Glatiramer acetate	Brand: Copaxone;	SQ injection	NP
		Generic: Glatopa (Sandoz)	SQ injection	NP
		Generic: Glatiramer acetate (Mylan)	SQ injection	NP
Reduced proliferation of activated T and B lymphocytes	Teriflunomide	Aubagio	Oral	NP
	Leflunomide** (pro-drug of teriflunomide)	Generic only (Brand: Arava)	Oral	P
Stimulator of Nrf2 pathway (aka Fumaric Acid Derivatives)	Dimethyl fumarate (pro-drug of MMF)	Tecfidera	Oral	Generic – P Brand – NP
	Diroximel fumarate (pro-drug of MMF)	Vumerity (bioequivalent to Tecfidera)	Oral	NP
	Monomethyl fumarate (active metabolite)	Bafiertam	Oral	NP
S1P Receptor Modulator	Fingolimod	Gilenya	Oral	P
	Ozanimod	Zeposia	Oral	NP
	Siponimod	Mayzent	Oral	NP
	Ponesimod	Ponvory	Oral	NP
T and B cell Depleting Small Molecule	Cladribine	Mavenclad	Oral	NP
T and B cell Depleting Antibody	Alemtuzumab	Lemtrada	Infusion	NP
Lymphocyte Anti-migration Antibody	Natalizumab	Tysabri	Infusion	P
B-cell Depleting Antibodies	Rituximab-abbs**	Biosimilar: Truxima	Infusion	NP
	Rituximab-arrx	Biosimilar: Riabni	Infusion	P
	Rituximab-pvvr**	Biosimilar: Ruxience	Infusion	NP
	Rituximab**	Brand: Rituxan	Infusion	NP
	Ocrelizumab	Ocrevus	Infusion	NP
	Ofatumumab	Kesimpta	SQ injection	NP
	Ublituximab	Briumvi	Infusion	NP

Off-label as a disease modifying treatment for MS

REFERENCES

KPCO Neurology Clinical Pharmacy Services

Creation date: 05/2020
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2025

S1P - OZANIMOD (ZEPOSIA)

Generic	Brand	HICL	GCN	Exception/Other
OZANIMOD	ZEPOSIA	46431	47863, 47864, 54286	Nonformulary specialty tier

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet the following:

1. Patient is new to KPCO within the past 90 days, is being managed by a gastroenterologist, is 18 years of age or older, and is stable on ozanimod (Zeposia) for the treatment of ulcerative colitis.
2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.

If met, approve indefinitely at HICL, max 1 capsule per day.
If not met, review Initial Criteria.

INITIAL CRITERIA: Must have one of the following diagnoses and meet diagnosis-specific criteria below:

A. Multiple Sclerosis
B. Ulcerative Colitis

A. To treat Multiple Sclerosis: Must meet all the following:
   1. The requesting provider is a CPMG or affiliated neurologist.
   2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include non-active Secondary-Progressive MS or Primary-Progressive MS.)
   3. Patient has tried and failed, or has an intolerance or contraindication to fingolimod, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

   If initial criteria are met, approve at HICL x1 year.
   If initial criteria are not met, do not approve.

B. To treat Ulcerative Colitis: Must meet all the following:
   1. The patient has a diagnosis of moderate to severe ulcerative colitis.
   2. The requesting provider is a CPMG or affiliated gastroenterologist.
   3. The patient is 18 years of age or older.
   4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   5. Patient has tried and failed, or has an intolerance or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the

patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

a. at least 1 anti-TNF [infliximab (Inflectra or Remicade) [F], adalimumab (Amjevita) [F], or golimumab (Simponi) [NF, PA]]
b. at least one JAK-inhibitor indicated for ulcerative colitis [tofacitinib (Xeljanz) [F] or upadacitinib (Rinvoq) [NF, PA]]
c. vedolizumab (Entyvio) [F]
d. Ustekinumab-kfce (Yesintek) [IL-12/23 Inhibitor, F, PA] OR risankizumab-rzaa (Skyrizi) [IL-23 Inhibitor, NF]
e. Etrasimod (Velsipity) [NF, PA]

If initial criteria are met, approve indefinitely at HICL, max 1 capsule per day.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA

1. The requesting provider is a CPMG or affiliated neurologist.
2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include *non-active* Secondary-Progressive MS or Primary-Progressive MS)

If renewal criteria are met, approve x1 year at HICL.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Is the patient stable on therapy with ozanimod (Zeposia)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: relapsing or active form of multiple sclerosis, non-active Secondary-Progressive MS, Primary-Progressive MS, Ulcerative Colitis]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Relapsing or Active form of Multiple Sclerosis

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (fingolimod capsules (0.5 mg)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Ulcerative Colitis

1. Will ozanimod (Zeposia) be used in combination with another biologic or advanced small molecule for the same indication?
2. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (infliximab (Inflectra or Remicade), Xeljanz 10 mg tablets – half tablet twice daily; adalimumab-atto (Amjevita); vedolizumab (Entyvio)) are not

suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Renewal Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Relapsing or active form of multiple sclerosis, Non-active Secondary-Progressive MS, Primary-Progressive MS]

RATIONALE

Per Plan.

FDA APPROVED INDICATIONS

Treatment of patients with relapsing forms of multiple sclerosis
Treatment of moderately to severely active ulcerative colitis in adults

Disease Modifying Therapies

Class	Generic name	Brand or alternative name	Formulation	Preferred or Non-preferred per IR KP guidelines *(Does NOT refer to formulary status)*
Synthetic Cytokines	Interferon-beta 1a	Avonex	IM injection	NP
	Interferon-beta 1a	Plegridy	SQ injection	NP
	Interferon-beta 1a	Rebif	SQ injection	NP
	Interferon-beta 1b	Extavia	SQ injection	P
		Betaseron	SQ Injection	NP
Synthetic Myelin Basic Protein	Glatiramer acetate	Brand: Copaxone;	SQ injection	NP
		Generic: Glatopa (Sandoz)	SQ injection	NP
		Generic: Glatiramer acetate (Mylan)	SQ injection	NP
Reduced proliferation of activated T and B lymphocytes	Teriflunomide	Aubagio	Oral	NP
	Leflunomide** (pro-drug of teriflunomide)	Generic only (Brand: Arava)	Oral	P
Stimulator of Nrf2 pathway (aka Fumaric Acid Derivatives)	Dimethyl fumarate (pro-drug of MMF)	Tecfidera	Oral	Generic – P Brand – NP
	Diroximel fumarate (pro-drug of MMF)	Vumerity (bioequivalent to Tecfidera)	Oral	NP
	Monomethyl fumarate (active metabolite)	Bafiertam	Oral	NP
S1P Receptor Modulator	Fingolimod	Gilenya	Oral	P
	Ozanimod	Zeposia	Oral	NP
	Siponimod	Mayzent	Oral	NP
	Ponesimod	Ponvory	Oral	NP
T and B cell Depleting Small Molecule	Cladribine	Mavenclad	Oral	NP
T and B cell Depleting Antibody	Alemtuzumab	Lemtrada	Infusion	NP
Lymphocyte Anti-migration Antibody	Natalizumab	Tysabri	Infusion	P
B-cell Depleting Antibodies	Rituximab-abbs**	Biosimilar: Truxima	Infusion	NP
	Rituximab-arrx	Biosimilar: Riabni	Infusion	P
	Rituximab-pvvr**	Biosimilar: Ruxience	Infusion	NP
	Rituximab**	Brand: Rituxan	Infusion	NP
	Ocrelizumab	Ocrevus	Infusion	NP
	Ofatumumab	Kesimpta	SQ injection	NP

	Ublituximab	Briumvi	Infusion	NP

Off-label as a disease modifying treatment for MS

REFERENCES

KPCO Neurology Clinical Pharmacy Services
KPCO Gastroenterology Clinical Pharmacy Services

Creation date: 05/2020
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2025

S1P - PONESIMOD (PONVORY)

Generic	Brand	HICL	GCN	Exception/Other
PONESIMOD	PONVORY	47221	49395, 49396	Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. The requesting provider is a CPMG or affiliated neurologist.
2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include non-active Secondary-Progressive MS or Primary-Progressive MS.)
3. The patient has an intolerance or contraindication to fingolimod, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve at HICL x1 year.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA
1. The requesting provider is a CPMG or affiliated neurologist.
2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include *non-active* Secondary-Progressive MS or Primary-Progressive MS.)

If renewal criteria are met, approve x1 year.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: relapsing or active form of multiple sclerosis, non-active Secondary-Progressive MS, Primary-Progressive MS]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (fingolimod capsules (0.5 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Relapsing or active form of multiple sclerosis, Non-active Secondary-Progressive MS, Primary-Progressive MS]

RATIONALE
Per Plan.

FDA APPROVED INDICATIONS
Treatment of patients with relapsing forms of multiple sclerosis

Disease Modifying Therapies

Class	Generic name	Brand or alternative name	Formulation	Preferred or Non-preferred per IR KP guidelines *(Does NOT refer to formulary status)*
Synthetic Cytokines	Interferon-beta 1a	Avonex	IM injection	NP
	Interferon-beta 1a	Plegridy	SQ injection	NP
	Interferon-beta 1a	Rebif	SQ injection	NP
	Interferon-beta 1b	Extavia	SQ injection	P
		Betaseron	SQ Injection	NP
Synthetic Myelin Basic Protein	Glatiramer acetate	Brand: Copaxone;	SQ injection	NP
		Generic: Glatopa (Sandoz)	SQ injection	NP
		Generic: Glatiramer acetate (Mylan)	SQ injection	NP
Reduced proliferation of activated T and B lymphocytes	Teriflunomide	Aubagio	Oral	NP
	Leflunomide** (pro-drug of teriflunomide)	Generic only (Brand: Arava)	Oral	P
Stimulator of Nrf2 pathway (aka Fumaric Acid Derivatives)	Dimethyl fumarate (pro-drug of MMF)	Tecfidera	Oral	Generic – P Brand – NP
	Diroximel fumarate (pro-drug of MMF)	Vumerity (bioequivalent to Tecfidera)	Oral	NP
	Monomethyl fumarate (active metabolite)	Bafiertam	Oral	NP
S1P Receptor Modulator	Fingolimod	Gilenya	Oral	P
	Ozanimod	Zeposia	Oral	NP
	Siponimod	Mayzent	Oral	NP
	Ponesimod	Ponvory	Oral	NP
T and B cell Depleting Small Molecule	Cladribine	Mavenclad	Oral	NP
T and B cell Depleting Antibody	Alemtuzumab	Lemtrada	Infusion	NP
Lymphocyte Anti-migration Antibody	Natalizumab	Tysabri	Infusion	P
B-cell Depleting Antibodies	Rituximab-abbs**	Biosimilar: Truxima	Infusion	NP
	Rituximab-arrx	Biosimilar: Riabni	Infusion	P
	Rituximab-pvvr**	Biosimilar: Ruxience	Infusion	NP
	Rituximab**	Brand: Rituxan	Infusion	NP
	Ocrelizumab	Ocrevus	Infusion	NP
	Ofatumumab	Kesimpta	SQ injection	NP
	Ublituximab	Briumvi	Infusion	NP

Off-label as a disease modifying treatment for MS

REFERENCES

KPCO Neurology Clinical Pharmacy Services

Creation date: 05/2020
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2025

SARILUMAB (KEVZARA)

Generic	Brand	HICL	GPID	SIZE	COMMENTS
SARILUMAB	KEVZARA 150MG/1.14 SYRINGE	44183	43223	1.14	NF
SARILUMAB	KEVZARA 150MG/1.14 PEN	44183	43224	1.14	NF
SARILUMAB	KEVZARA 200MG/1.14 SYRINGE	44183	44269	1.14	NF
SARILUMAB	KEVZARA 200MG/1.14 PEN	44183	44277	1.14	NF

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on Kevzara.
2. Medication is not being used in combination with another biologic for the same indication.
3. Medication is being prescribed by a CPMG or affiliated rheumatologist.
4. Patient has ONE of the following diagnoses:
    a. Rheumatoid Arthritis (RA)
    b. Polymyalgia Rheumatica (PMR)
    c. Polyarticular Juvenile Idiopathic Arthritis (PJIA)

If met, approve indefinitely at HICL, max 2 pens/syringes per 28 days [MDD 0.09].
If not met, Use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications and must meet all indication-specific criteria:

A. Rheumatoid Arthritis (RA)
B. Polymyalgia Rheumatica (PMR)
C. Juvenile Idiopathic Arthritis (JIA)

A. **Rheumatoid Arthritis (RA):** All the following must be met:
1. Patient is 18 years or older, has a diagnosis of RA, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. At least 2 of the following: Methotrexate, Leflunomide, Hydroxychloroquine, Sulfasalazine
    b. At least 1 TNF inhibitor (e.g. infliximab-dyyb (Inflectra) - preferred [F], adalimumab-atto (Amjevita) - preferred [F])
    c. tocilizumab-aazg (Tyenne) - preferred [F, PA]

If criteria are met, approve at HICL indefinitely, max 2 pens/syringes per 28 days [MDD 0.09].
If criteria are not met, do not approve.

B. **Polymyalgia Rheumatica (PMR):** All the following must be met:

1. Patient is 18 years or older, has a diagnosis of PMR, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Corticosteroids or cannot tolerate a corticosteroid taper
   b. Methotrexate
   c. tocilizumab-aazg (Tyenne) - preferred [F, PA]

If criteria are met, approve at HICL indefinitely, max 2 pens/syringes per 28 days [MDD 0.09].
If criteria are not met, do not approve.

C. **Juvenile Idiopathic Arthritis (JIA):** All the following must be met:
1. Patient has a diagnosis of JIA, and medication is prescribed by CPMG or affiliated rheumatologist
2. Patient is 2 years of age or older weighing ≥63 kg
3. Medication is not being used in combination with another biologic
4. Patient with failure, intolerance, or contraindication to at least 1 of the following medications, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Methotrexate
   b. Leflunomide
   c. Hydroxychloroquine
   d. Sulfasalazine

If criteria are met, approve at HICL indefinitely, max 2 pens/syringes per 28 days [MDD 0.15].
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient stable on therapy with sarilumab?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Rheumatoid Arthritis (RA); Polymyalgia Rheumatica (PMR); Juvenile Idiopathic Arthritis (JIA)]
   QUESTIONS BASED ON DIAGNOSIS SELECTED
   Rheumatoid Arthritis (RA)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic for the same indication?

Polymyalgia Rheumatica (PMR)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (corticosteroid; methotrexate 2.5 mg tablets, 25mg/ml vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic for the same indication?

Juvenile Idiopathic Arthritis (JIA)

1. Has the patient ailed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic for the same indication?

FDA APPROVED INDICATIONS

Actemra: RA, GCA, PJIA, SJIA, SSLD
Tyenne: RA, GCA, PJIA, SJIA
Kevzara: RA, PMR

REFERENCES

1. Actemra:
   - Actemra ACTPen: 162 mg/0.9 mL (0.9 mL) Solution Auto-injector, Subcutaneous [preservative free]
   - Actemra 162 mg/0.9 mL (0.9 mL) Solution Prefilled Syringe, Subcutaneous [preservative free]
2. Kevzara:
   - Kevzara 150 mg/1.14 mL; 200 mg/1.14 mL Solution Auto-injector, Subcutaneous [preservative free]
   - Kevzara 150 mg/1.14 mL; 200 mg/1.14 mL Solution Prefilled Syringe, Subcutaneous [preservative free]
3. "*Currently stable*" means patient is tolerating well, medication appears to be effective, and provider wishes to continue therapy.
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management of tocilizumab in polymyalgia rheumatica: results of a multicenter retrospective observational study. Rheumatology (Oxford). 2023 Aug 21:kead426. doi: 10.1093/rheumatology/kead426.

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Creation Date: 11/2023
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

SIPONIMOD (MAYZENT)

Generic	Brand	HICL	GCN	Exception/Other
SIPONIMOD	MAYZENT	45670	46133, 46134, 46135, 52075, 52076	Nonformulary specialty tier, least preferred

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. The requesting provider is a CPMG or affiliated neurologist.
2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include non-active Secondary-Progressive MS or Primary-Progressive MS.)
3. The CYP2C9 genotype has been confirmed prior to starting treatment.
   a. Patient does NOT have CYP2C9*3/*3 genotype (siponimod is contraindicated in this genotype)
   b. For genotypes CYP2C9 *1/*3 and *2/*3 only: prescriber will not exceed FDA labeled dose of 1 mg/day
   c. For all other genotypes: prescriber will not exceed FDA labeled maximum dose of 2 mg/day
4. The patient has an intolerance or contraindication to fingolimod, ozanimod, and/or ponesimod that is not expected to occur with siponimod, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve at HICL x1 year.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. The requesting provider is a CPMG or affiliated neurologist.
2. The patient has a diagnosis of relapsing or active form of multiple sclerosis. (This does not include *non-active* Secondary-Progressive MS or Primary-Progressive MS.)

If renewal criteria are met, approve x1 year.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: relapsing or active form of multiple sclerosis, non-active Secondary-Progressive MS, Primary-Progressive MS]
2. Patient's CYP2C9 genotype:
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (fingolimod capsules (0.5 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Relapsing or active form of multiple sclerosis, Non-active Secondary-Progressive MS, Primary-Progressive MS]

RATIONALE
Per Plan.

FDA APPROVED INDICATIONS
Treatment of patients with relapsing forms of multiple sclerosis

Disease Modifying Therapies

Class	Generic name	Brand or alternative name	Formulation	Preferred or Non-preferred per IR KP guidelines *(Does NOT refer to formulary status)*
Synthetic Cytokines	Interferon-beta 1a	Avonex	IM injection	NP
	Interferon-beta 1a	Plegridy	SQ injection	NP
	Interferon-beta 1a	Rebif	SQ injection	NP
	Interferon-beta 1b	Extavia	SQ injection	P
		Betaseron	SQ Injection	NP
Synthetic Myelin Basic Protein	Glatiramer acetate	Brand: Copaxone;	SQ injection	NP
		Generic: Glatopa (Sandoz)	SQ injection	NP
		Generic: Glatiramer acetate (Mylan)	SQ injection	NP
Reduced proliferation of activated T and B lymphocytes	Teriflunomide	Aubagio	Oral	NP
	Leflunomide** (pro-drug of teriflunomide)	Generic only (Brand: Arava)	Oral	P
Stimulator of Nrf2 pathway (aka Fumaric Acid Derivatives)	Dimethyl fumarate (pro-drug of MMF)	Tecfidera	Oral	Generic – P Brand – NP
	Diroximel fumarate (pro-drug of MMF)	Vumerity (bioequivalent to Tecfidera)	Oral	NP
	Monomethyl fumarate (active metabolite)	Bafiertam	Oral	NP
S1P Receptor Modulator	Fingolimod	Gilenya	Oral	P
	Ozanimod	Zeposia	Oral	NP
	Siponimod	Mayzent	Oral	NP
	Ponesimod	Ponvory	Oral	NP
T and B cell Depleting Small Molecule	Cladribine	Mavenclad	Oral	NP
T and B cell Depleting Antibody	Alemtuzumab	Lemtrada	Infusion	NP
Lymphocyte Anti-migration Antibody	Natalizumab	Tysabri	Infusion	P
B-cell Depleting Antibodies	Rituximab-abbs**	Biosimilar: Truxima	Infusion	NP
	Rituximab-arrx	Biosimilar: Riabni	Infusion	P
	Rituximab-pvvr**	Biosimilar: Ruxience	Infusion	NP
	Rituximab**	Brand: Rituxan	Infusion	NP
	Ocrelizumab	Ocrevus	Infusion	NP
	Ofatumumab	Kesimpta	SQ injection	NP
	Ublituximab	Briumvi	Infusion	NP

Off-label as a disease modifying treatment for MS

REFERENCES
KPCO Neurology Clinical Pharmacy Services

Creation date: 05/2020
Effective date: 06/2025
Reviewed date: 05/2025
Revised date: 05/2025

SATRALIZUMAB (ENSPRYNG)

Generic	Brand	HICL	GPID	Comments
SATRALIZUMAB-MWGE	ENSPRYNG	46781	48477	Non-Formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA:
For patients new to KPCO within the past 90 days stable on satralizumab (Enspryng).

Approve x3 months for transitional supply.

INITIAL CRITERIA: For new starts and for new members after the one-time transitional approval: Must meet all the following:
1. Patient must be age 18 or older
2. Medication must be prescribed by a Neurologist
3. At the time of request, the patient does not have either of the following: active hepatitis B infection (positive results for hepatitis B surface antigen and anti-hepatitis B virus tests), or active or untreated latent tuberculosis
4. Patient has a diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) with positive serologic test for anti-AQP4 antibodies.
5. Patient must have experienced one of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. A severe* breakthrough relapse while on rituximab or biosimilar for at least 6-months at recommended NMOSD dosing** not attributed rapid steroid withdrawal or discontinuation
    b. Recurrent breakthrough relapse after 6-month trial of rituximab or its biosimilar at recommended NMOSD dosing** in combination with maximum tolerated doses of either mycophenolate mofetil or azathioprine
    c. Patient has a severe intolerance or contraindication to rituximab or its biosimilar.

    If initial criteria are met, approve at HICL (override PA Res and Formulary) indefinitely.
    If criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Does the patient have either of the following: active hepatitis B infection, or active or untreated latent tuberculosis?
2. Does the patient have a diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) with positive serologic test for anti-AQP4 antibodies?
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (rituximab or biosimilar) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Current treatment for relapse prevention in NMOSD are off-label immunosuppressive therapies including corticosteroids and immunosuppressive drugs such as rituximab (or biosimilar), tocilizumab, mycophenolate mofetil, and azathioprine in both AQP4 antibody positive and negative patients. Treatment with these agents was associated with significant reductions in annualized relapse rates in the range of 72%-88%. Satralizumab (Enspryng) is a humanized monoclonal antibody targeting the interleukin 6 (IL-6) receptor and is given via subcutaneous injection every 4 weeks. There is no data that satralizumab is more effective or safer than current standards of treatment. Satralizumab was designed to be a longer lasting, subcutaneous version of tocilizumab. Satralizumab is the third FDA-approved agent for patient with AQP4 antibody-positive NMOSD and the first self-administered product available. It follows the approval of eculizumab (Soliris) and inebilizumab (Uplizna).

FDA APPROVED INDICATIONS

Satralizumab is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

APPENDIX

*Examples of severe breakthrough relapse include but are not limited to:

- Hospitalization for neurological deficits from NMOSD relapse (e.g., muscle weakness that affects both legs (paraparesis); muscle weakness that affects one side of body such as left arm and left leg (hemiparesis); muscle weakness that affects all four limbs (quadriparesis)
- Optic neuritis severity (hand motion only or worse) confirmed by an ophthalmologist

**NMO dosing for rituximab or biosimilar requires a minimum of 1000mg at a fixed interval of every 6 months dosing.

REFERENCES

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2. Glisson CC. Neuromyelitis optica spectrum disorders. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed December 2022.
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Creation Date: 3/2021
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

SECUKINUMAB (COSENTYX)

Generic	Brand	HICL	GPID	SIZE	Exception/Other
SECUKINUMAB	COSENTYX 150 MG/ML Syringes (2 syringes)	41715	37788	1	Formulary
SECUKINUMAB	COSENTYX 150 MG/ML Syringes	41715	37788	1	Non-Formulary
SECUKINUMAB	COSENTYX 150 MG/ML Pens (2 pens)	41715	37789	1	Formulary
SECUKINUMAB	COSENTYX 150 MG/ML Pens	41715	37789	1	Non-Formulary
SECUKINUMAB	COSENTYX 75MG/0.5ML Syringe	41715	49732	0.5	F
SECUKINUMAB	COSENTYX 300 MG/2ML UNOREADY PEN	41715	49468	2	Non-Formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on therapy.
2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
3. Patient has one of the following indications and medication is prescribed by the appropriate specialist as noted:
   a. Patient has a diagnosis of ankylosing spondylitis (AS) or nonradiographic axial spondylarthritis (nr-axSpA) and medication is prescribed by a CPMG or affiliated rheumatologist.
   b. Patient has a diagnosis of psoriatic arthritis (PsA) or enthesitis-related arthritis and medication is prescribed by a CPMG or affiliated rheumatologist or dermatologist.
   c. Patient has a diagnosis of psoriasis or hidradenitis suppurativa and medication is prescribed by a CPMG or affiliated dermatologist.

If met, approve indefinitely at HICL, max 2 mL per 28 days [MDD 0.08].
If not met, use Initial criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria:

A. Psoriatic Arthritis (PsA)
B. Ankylosing Spondylitis or subtype
C. Enthesitis-Related Arthritis
D. Psoriasis
E. Hidradenitis Suppurativa (HS)

A. Psoriatic Arthritis: All the following must be met:
   1. Patient has a diagnosis of PsA.
   2. Medication is prescribed by a rheumatologist or dermatologist.
   3. The patient is 2 years of age or older.
   4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   5. Patient with failure, intolerance, contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the

same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. At least 2 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, leflunomide, sulfasalazine
   b. At least one TNF inhibitor (adalimumab (Amjevita) - preferred [F], infliximab (Inflectra) - preferred [F])

If criteria are met, approve x1 month (loading dose), max 8 mL per 28 days [MDD 0.29], then max 2 mL per 28 days [MDD 0.08] (maintenance dose) at HICL indefinitely.
If criteria are not met, do not approve.

B. Ankylosing Spondylitis (AS) or Nonradiographic Axial Spondylarthritis (nr-axSpA): All the following must be met:
   1. Patient has a diagnosis of AS or nr-axSpA
   2. Medication is prescribed by a rheumatologist.
   3. Patient is 18 years of age or older.
   4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   5. Patient has experienced an inadequate response, intolerance, or has a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Methotrexate or sulfasalazine, or the patient has documented high disease activity in which these medications would not be suitable treatment
      b. At least one TNF inhibitor (adalimumab (Amjevita) - preferred [F], infliximab (Inflectra) - preferred [F])

If criteria are met, approve x1 month (loading dose), max 8 mL per 28 days [MDD 0.29], then max 2 mL per 28 days [MDD 0.08] (maintenance dose) at HICL indefinitely.
If criteria are not met, do not approve.

C. Enthesitis-Related Arthritis: All the following must be met:
   1. Patient has a diagnosis of enthesitis-related arthritis.
   2. Medication is being prescribed by a rheumatologist or dermatologist.
   3. The patient is 4 years of age or older.
   4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   5. Patient has experienced an inadequate response, intolerance, or has a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was

discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Methotrexate or sulfasalazine, or the patient has documented high disease activity in which these medications would not be suitable treatment
   b. At least one TNF inhibitor (adalimumab (Amjevita) - preferred [F], infliximab (Inflectra) - preferred [F])

If criteria are met, approve x1 month (loading dose), max 8 mL per 28 days [MDD 0.29], then max 2 mL per 28 days [MDD 0.08] (maintenance dose) at HICL indefinitely.
If criteria are not met, do not approve.

D. PSORIASIS: All the following must be met:
1. Patient has a diagnosis of moderate to severe psoriasis.
2. Medication is prescribed by a dermatologist.
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Patient has experienced an inadequate response, intolerance, or has a contraindication to a topical corticosteroid or topical calcineurin inhibitor (pimecrolimus, tacrolimus), or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate.
   b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one** or contraindication to at least **two** of the following therapies, or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate: Acitretin, Cyclosporine, Methotrexate, Apremilast (Otezla), Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
   c. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one TNF inhibitor (adalimumab (Amjevita) - preferred [F], infliximab (Inflectra) - preferred [F]) or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis) making this therapy inappropriate.
   d. Patient has experienced an inadequate response, intolerance, or has a contraindication to an IL12-23 inhibitor (ustekinumab-kfce (Yesintek) - preferred [F, PA])

If criteria are met, approve x1 month (loading dose), max 8 mL per 28 days [MDD 0.29], then max 2 mL per 28 days [MDD 0.08] (maintenance dose) at HICL indefinitely.
If criteria are not met, do not approve.

E. HIDRADENITIS SUPPURATIVA (HS): All the following must be met:
1. Patient has a diagnosis of moderate to severe HS (Hurley stage II-III).

2. Medication is prescribed by a dermatologist.
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
4. Patient with inadequate response, intolerance, or contraindication to all of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. At least 3 of the following [medication trials can be within the same drug category], or the patient is noted as Hurley Stage III, making these therapies inappropriate:
        i. Oral antibiotic (8-week trial unless intolerance is documented)
        ii. Topical antibiotic (ex: clindamycin)
        iii. Oral retinoid (ex: isotretinoin, acitretin)
        iv. Intralesional steroid
        v. Hormonal agent (ex: metformin, spironolactone, oral contraceptive for women)
        vi. Laser hair removal
        vii. Infliximab (Inflectra, Remicade, or other biosimilar) infusion
    b. 12-week trial of at least one TNF inhibitor (adalimumab (Amjevita) - preferred [F], infliximab (Inflectra) - preferred [F])

If criteria are met, approve x1 month (loading dose), max 8 mL per 28 days [MDD 0.29], then max 4 mL per 28 days [MDD 0.15] (maintenance dose) at HICL indefinitely.
If criteria are not met, do not approve.

ESCALATION CRITERIA/QTY LIMIT OVERRIDES: Patient must meet New Member or Initial Criteria prior to review for Quantity Overrides. Escalation Criteria review only the quantities authorized upon PA approval.

A. Patient diagnosis of PSORIASIS:
    1. Documentation by dermatology provider of the patient resuming therapy after a gap of ≥ 3 months (to reload)

        If criteria are met, approve x1 month (loading dose), max 8 mL per 28 days [MDD 0.29], then max 2 mL per 28 days [MDD 0.08] (maintenance dose) at HICL indefinitely.
        If not met, deny and offer maximum 2 mL per 28 days indefinitely [MDD 0.08].

B. Patient diagnosis of HIDRADENITIS SUPPURATIVA:
    1. Documentation by dermatology provider of the patient resuming therapy after a gap of ≥ 3 months (to reload)

        If criteria are met, approve x1 month (loading dose), max 8 mL per 28 days [MDD 0.29], then max 4 mL per 28 days [MDD 0.15] (maintenance dose) at HICL indefinitely.
        If not met, deny and offer maximum 4 mL per 28 days indefinitely [MDD 0.15].

ePA Questions
Initial Review Questions

1. Is the patient stable on therapy with secukinumab?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Ankylosing Spondylitis (AS) or Nonradiographic Axial Spondylarthritis (nr-axSpA), Psoriatic Arthritis (PsA), Enthesitis-Related Arthritis, Psoriasis, Hidradenitis Suppurativa]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Ankylosing Spondylitis (AS) or Nonradiographic Axial Spondylarthritis (nr-axSpA)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets, adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Psoriatic Arthritis (PsA)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg), adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Enthesitis-Related Arthritis

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets, adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Psoriasis

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (tacrolimus ointment, acitretin capsules (10 mg, 25 mg), cyclosporine capsules (25 mg, 100 mg), methotrexate tablets (2.5 mg) or injection (25 mg/mL), Otezla tablets, Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy, adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Current BSA (%):
4. Date of BSA assessment (MMDDYY):

Hidradenitis Suppurativa

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (oral antibiotics, topical clindamycin, oral isotretinoin, acitretin, intralesional steroids, metformin, spironolactone, oral contraceptives for females,

laser hair removal, adalimumab-atto (Amjevita)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

3. Hurley Stage:

RATIONALE
Per Health Plan.

FDA APPROVED INDICATIONS:
1. Treatment of psoriatic arthritis (PsA) in patients 2 years and older
2. Treatment of ankylosing spondylitis (AS) in adults
3. Treatment of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in adults
4. Treatment of active enthesitis-related arthritis (ERA) in patients 4 years of age and older
5. Treatment of moderate to severe plaque psoriasis in patients 6 years of age and older
6. Treatment of hidradenitis suppurativa in patients 18 years of age and older

REFERENCES
Secukinumab (Cosentyx) 75 mg/0.5 mL, 150 mg/mL

“Currently stable on medication,” means patient is tolerating well, medication appears to be effective, and provider wishes to continue therapy.

Treatment	Relative Contraindications in Psoriasis
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses (ex: systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for psoriasis.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities, active malignancy, and hypersensitivity*
Acitretin	*Caution in women of child potential (cannot consider pregnancy up to 3 years after completion of treatment), pregnancy, lactation, severe hepatic or renal dysfunction, chronically abnormal elevated lipid values, and hypersensitivity*

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

SELEXIPAG TABLETS (UPTRAVI)

Generic	Brand	HICL	GPID	Exception/Other
SELEXIPAG	UPTRAVI	42922	40355, 40356, 40357, 40358, 40359, 40374, 40375, 40376, 40378	

GUIDELINES FOR COVERAGE:

NEW MEMBER CRITERIA: Must meet the following:
1. Patient is new to KPCO within the past 90 days and is currently stable on Uptravi

If met, approve at HICL indefinitely.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Prescriber must be either a pulmonologist or a cardiologist
2. Patient has a diagnosis of pulmonary arterial hypertension (PAH, WHO Group 1) verified by right heart catheterization
3. Patient currently has WHO Functional Class II, III or IV symptoms
4. Patient has tried and failed, has an intolerance to or a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. one phosphodiesterase type 5 (PDE5) inhibitor (e.g., Adcirca, Revatio)
   b. one endothelin receptor antagonist (ERA) [e.g., Tracleer, Letairis or Opsumit]

If Initial Criteria are met, approve at HICL indefinitely.
If Initial Criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with Uptravi?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Pulmonary Arterial Hypertension (PAH, WHO Group 1) verified by right heart catheterization]
4. Patient's current WHO Functional Class:
5. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
6. Is there reasoning why alternatives (sildenafil tablets or suspension, tadalafil tablets or suspension, bosentan tablets, ambrisentan tablets, macitentan tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Health Plan.

FDA APPROVED INDICATIONS

Indicated for the treatment of pulmary arterial hypertension (PAH, WHO group I) to delay disease progression and reduce the risk of hospitalization for PAH.

REFERENCES

1. Uptravi [package insert]. South San Francisco, CA: Actelion Pharmacueticals US, Inc.; Revised 12/2017
2. Simonneau G, Robbins IM, Beghetti M, et al. Updated clinical classification of pulmonary hypertension. J Am Coll Cardiol. 2013; 62:034-841.

Creation date: 3/15/2017
Effective date: 06/2024
Reviewed date: 05/2024
Revised date: 05/2024

SELINEXOR (XPOVIO)

Generic	Brand	HICL	GPID	Comments
SELINEXOR	XPOVIO	45854		Non-formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following criteria:

A. Patient must be age 18 or older
B. Must be prescribed by a Hematologist/Oncologist
C. Must have a diagnosis of multiple myeloma or diffuse large B cell lymphoma
D. Must meet the diagnosis/drug specific criteria below:
   1. Multiple Myeloma - using in combination with dexamethasone AND one of the following: bortezomib (Velcade), carfilzomib (Kyprolis), anti-CD38 monoclonal antibody (daratumumab, daratumumab and hyaluronidase-fihi, or isatuximab-irfc) or pomalidomide (Pomalyst): Patient must have received at least 1 prior therapy for treatment of multiple myeloma.

      If all above criteria are met, approve at HICL x 12 months.
      If all above criteria are not met, do not approve.

   2. Multiple Myeloma - using in combination with dexamethasone only: Patient must have been treated with at least 4 prior therapies and whose disease is refractory to at least two proteasome inhibitors (bortezomib, carfilzomib, ixazomib), at least two immunomodulatory agents (thalidomide, lenalidomide, pomalidomide) and one anti-CD38 monoclonal antibody (daratumumab, daratumumab and hyaluronidase-fihi, or isatuximab-irfc).

      If all the above criteria are met, approve at HICL x 6 months.
      If all above criteria are not met, do not approve.

   3. Diffuse Large B-cell Lymphoma: Patient must have been treated with at least 2 prior lines of systemic therapy.

      If all the above criteria are met, approve at HICL x 6 months.
      If all above criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet the diagnosis specific criteria below:

A. Multiple Myeloma: Patient's disease has not progressed since initiation of medication OR treating provider believes patient is deriving significant clinical benefit to justify treatment continuation.
B. Diffuse Large B-cell Lymphoma: Patient's disease has not progressed since initiation of medication OR treating provider believes patient is deriving significant clinical benefit to justify treatment continuation.

   If met, approve at HICL x 6 months.
   If not met, do not approve.

RATIONALE

Selinexor is a newly approved agent with specific criteria included in the FDA indication intended to direct therapy to the patients who may be most likely to respond in terms of the risk/benefit. Clinical trials have illustrated that this agent is quite toxic and thus may not be worth the risk of treatment in patients who have not progressed on lesser lines of therapy. The duration of approval and renewal is based upon the typical duration seen for patients to respond to treatment.

FDA APPROVED INDICATIONS

XPOVIO is a nuclear export inhibitor indicated:

- In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy
- In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody
- For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy

REFERENCES

1. Xpovio prescribing information. Viewed at: https://www.karyopharm.com/wp-content/uploads/2019/07/NDA-212306-SN-0071-Prescribing-Information-01July2019.pdf. Accessed November 7, 2024
2. Kalakonda N, et al. Lancet Haematol. 2020;7:e511-22
3. Chari A, et al. N Engl J Med. 2019;381:727-38
4. Grosicki S, et al. Lancet. 2020; 396(10262): 1563-1573
5. NCCN Clinical Practice Guidelines in Oncology. Multiple Myeloma. Version 1.2025

Creation Date: 09/2020
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

SHORT-ACTING MUSCARINIC ANTAGONIST (SAMA) CLASS
IPRATROPIUM BROMIDE HFA

Generic	Brand	HICL	GPID	Comments
IPRATROPIUM BROMIDE	ATROVENT HFA		24621	Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of COPD.
2. Patient must be age 18 or older.
3. Medication will not be used in combination with any long-acting anticholinergic inhaler [Spiriva (tiotropium), Stiolto (tiotropium/olodaterol), etc.].
4. Patient has tried and failed, or has an intolerance or a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed another drug in the same pharmacological class or with the same mechanism of action as the required drug(s) and the drug was discontinued due to lack of efficacy, diminished effect, or adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    - Spiriva Respimat 2.5 mcg/inhalation (tiotropium)
    - Stiolto (tiotropium/olodaterol)
    - Combivent Respimat

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Will this medication be used in combination with any long-acting anticholinergic inhaler [Spiriva (tiotropium), Stiolto (tiotropium/olodaterol), etc.]?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (Spiriva Respimat 2.5 mcg, Stiolto Respimat) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Guidelines recommend use of a long-acting bronchodilator (i.e., Spiriva) in patients whose symptoms are not controlled with intermittent use of a short-acting bronchodilator (i.e., albuterol). In a systematic review that compared tiotropium (long-acting anticholinergic) with ipratropium (short-acting anticholinergic) in patients with COPD, tiotropium was associated with improved lung function, fewer hospitalizations, fewer exacerbations of COPD, and improved quality of life.

FDA APPROVED INDICATIONS
Atrovent HFA is an anticholinergic indicated for the maintenance treatment of bronchospasm associated with COPD. Combivent Respimat is indicated for the treatment of COPD in those patients who are currently on a regular bronchodilator who continue to have bronchospasms and require a second bronchodilator.

Neither Combivent Respimat nor Atrovent HFA are FDA-indicated for use in patients with asthma. Compared to short-acting beta agonists (SABA), ipratropium has a slower onset (15-20 minutes) and achieves less bronchodilation in patients with asthma. Ipratropium may be recommended for management of a severe asthma exacerbation in a primary care or acute care facility. A meta-analysis showed that except in the setting of acute, severe asthmatic attacks, combination therapy with ipratropium and SABA is not superior to SABA alone in adults with asthma.

REFERENCES

Per Health Plan.

Creation Date: 05/2022
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

SHORT-ACTING MUSCARINIC ANTAGONIST (SAMA) CLASS
IPRATROPIUM BROMIDE/ALBUTEROL

Generic	Brand	HICL	GPID	Comments
IPRATROPIUM BROMIDE/ALBUTEROL	COMBIVENT RESPIMAT		32395	Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of COPD.
2. Patient must be age 18 or older.
3. Medication will not be used in combination with any long-acting anticholinergic inhaler [Spiriva (tiotropium), Stiolto (tiotropium/olodaterol), etc.].
4. Patient has tried and failed, or has an intolerance or a contraindication all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed another drug in the same pharmacological class or with the same mechanism of action as the required drug(s) and the drug was discontinued due to lack of efficacy, diminished effect, or adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    - Spiriva Respimat 2.5 mcg/inhalation (tiotropium)
    - Stiolto (tiotropium/olodaterol)

If criteria are met, approve at GPID indefinitely.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Will this medication be used in combination with any long-acting anticholinergic inhaler [Spiriva (tiotropium), Stiolto (tiotropium/olodaterol), etc.]?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (Spiriva Respimat 2.5 mcg, Stiolto Respimat) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Guidelines recommend use of a long-acting bronchodilator (i.e., Spiriva) in patients whose symptoms are not controlled with intermittent use of a short-acting bronchodilator (i.e., albuterol). In a systematic review that compared tiotropium (long-acting anticholinergic) with ipratropium (short-acting anticholinergic) in patients with COPD, tiotropium was associated with improved lung function, fewer hospitalizations, fewer exacerbations of COPD, and improved quality of life.

FDA APPROVED INDICATIONS
Atrovent HFA is an anticholinergic indicated for the maintenance treatment of bronchospasm associated with COPD. Combivent Respimat is indicated for the treatment of COPD in those patients who are currently on a regular bronchodilator who continue to have bronchospasms and require a second bronchodilator.

Neither Combivent Respimat nor Atrovent HFA are FDA-indicated for use in patients with asthma. Compared to short-acting beta agonists (SABA), ipratropium has a slower onset (15-20 minutes) and achieves less bronchodilation in patients with asthma. Ipratropium may be recommended for management of a severe asthma exacerbation in a primary care or acute care facility. A meta-analysis showed that except in the setting of acute, severe asthmatic attacks, combination therapy with ipratropium and SABA is not superior to SABA alone in adults with asthma.

REFERENCES

Per Health Plan.

Creation Date: 05/2022
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

SIMPONI (GOLIMUMAB)

Generic	Brand	HICL	GPID	SIZE	Notes
GOLIMUMAB	SIMPONI 50MG/0.5ML PEN INJCTR	36278	22533	0.5	NF- Comm, Hx, Fed; F- SF
GOLIMUMAB	SIMPONI 50MG/0.5ML SYRINGE	36278	22536	0.5	NF- Comm, Hx, Fed; F- SF
GOLIMUMAB	SIMPONI 100 MG/ML PEN INJCTR	36278	35001	1	NF- Comm, Hx, Fed; F- SF
GOLIMUMAB	SIMPONI 100 MG/ML SYRINGE	36278	34697	1	NF- Comm, Hx, Fed; F- SF

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on therapy.
2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
3. Patient has one of the following indications and medication is prescribed by the appropriate specialist as noted:
   a. Patient has a diagnosis of rheumatoid arthritis (RA), psoriatic arthritis (PsA), or ankylosing spondylitis or subtype and is being managed by a CPMG or affiliated rheumatologist.
   b. Patient has a diagnosis of ulcerative colitis and is being managed by a CPMG or affiliated gastroenterologist.

If met, approve indefinitely, max 1 pen/syringe per 28 days.
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria:

A. Rheumatoid Arthritis (RA)
B. Psoriatic Arthritis (PsA)
C. Ankylosing Spondylitis or subtype
D. Ulcerative Colitis

A. RHEUMATOID ARTHRITIS: All the following must be met:
   1. Patient has a diagnosis of RA.
   2. Medication is prescribed by a rheumatologist.
   3. Patient is 18 years of age or older.
   4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   5. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

a. At least 2 of the following medications: methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
b. At least 1 TNF inhibitor (e.g., infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F])
c. At least 2 of the following:
   - JAK inhibitor (e.g. tofacitinib (Xeljanz)-preferred [F])
   - IL-6 inhibitor (e.g. tocilizumab (Tyenne)-preferred [F, PA])
   - Abatacept (Orencia) [F, PA]

If criteria are met, approve indefinitely, max 1 pen/syringe per 28 days.
If criteria are not met, do not approve.

B. PSORIATIC ARTHRITIS (PsA): All the following must be met:
1. Patient has a diagnosis of PsA.
2. Medication is prescribed by a rheumatologist.
3. Patient is 18 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. At least 2 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, leflunomide, sulfasalazine
   b. At least 1 TNF inhibitor (e.g., infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F])
   c. At least 1 IL-17 inhibitor (e.g. secukinumab (Cosentyx) [F, PA])
   d. At least 1 IL-23 inhibitor (e.g. guselkumab (Tremfya) [NF, PA])
   e. At least 1 of the following:
      - IL-12/23 inhibitor (ustekinumab-kfce (Yesintek) preferred [F, PA])
      - abatacept (Orencia) [F, PA]
      - JAK inhibitor (e.g., tofacitinib (Xeljanz) [F])

If criteria are met, approve indefinitely, max 1 pen/syringe per 28 days.
If criteria are not met, do not approve.

C. ANKYLOSING SPONDYLITIS: All the following must be met:
1. Patient has a diagnosis of ankylosing spondylitis or one of the following subtype diagnoses: spondyloarthritis (SpA), axial SpA, nonradiographic axial SpA, radiographic axial SpA, sacroiliitis, undifferentiated spondyloarthropathy, spondyloarthropathy, or enteropathic arthropathy.
2. Medication is prescribed by a rheumatologist.
3. Patient is 18 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.

5. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. At least 1 TNF inhibitor (e.g., infliximab-dyyb (Inflectra)-preferred, adalimumab-atto (Amjevita)-preferred [F])
   b. At least 1 IL-17 inhibitor (e.g. secukinumab (Cosentyx) [F, PA])
   c. At least 1 JAK inhibitor (e.g. tofacitinib (Xeljanz)-preferred)

If criteria are met, approve indefinitely, max 1 pen/syringe per 28 days.
If criteria are not met, do not approve.

D. ULCERATIVE COLITIS: All the following must be met:
1. Patient has a diagnosis of ulcerative colitis or indeterminant colitis with ulcerative colitis features.
2. Medication is prescribed by a gastroenterologist.
3. Patient is 6 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient with failure, intolerance, or contraindication to at least one TNF inhibitor (e.g. infliximab [F], adalimumab (Amjevita) [F]), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve a max of 3 pens/syringes (loading dose) per 28 days x1 month, then 1 pen/syringe per 28 days (maintenance dose) indefinitely.
If criteria are not met, do not approve.

ESCALATION CRITERIA/QTY LIMIT OVERRIDES: Patient must meet New Member or Initial Criteria prior to review for Quantity Overrides. Escalation Criteria review only the quantities authorized upon PA approval.

Applicable only to patients with a diagnosis of Ulcerative Colitis: Must meet ONE of the following:
1. To Reload: Gastroenterology provider has submitted documentation stating the patient is resuming therapy after a gap of 3 months or longer in treatment.

   If met, approve at HICL, max 3 pens/syringes (loading dose) per 28 days x1 month, then 1 pen/syringe per 28 days indefinitely.
   If not met, deny and offer a maximum of 1 pen/syringe per 28 days indefinitely.

2. For requests to start on escalated doses (>1 pen/syringe per 28 days): Patient has been on standard maintenance dose of 1 pen/syringe per 28 days for at least 3 months with inadequate drug level (< 2.4 mcg/mL).

   If met, approve at HICL, max 2 pens/syringes per 28 days x 1 year.
   If not met, deny and offer a maximum of 1 pen/syringe per 28 days indefinitely.

3. For requests to continue escalated doses (2 pens/syringes per 28 days): Patient has been assessed by a gastroenterologist in the last 1 year, and the gastroenterologist has evaluated if the dose can be de-escalated and determined that the escalated dose continues to be medically necessary.

   If met, approve at HICL, max 2 pens/syringes per 28 days x 2 years.
   If not met, deny and offer a maximum of 1 pen/syringe per 28 days indefinitely.

ePA Questions

1. Is the patient stable on therapy with golimumab?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Will this medication be used in combination with a biologic or advanced small molecule for the same indication?
4. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Rheumatoid Arthritis (RA); Psoriatic Arthritis (PsA); Ankylosing Spondylitis or subtype; Ulcerative Colitis]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Rheumatoid Arthritis

2. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); infliximab; Xeljanz 10 mg tablets - half tablet twice daily) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Psoriatic Arthritis (PsA)

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); infliximab; Xeljanz 10 mg tablets - half tablet twice daily) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Ankylosing Spondylitis or Subtype

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (infliximab) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

Ulcerative Colitis

1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.

2. Is there reasoning why alternatives (infliximab) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.

REFERENCES:
"Stable on therapy," means patient is tolerating well, appears to be effective and provider wishes to continue.

ICD-10 Diagnosis Codes

Diagnosis	ICD-10 code
ankylosing spondylitis (also termed radiographic axial spondyloarthritis)	subcategory M45*
spondyloarthritis (SpA)	M47.9, M47.812, M47.12, M47.813, M47.816, M47.16, M47.817, M47.811, M47.818, M47.10, M47.819, M46.814, M46.815
axial SpA	subcategory M46.8
nonradiographic axial SpA	subcategory M46.8
sacroiliitis	M12.9, M46.1
undifferentiated spondyloarthropathy	M47.9
spondyloarthropathy	M47.9
enteropathic arthropathy	M07.60

Created: 11/2020
Effective: 06/2025
Reviewed: 05/2025
Revised: 05/2025

SODIUM OXYBATE (XYREM)

Generic	Brand	HICL	GPID	Exception/Other
SODIUM OXYBATE	XYREM* (Brand name excluded while AG is available)	12346	18104	Non-Formulary 3rd preferred in narcolepsy class (generic only*)

GUIDELINES FOR COVERAGE

CRITERIA FOR ALL PATIENTS CURRENTLY TAKING THE REQUESTED MEDICATION: MUST MEET ALL THE FOLLOWING:

1. Medication is prescribed by a Neurology or a Board-Certified Sleep Medicine provider.
2. Medication is being prescribed for Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia; or Cataplexy (not excessive daytime sleepiness) due to narcolepsy.
3. Medication requested is not be used in combination with solriamfetol (Sunosi), pitolisant (Wakix) or any other oxybate product (i.e. Xywav, Lumryz).

If criteria are met, approve at GPID indefinitely, max 18 mL/day.
If criteria are not met, do not approve.

CRITERIA FOR ANY PATIENT NOT CURRENTLY TAKING THE REQUESTED MEDICATION: MUST MEET ALL THE FOLLOWING:

A. Medication is prescribed by Neurology or a Board-Certified Sleep Medicine provider.
B. Medication requested is not be used in combination with solriamfetol (Sunosi), pitolisant (Wakix) or any other oxybate product (i.e. Xywav, Lumryz).
C. Patient must have one of the following indications and meet all criteria pertaining to that indication:
    1. Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia: Must meet all the following, or the provider submitted justification and supporting clinical documentation that states one of the following: i) the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
        a. Patient must have tried and failed or have a contraindication to each of the following: amphetamines, methylphenidate, and either modafinil or armodafinil.
        b. Patient must have tried and failed or have a contraindication to Sunosi and Wakix [Prior Authorization required for all].

    If criteria are met, approve indefinitely at GPID, max 18 mL/day.
    If criteria are not met, do not approve.

    2. Cataplexy (not excessive daytime sleepiness) due to narcolepsy: Must meet all the following, or the provider submitted justification and supporting clinical documentation that states one of the following: i) the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv)

the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
a. Patient must have tried and failed or have a contraindication to each of the following: a tricyclic antidepressant (TCA), a selective serotonin reuptake inhibitor (SSRI), and a selective serotonin-norepinephrine (SNRI).
b. Patient must have tried and failed or have a contraindication to Wakix [Prior Authorization required].

If critieria are met, approve indefinitely at GPID, max 18 mL/day.
If criteria are not met, do not approve.

ePA Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia; Cataplexy (not excessive daytime sleepiness) due to narcolepsy]

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia

   1. Is the patient stable on therapy with this medication?
   2. For patients noted stable on therapy, start date of therapy (MMDDYY):
   3. Is the medication being used in combination with solriamfetol (Sunosi), pitolisant (Wakix) or any other oxybate product (i.e. Xywav, Lumryz)?
   4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   5. Is there reasoning why alternatives (amphetamines, methylphenidate, modafinil, armodafinil) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

   Cataplexy (not excessive daytime sleepiness) due to narcolepsy

   1. Is the patient stable on therapy with this medication?
   2. For patients noted stable on therapy, start date of therapy (MMDDYY):
   3. Is the medication being used in combination with solriamfetol (Sunosi), pitolisant (Wakix) or any other oxybate product (i.e. Xywav, Lumryz)?
   4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   5. Is there reasoning why alternatives (amitriptyline tablets, desipramine tablets, nortriptyline capsules; citalopram tablets/solution, escitalopram tablets, fluoxetine capsules/solution, paroxetine IR tablets, sertraline tablets/susp; venlafaxine ER capsules (37.5 mg, 75 mg, 150 mg), duloxetine capsules (20 mg, 30 mg, 60 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Brand Xyrem is excluded from coverage as an authorized generic [AG] is available.
Lumryz, sodium oxybate oral solution. and Xywav have the same active ingredient (oxybate, a CNS depressant) and have not been studied for use in combination or as alternating treatments. Sunosi, a dopamine and norepinephrine reuptake inhibitor, is indicated to improve wakefulness in adults with excessive daytime sleepiness due to narcolepsy or obstructive sleep apnea. Wakix, an antagonist/inverse agonist of the histamine-3 receptor, is indicated for excessive daytime sleepiness and cataplexy in adults with narcolepsy. Currently, there are no published studies evaluating combination use of these medications.

Is an Authorized Generic Drug the Same Thing as a Generic Drug? No.

AUTHORIZED GENERIC [AG]: The term “authorized generic” drug is most commonly used to describe an approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, **it is the exact same drug product as the branded product**. An authorized generic may be marketed by the brand name drug company, or another company with the brand company’s permission. In some cases, even though it is the same as the brand name product, a company may choose to sell the authorized generic at a lower cost than the brand name drug.

GENERIC: A generic drug, as that term is commonly understood and referred to by health care providers and insurers, is a copy of a brand-name drug that is developed and made by a company other than the company that makes the brand-name drug. A generic drug is the same as the brand-name drug in active ingredient, conditions of use, dosage form, strength, route of administration, and (with certain permissible differences) labeling. However, a generic drug may have certain minor differences from the brand-name product, such as different inactive ingredients.

https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs

FDA APPROVED INDICATIONS AND SUPPORTED OFF-LABEL INDICATIONS

Xyrem/Xywav/Lumryz = Cataplexy; Narcolepsy; Idiopathic hypersomnia
Sunosi = Narcolepsy; Idiopathic hypersomnia; Hypersomnia associated with Obstructive sleep apnea
Wakix = Cataplexy; Narcolepsy; Idiopathic hypersomnia

Creation date: 03/2020
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2025

SODIUM OXYBATE EXTENDED RELEASE (LUMRYZ)

Generic	Brand	HICL	GPID	Exception/Other
SODIUM OXYBATE EXTENDED RELEASE	LUMRYZ	12346	54076, 54077, 54079, 54092, 56293	Non-Formulary 5th preferred in narcolepsy class

GUIDELINES FOR COVERAGE

CRITERIA FOR ALL PATIENTS CURRENTLY TAKING THE REQUESTED MEDICATION: MUST MEET ALL THE FOLLOWING:

1. Medication is prescribed by a Neurology or a Board-Certified Sleep Medicine provider.
2. Medication is being prescribed for Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia; or Cataplexy (not excessive daytime sleepiness) due to narcolepsy.
3. Medication requested is not be used in combination with solriamfetol (Sunosi), pitolisant (Wakix) or any other oxybate product (i.e. Xyrem, Xywav).
4. Patient must have tried and failed or have intolerance or contraindication to sodium oxybate (generic Xyrem) and/or Xywav [Prior Authorization required for all], or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at HICL indefinitely, max 1 packet/day.
If criteria are not met, do not approve.

CRITERIA FOR ANY PATIENT NOT CURRENTLY TAKING THE REQUESTED MEDICATION: MUST MEET ALL THE FOLLOWING:

A. Medication is prescribed by Neurology or a Board-Certified Sleep Medicine provider.
B. Medication requested is not be used in combination with solriamfetol (Sunosi), pitolisant (Wakix) or any other oxybate product (i.e. Xyrem, Xywav).
C. Patient must have one of the following indications and meet all criteria pertaining to that indication:
    1. Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia: Must meet all the following, or the provider submitted justification and supporting clinical documentation that states one of the following: i) the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
        a. Patient must have tried and failed or have a contraindication to each of the following: amphetamines, methylphenidate, and either modafinil or armodafinil.
        b. Patient must have tried and failed or have a contraindication to Sunosi, Wakix, and sodium oxybate (generic Xyrem) or Xywav [Prior Authorization required for all].

If criteria are met, approve at HICL indefinitely, max 1 packet/day.
If criteria are not met, do not approve.

2. Cataplexy (not excessive daytime sleepiness) due to narcolepsy: Must meet all the following, or the provider submitted justification and supporting clinical documentation that states one of the following: i) the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Patient must have tried and failed or have a contraindication to each of the following: a tricyclic antidepressant (TCA), a selective serotonin reuptake inhibitor (SSRI), and a selective serotonin-norepinephrine (SNRI).
   b. Patient must have tried and failed or have a contraindication to Wakix, and sodium oxybate (generic Xyrem) or Xywav [Prior Authorization required for all].

   If critieria are met, approve at HICL indefinitely, max 1 packet/day.
   If criteria are not met, do not approve.

ePA Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia; Cataplexy (not excessive daytime sleepiness) due to narcolepsy]

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia

   1. Is the patient stable on therapy with this medication?
   2. For patients noted stable on therapy, start date of therapy (MMDDYY):
   3. Is the medication being used in combination with solriamfetol (Sunosi), pitolisant (Wakix) or any other oxybate product (i.e. Xywav, Xyrem)?
   4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   5. Is there reasoning why alternatives (amphetamines, methylphenidate, modafinil, armodafinil) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

   Cataplexy (not excessive daytime sleepiness) due to narcolepsy

   1. Is the patient stable on therapy with this medication?
   2. For patients noted stable on therapy, start date of therapy (MMDDYY):
   3. Is the medication being used in combination with solriamfetol (Sunosi), pitolisant (Wakix) or any other oxybate product (i.e. Xywav, Xyrem)?
   4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   5. Is there reasoning why alternatives (amitriptyline tablets, desipramine tablets, nortriptyline capsules; citalopram tablets/solution, escitalopram tablets, fluoxetine capsules/solution, paroxetine IR tablets, sertraline tablets/susp; venlafaxine ER capsules (37.5 mg, 75 mg, 150 mg), duloxetine capsules (20 mg, 30 mg, 60 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Lumryz, sodium oxybate oral solution. and Xywav have the same active ingredient (oxybate, a CNS depressant) and have not been studied for use in combination or as alternating treatments. Sunosi, a dopamine and norepinephrine reuptake inhibitor, is indicated to improve wakefulness in adults with excessive daytime sleepiness due to narcolepsy or obstructive sleep apnea. Wakix, an antagonist/inverse agonist of the histamine-3 receptor, is indicated for excessive daytime sleepiness and cataplexy in adults with narcolepsy. Currently, there are no published studies evaluating combination use of these medications.

FDA APPROVED INDICATIONS AND SUPPORTED OFF-LABEL INDICATIONS

Xyrem/Xywav/Lumryz = Cataplexy; Narcolepsy; Idiopathic hypersomnia
Sunosi = Narcolepsy; Idiopathic hypersomnia; Hypersomnia associated with Obstructive sleep apnea
Wakix = Cataplexy; Narcolepsy; Idiopathic hypersomnia

Creation date: 03/2020
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2025

LOKELMA MD RESTRICTION

Generic	Brand	HICL	GPID	Other
SODIUM ZIRCONIUM CYCLOSILICATE	LOKELMA	44935	44774, 44775	Formulary

GUIDELINES FOR COVERAGE: Must meet the following:

1. Is the requesting provider a CPMG or an affiliated network cardiologist, cardiology specialist, nephrologist, nephrology specialist, or transplant hepatologist with appropriate referral, if needed?

If yes, approve the MD restriction at HICL x 1 year.
If no, do not approve.

RATIONALE
Lokelma is formulary, however it should only be prescribed by appropriate specialists. There are other formulary alternatives available for other prescribers.

Creation Date: 03/2021
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 05/2024

SOVALDI (SOFOSBUVIR)

Generic	Brand	HICL	GCN	Exception/Other
SOFOSBUVIR	SOVALDI	40795		Formulary

GUIDELINES FOR COVERAGE
Must meet all general criteria, have one of the following diagnoses, and meet diagnosis-specific criteria below:

A. General criteria for all requests
B. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past glecaprevir/pibrentasvir treatment failure
C. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with multiple past direct-acting antiviral (DAA) treatment failure

A. General criteria for all requests: Must meet all the following:
1. Patient is at least 3 years old and currently supervised by a gastroenterologist, infectious disease specialist, provider specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model.
2. Patient does not have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
3. Patient is not currently taking any medications that have a clinically significant interaction with the Hepatitis C medication ordered.*

B. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past glecaprevir/pibrentasvir treatment failure: Must meet all the following:
1. Patient has a detectable HCV RNA level. The detectable HCV RNA level must be from at least 12 weeks after completion of the previous treatment.
2. Patient does not have a suspected acute HCV exposure in the last 6 months.
3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
4. Patient has intolerance or contraindication to sofosbuvir/velpatasvir/voxilaprevir.
5. Provider attests sofosbuvir will be used in combination with glecaprevir/pibrentasvir and ribavirin.

If met, approve x16 weeks at HICL.
If criteria are not met, do not approve.

C. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with multiple past direct-acting antiviral (DAA) treatment failure: Must meet all the following:
1. Patient has a detectable HCV RNA level. The detectable HCV RNA level must be from at least 12 weeks after completion of the previous treatment.
2. Patient does not have a suspected acute HCV exposure in the last 6 months.
3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
4. Patient has failed 2+ previous DAA treatments, including sofosbuvir/velpatasvir/voxilaprevir.
5. Provider attests sofosbuvir will be used in combination with glecaprevir/pibrentasvir and ribavirin.

If met, approve x24 weeks at HICL.
If criteria are not met, do not approve.

ePA Questions

1. Hep C Genotype:
2. Has the patient failed other treatments for this indication? If yes, must list the medication, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Does the patient have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions?
4. Is the patient taking any medications that have a clinically significant interaction with the Hepatitis C medication ordered?
5. Diagnosis/Indication associated with this request: [check boxes for all diagnoses listed in criteria: Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past glecaprevir/pibrentasvir treatment failure; Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with multiple past direct-acting antiviral (DAA) treatment failure]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past glecaprevir/pibrentasvir treatment failure

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
5. Yes/No: The provider attests sofosbuvir will be used in combination with glecaprevir/pibrentasvir and ribavirin.

Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with multiple past direct-acting antiviral (DAA) treatment failure

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
5. Yes/No: The provider attests sofosbuvir will be used in combination with glecaprevir/pibrentasvir and ribavirin.

RATIONALE

*Clinically significant is defined as an interaction that is moderate to severe and cannot be mitigated easily

Note: There are no renewal criteria as reviews using above criteria apply for a one-time treatment regimen.

FDA APPROVED INDICATIONS

Hepatitis C

REFERENCES

AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C
Kaiser Permanente Inter-Regional Consensus Hepatitis C Treatment Recommendations

Creation date: 05/2024
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: n/a

EPCLUSA (SOFOSBUVIR/VELPATASVIR)

Generic	Brand	HICL	GPID	Exception/Other
SOFOSBUVIR/VELPATASVIR	EPCLUSA	43561		Formulary (generic)

GUIDELINES FOR COVERAGE
Must meet all general criteria, have one of the following diagnoses, and meet diagnosis-specific criteria below:

A. General criteria for all requests
B. Diagnosis of Hepatitis C virus (HCV)+ transplant recipient
C. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis
D. Diagnosis of chronic Hepatitis C virus (HCV) with compensated cirrhosis
E. Diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis with past failure of a sofosbuvir- or NS5A-based treatment
F. Diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis without past failure of a sofosbuvir- or NS5A-based treatment
G. Diagnosis of pediatric chronic Hepatitis C virus (HCV) and weight < 30 kg

A. **General criteria for all requests:** Must meet all the following:
   1. Patient is at least 3 years old and currently supervised by a gastroenterologist, infectious disease specialist, provider specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model.
   2. Patient does not have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
   3. Patient is not currently taking any medications that have a clinically significant interaction with the Hepatitis C medication ordered.*

B. The patient is receiving or has received an HCV+ transplant: Must meet all the following:
   1. Request must be for 400-100 mg strength.

      If criteria are met, approve x12 weeks at GPID. Must "Override Force Flag" in the "Override Restriction" field to allow dispense by the Mayo pharmacy in Arizona (post-transplant).
      If criteria are not met, do not approve.

      Note: Only if patient is out of state at Mayo Clinic and immediate post-HCV+ liver transplant may you place a force override to allow the Hep C drug to be dispensed by a non-KP pharmacy.

C. The patient has diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis: Must meet all the following:
   1. Patient has a detectable HCV RNA level.
   2. Patient does not have a suspected acute HCV exposure in the last 6 months.
   3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
   4. Patient is treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir).
   5. Request must be for 400-100 mg strength.

If met, approve x12 weeks at GPID.
If criteria are not met, do not approve.

D. The patient has diagnosis of chronic Hepatitis C virus (HCV) with compensated cirrhosis: Must meet all the following:
1. Patient has a detectable HCV RNA level.
2. Patient does not have a suspected acute HCV exposure in the last 6 months.
3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
4. Patient is treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir).
5. If genotype 3, and positive for NS5A RAS Y93H or if this result is unknown, the provider confirms that ribavirin will be added to sofosbuvir-velpatasvir*.
6. Request must be for 400-100 mg strength.

If met, approve x12 weeks at GPID.
If not met, do not approve. [*If contraindication or intolerance to ribavirin, Mavyret should be considered.]

E. The patient has diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis and has past failure of a sofosbuvir- or NS5A-based treatment: Must meet all the following:
1. Patient has a detectable HCV RNA level.
2. Patient does not have a suspected acute HCV exposure in the last 6 months.
3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
4. The provider confirms the patient will use ribavirin in combination with sofosbuvir-velpatasvir*.
5. Request must be for 400-100 mg strength.

If met, approve x24 weeks at GPID.
If not met, do not approve. [*Sofosbuvir-velpatasvir is not indicated in this patient population without ribavirin.]

F. The patient has diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis and no past failure of a sofosbuvir- or NS5A-based treatment: Must meet all the following:
1. Patient has a detectable HCV RNA level.
2. Patient does not have a suspected acute HCV exposure in the last 6 months.
3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
4. Patient is treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir).
5. The provider confirms the patient will use ribavirin in combination with sofosbuvir-velpatasvir, or the provider notes that the patient has an intolerance or contraindication to ribavirin.
6. Request must be for 400-100 mg strength.

If criteria are met and provider notes use of ribavirin, approve x12 weeks at GPID.
If criteria are met and provider notes patient has intolerance or contraindication to ribavirin, approve x24 weeks at GPID.
If criteria are not met, do not approve.

G. The patient has diagnosis of pediatric chronic Hepatitis C virus (HCV) and weighs < 30 kg:
Must meet all the following:
1. Patient has a detectable HCV RNA level.
2. Patient does not have a suspected acute HCV exposure in the last 6 months.
3. Patient is treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir).

If met, approve x12 weeks at HICL.
If not met, do not approve.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Does the patient have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions?
3. Is the patient taking any medications that have a clinically significant interaction with the Hepatitis C medication ordered?
4. Diagnosis/Indication associated with this request: [check boxes for all diagnoses listed in criteria: Hepatitis C virus (HCV)+ transplant recipient; Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis; Diagnosis of chronic Hepatitis C virus (HCV) with compensated cirrhosis; Diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis with past failure of a sofosbuvir- or NS5A-based treatment; Diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis without past failure of a sofosbuvir- or NS5A-based treatment; Diagnosis of pediatric chronic Hepatitis C virus (HCV) and weight < 30 kg]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis
1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
5. Is the patient treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)?

Diagnosis of chronic Hepatitis C virus (HCV) with compensated cirrhosis
1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Hep C Genotype:
4. Does the patient have a suspected acute HCV exposure in the last 6 months?
5. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.

6. Is the patient treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)?
7. Is the patient positive for NS5A RAS Y93H or is this result unknown?
8. Will ribavirin be added to sofosbuvir-velpatasvir?

Diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis with past failure of a sofosbuvir- or NS5A-based treatment

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
5. Yes/No: The provider confirms the patient will use ribavirin in combination with sofosbuvir-velpatasvir.

Diagnosis of chronic Hepatitis C virus (HCV) with decompensated cirrhosis without past failure of a sofosbuvir- or NS5A-based treatment

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
5. Is the patient treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)?
6. Yes/No: The provider confirms the patient will use ribavirin in combination with sofosbuvir-velpatasvir, or the provider notes that the patient has an intolerance or contraindication to ribavirin.

Diagnosis of pediatric chronic Hepatitis C virus (HCV) and weight < 30 kg

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Is the patient treatment naïve or treatment experienced with only interferon or interferon plus first-generation protease inhibitor (telaprevir, boceprevir, simeprevir)?

RATIONALE

*Clinically significant is defined as an interaction that is moderate to severe and cannot be mitigated easily

Note: There are no renewal criteria as reviews using above criteria apply for a one-time treatment regimen.

Generic Name	Brand Name	Strength	Form	Size	GPID	HICL
sofosbuvir/velpatasvir	Eplucsa	150-37.5mg	Pelet Pack	28	49798	43561
sofosbuvir/velpatasvir	Eplucsa	150-37.5mg	Pelet Pack	1	49798	43561
sofosbuvir/velpatasvir	Eplucsa	200mg-50mg	Tablet	28	48517	43561
sofosbuvir/velpatasvir	Eplucsa	200mg-50mg	Pelet Pack	28	49799	43561
sofosbuvir/velpatasvir	Eplucsa	200mg-50mg	Pelet Pack	1	49799	43561
sofosbuvir/velpatasvir	Eplucsa	400-100mg	Tablet	28	41729	43561
sofosbuvir/velpatasvir	Sofosbuvir-velpatasvir	400-100mg	Tablet	28	41729	43561

FDA APPROVED INDICATIONS
Hepatitis C

REFERENCES
AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C
Kaiser Permanente Inter-Regional Consensus Hepatitis C Treatment Recommendations

Creation date: 05/2024
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: n/a

VOSEVI (SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR)

Generic	Brand	HICL	GCN	Exception/Other
SOFOSBUVIR/VELPATASVIR/ VOXILAPREVIR	VOSEVI	44428		Formulary

GUIDELINES FOR COVERAGE
Must meet all general criteria, have one of the following diagnoses, and meet diagnosis-specific criteria below:

A. General criteria for all requests
B. Diagnosis of Hepatitis C virus (HCV)+ transplant recipient
C. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past sofosbuvir-based and elbasvir/grazoprevir treatment failure
D. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past glecaprevir/pibrentasvir treatment failure
E. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with multiple past direct-acting antiviral (DAA) treatment failure

A. General criteria for all requests: Must meet all the following:
1. Patient is at least 18 years old and currently supervised by a gastroenterologist, infectious disease specialist, provider specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model.
2. Patient does not have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
3. Patient is not currently taking any medications that have a clinically significant interaction with the Hepatitis C medication ordered.*

B. The patient is receiving or has received an HCV+ transplant: Must meet all the following:
1. Patient has past direct-acting antiviral (DAA) treatment experience.

   If criteria are met, approve x12 weeks at HICL. Must "Override Force Flag" in the "Override Restriction" field to allow dispense by the Mayo pharmacy in Arizona (post-transplant).
   If criteria are not met, do not approve.

   Note: Only if patient is out of state at Mayo Clinic and immediate post-HCV+ liver transplant may you place a force override to allow the Hep C drug to be dispensed by a non-KP pharmacy.

C. Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past sofosbuvir-based and elbasvir/grazoprevir treatment failure: Must meet all the following:
1. Patient has a detectable HCV RNA level. The detectable HCV RNA level must be from at least 12 weeks after completion of the previous treatment.
2. Patient does not have a suspected acute HCV exposure in the last 6 months.
3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
4. Provider attests ribavirin will be added if patient has genotype 3 with compensated cirrhosis, unless contraindication to ribavirin.

If met, approve x12 weeks at HICL.
If criteria are not met, do not approve.

D. **Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past glecaprevir/pibrentasvir treatment failure**: Must meet all the following:
   1. Patient has a detectable HCV RNA level. The detectable HCV RNA level must be from at least 12 weeks after completion of the previous treatment.
   2. Patient does not have a suspected acute HCV exposure in the last 6 months.
   3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
   4. Provider attests ribavirin will be added if patient has compensated cirrhosis.

   If met, approve x12 weeks at HICL.
   If criteria are not met, do not approve.

E. **Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with multiple past direct-acting antiviral (DAA) treatment failure**: Must meet all the following:
   1. Patient has a detectable HCV RNA level. The detectable HCV RNA level must be from at least 12 weeks after completion of the previous treatment.
   2. Patient does not have a suspected acute HCV exposure in the last 6 months.
   3. Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
   4. Patient has failed 2+ previous DAA treatments, including sofosbuvir/velpatasvir/voxilaprevir x 12 weeks.
   5. Provider attests ribavirin will be added.

   If met, approve x24 weeks at HICL.
   If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Does the patient have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions?
3. Is the patient taking any medications that have a clinically significant interaction with the Hepatitis C medication ordered?
4. Diagnosis/Indication associated with this request: [check boxes for all diagnoses listed in criteria: Hepatitis C virus (HCV)+ transplant recipient; Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past sofosbuvir-based and elbasvir/grazoprevir treatment failure; Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past glecaprevir/pibrentasvir treatment failure; Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with multiple past direct-acting antiviral (DAA) treatment failure]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past sofosbuvir-based and elbasvir/grazoprevir treatment failure

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. HCV genotype:
4. Does the patient have a suspected acute HCV exposure in the last 6 months?
5. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
6. Yes/No: Provider attests ribavirin will be added if patient has genotype 3 with compensated cirrhosis, unless contraindication to ribavirin.

Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with past glecaprevir/pibrentasvir treatment failure

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
5. Does the patient have compensated cirrhosis?
6. Will ribavirin be used as part of this patient's HCV treatment regimen?

Diagnosis of chronic Hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis, with multiple past direct-acting antiviral (DAA) treatment failure

1. Current HCV RNA level:
2. Date of HCV RNA lab (MMDDYY):
3. Does the patient have a suspected acute HCV exposure in the last 6 months?
4. Yes/No: Provider attests to the best of their knowledge that patient is NOT abusing/misusing alcohol and/or illegal drugs (per Colorado state law) OR if patient is abusing/misusing alcohol and/or illegal drugs (per Colorado state law), provider attests that the patient is receiving or will be enrolled in counseling or substance use treatment program prior to initiating HCV treatment.
5. Yes/No: The provider attests ribavirin will be used as part of this patient's HCV treatment.

RATIONALE

*Clinically significant is defined as an interaction that is moderate to severe and cannot be mitigated easily

Note: There are no renewal criteria as reviews using above criteria apply for a one-time treatment regimen.

FDA APPROVED INDICATIONS

Hepatitis C

REFERENCES

AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C
Kaiser Permanente Inter-Regional Consensus Hepatitis C Treatment Recommendations

Reviewed date: 03/2025
Revised date: n/a

SOLRIAMFETOL (SUNOSI)

Generic	Brand	HICL	GPID	Exception/Other
SOLRIAMFETOL HCL	SUNOSI	45666	46126, 46127	Non-Formulary Most Preferred in Narcolepsy class

GUIDELINES FOR COVERAGE

CRITERIA FOR ALL PATIENTS CURRENTLY TAKING THE REQUESTED MEDICATION: MUST MEET ALL THE FOLLOWING:

1. Medication is prescribed by a Neurology or a Board-Certified Sleep Medicine provider.
2. Medication is being prescribed for Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia; or Hypersomnia associated with obstructive sleep apnea (OSA).
3. Medication requested is not be used in combination with pitolisant (Wakix) or any oxybate product (i.e. Xyrem, Xywav, Lumryz).

If criteria are met, approve at HICL indefinitely, max 1 tablet/day.
If criteria are not met, do not approve.

CRITERIA FOR ANY PATIENT NOT CURRENTLY TAKING THE REQUESTED MEDICATION: MUST MEET ALL THE FOLLOWING:

1. Medication is prescribed by Neurology or a Board-Certified Sleep Medicine provider.
2. Medication requested is not be used in combination with pitolisant (Wakix) or any oxybate product (i.e. Xyrem, Xywav, Lumryz).
3. Medication is being prescribed for Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia; or Hypersomnia associated with obstructive sleep apnea (OSA).
4. Patient must have tried and failed or have a contraindication to each of the following, or the provider submitted justification and supporting clinical documentation that states one of the following: i) the required drug is contraindicated or will likely cause an adverse reaction or harm; ii) the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception: amphetamines, methylphenidate, and either modafinil or armodafinil.

If criteria are met, approve at HICL indefinitely, max 1 tablet/day.
If criteria are not met, do not approve.

ePA Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Excessive daytime sleepiness due to narcolepsy or idiopathic hypersomnia; Hypersomnia associated with obstructive sleep apnea (OSA)]
2. Is the medication being used in combination with pitolisant (Wakix) or any other oxybate product (i.e. Xywav, Xyrem, Lumryz)?
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (amphetamines, methylphenidate, modafinil, armodafinil) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Lumryz, sodium oxybate oral solution. and Xywav have the same active ingredient (oxybate, a CNS depressant) and have not been studied for use in combination or as alternating treatments. Sunosi, a dopamine and norepinephrine reuptake inhibitor, is indicated to improve wakefulness in adults with excessive daytime sleepiness due to narcolepsy or obstructive sleep apnea. Wakix, an antagonist/inverse agonist of the histamine-3 receptor, is indicated for excessive daytime sleepiness and cataplexy in adults with narcolepsy. Currently, there are no published studies evaluating combination use of these medications.

FDA APPROVED INDICATIONS AND SUPPORTED OFF-LABEL INDICATIONS

Xyrem/Xywav/Lumryz = Cataplexy; Narcolepsy; Idiopathic hypersomnia
Sunosi = Narcolepsy; Idiopathic hypersomnia; Hypersomnia associated with Obstructive sleep apnea
Wakix = Cataplexy; Narcolepsy; Idiopathic hypersomnia

Creation date: 03/2020
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2025

SOMAPACITAN-BECO (SOGROYA)

Generic	Brand	HICL	GCN	Exception/Other
SOMAPACITAN-BECO	SOGROYA	46831		Once weekly non-preferred; Omnitrope is preferred/formulary

GUIDELINES FOR COVERAGE
Must meet all the following:

1. Patient has one of the following diagnoses:
    a. Growth Hormone Deficiency alone or associated with hormone deficiencies resulting from pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma
    b. Growth failure due to inadequate secretion of endogenous growth hormone (GH)
2. Medication is prescribed by an Endocrinologist
3. Patient is 2.5 years of age or older
4. Patient has tried and failed, or has an intolerance or contraindication to Omnitrope cartridges, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Growth Hormone Deficiency alone or associated with hormone deficiencies resulting from pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma; Growth failure due to inadequate secretion of endogenous growth hormone (GH)]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (Omnitrope cartridges) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Ensure appropriate use of growth hormones with respect to evidence-based guidelines and direct usage to formulary agents. KPCO generally does not consider frequency of dosing and/or lack of compliance to dosing regimens an indication of medical necessity.

Growth Hormone medications in order of formulary preference (most preferred to least): Omnitrope cartridges, Genotropin, Omnitrope vials, Saizen, Nutropin, Humatrope, Norditropin, Norditropin, Zomacton, Sogroya, Skytrofa

OMNITROPE is indicated for Pediatric Patients: Treatment of children with growth failure due to growth hormone deficiency (GHD), Prader-Willi Syndrome, Small for Gestational Age, Turner syndrome, and

Idiopathic Short Stature. Adult Patients: Treatment of adults with either adult onset or childhood onset GHD.

SOGROYA is a human growth hormone analog indicated for replacement of endogenous growth hormone in adults with growth hormone deficiency and treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH).

REFERENCES

1. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children – 2003 update. Endocr Pract 2003; 9(1):64-76.
2. Consensus guidelines for the diagnosis and treatment of growth hormone (GH) deficiency in childhood and adolescence: summary statement of the GH Research Society. JCE & M 2000; 85(11):3990-3.
3. Bengtsson B, et al. Treatment of Growth Hormone Deficiency in Adults. JCE & M 2000; 85(3): 933-42.
4. Wilson, T et al. Update of Guidelines for the Use of Growth Hormone in Children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. J Pediatr 2003; 143:314-21.
5. Vance M, Mauras N. Growth hormone therapy in adults and children. NEJM 1999; 341(16):1206-16.
6. Hintz R, et al. Effect of Growth Hormone Treatment on Adult Height of Children with idiopathic Short Stature. NEJM 1999; 340:502-7.
7. Sandoz GmbH. Omnitrope package insert. Austria. June 2010.
8. Allen DB, Backeljauw P, Bidlingmaier M, Biller BMK, et al. GH safety workshop position paper: a critical appraisal of recombinant human GH therapy in children and adults. European Journal of Endocrinology (2016) 174 (2). doi:10.1530/EJE-15-0873 (ghresearchsociety.org)
9. Grimberg A, DiVall SA, Polychronakos C, Allen DB, Cohen LE, Quintos JB, Rossi WC, Feudtner C, Murad MH; Drug and Therapeutics Committee and Ethics Committee of the Pediatric Endocrine Society. Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency. Horm Res Paediatr. 2016;86(6):361-397. Doi: 10.1159/000452150.

Creation Date: 05/2024
Effective Date: 06/2024
Reviewed Date:
Revised Date:

SOMATROGON-GHLA (NGENLA)

Generic	Brand	HICL	GPID	Exception/Other
SOMATROGON-GHLA	NGENLA	47896	52062, 52063	Once weekly non-preferred; Omnitrope is preferred/formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH).
2. Medication is prescribed by an Endocrinologist.
3. Patient is between 3 and 18 years of age.
4. Patient has tried and failed, or has an intolerance or contraindication to Omnitrope cartridges, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve at HICL x1 year.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Medication is prescribed by an Endocrinologist.
2. Patient's height has increased by 2 cm or more from previous year, or the patient has not yet reached the 50th percentile of predicted height.

If renewal criteria are met, approve x1 year.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Does the patient have growth hormone deficiency/growth failure due to inadequate secretion of endogenous growth hormone (GH)? If yes, must attach chart notes with supporting documentation.
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (Omnitrope cartridges) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Has the patient's height increased by 2 cm or more from previous year? If yes, must attach chart notes with supporting documentation.
2. Has the patient reached 50th percentile of predicted height? If no, must attach chart notes with supporting documentation.

RATIONALE

Ensure appropriate use of growth hormones with respect to evidence-based guidelines and direct usage to formulary agents. KPCO generally does not consider frequency of dosing and/or lack of compliance to dosing regimens an indication of medical necessity.

Growth Hormone medications in order of formulary preference (most preferred to least): Omnitrope CARTRIDGE, Genotropin, Zomacton, Norditropin, Nutropin, Saizen, Humatrope, Omnitrope VIAL, Sogroya, Ngenla, Skytrofa.

OMNITROPE CARTRIDGE (KPCO preferred GH therapy) is indicated for Pediatric Patients: Treatment of children with growth failure due to growth hormone deficiency (GHD), Prader-Willi Syndrome, Small for Gestational Age, Turner syndrome, and Idiopathic Short Stature. Adult Patients: Treatment of adults with either adult onset or childhood onset GHD.

NGENLA is indicated for the treatment of growth failure in children 3 years of age and older with growth hormone deficiency (GHD).

REFERENCES

1. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children - 2003 update. Endocr Pract 2003; 9(1):64-76.
2. Consensus guidelines for the diagnosis and treatment of growth hormone (GH) deficiency in childhood and adolescence: summary statement of the GH Research Society. JCE & M 2000; 85(11):3990-3.
3. Wilson, T et al. Update of Guidelines for the Use of Growth Hormone in Children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. J Pediatr 2003; 143:314-21.
4. Vance M, Mauras N. Growth hormone therapy in adults and children. NEJM 1999; 341(16):1206-16.
5. Allen DB, Backeljauw P, Bidlingmaier M, Biller BMK, et al. GH safety workshop position paper: a critical appraisal of recombinant human GH therapy in children and adults. European Journal of Endocrinology (2016) 174 (2). doi:10.1530/EJE-15-0873 (ghresearchsociety.org)
6. Grimberg A, DiVall SA, Polychronakos C, Allen DB, Cohen LE, Quintos JB, Rossi WC, Feudtner C, Murad MH; Drug and Therapeutics Committee and Ethics Committee of the Pediatric Endocrine Society. Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency. Horm Res Paediatr. 2016;86(6):361-397. Doi: 10.1159/000452150.

Creation Date: 07/2024
Effective Date: 08/2024
Reviewed Date:
Revised Date:

FORMULARY SOMATROPIN - GROWTH HORMONE - OMNITROPE CARTRIDGES

Generic	Brand	HICL	GPID	Exception/Other
SOMATROPIN	OMNITROPE CARTRIDGES		92366, 92386	Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Review based on diagnosis/indication as outlined below:

A. Growth Hormone Deficiency (GHD) alone or with multiple hormone deficiencies (ex: hypopituitarism), Turner Syndrome, or Prader Willi Syndrome, or as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, or trauma
B. Pediatric (under 18 years of age) Small for Gestational Age (SGA)
C. Growth failure due to renal disease
D. All other indications

A. For treatment of growth hormone deficiency (GHD) alone or with multiple hormone deficiencies (ex: hypopituitarism), Turner Syndrome, or Prader Willi syndrome, or as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, or trauma: Must meet all the following:
   1. Medication is prescribed by an Endocrinologist.

      If initial criteria are met, approve at GPID indefinitely.
      If initial criteria are not met, do not approve.

B. Pediatric patients, age less than 18 years, Small for Gestational Age (SGA): Must meet all the following:
   1. Medication is prescribed by an Endocrinologist.
   2. Patient with no 'catch-up growth' by 2 years of age.
   3. Patient's height is either 2 or more standard deviations (SD) below the mean height for children of the same age and sex, or less than the second percentile for their age and sex.

      If initial criteria are met, approve at GPID x1 year.
      If initial criteria are not met, do not approve.

C. For pediatric patients, less than 18 years of age, with growth failure with pediatric chronic renal insufficiency (CRI)/chronic kidney disease (CKD) prior to renal transplant: Must meet all the following:
   1. Medication is prescribed by an Endocrinologist or a Nephrologist.
   2. Patient has a diagnosis of CRI/CKD with GHD and awaiting transplant.

      If initial criteria are met, approve at GPID x1 year.
      If initial criteria are not met, do not approve.

D. All other indications: The following indications are not covered:
   1. Idiopathic Short Stature (non-GH deficiency)
   2. Athletic Enhancement
   3. Anti-aging
   4. Infertility (female)

RENEWAL CRITERIA: Review based on diagnosis/indication as outlined, A-B below:

A. Pediatric (under 18 years of age) Small for Gestational Age (SGA)
B. Growth failure due to renal disease

A. Pediatric patient, age less than 18 years, Small for Gestational Age (SGA): Must meet all the following:
   1. Medication is prescribed by an Endocrinologist.
   2. Patient's height has increased by 2 cm or more from previous year, or the patient has not yet reached the 50th percentile of predicted height

   If renewal criteria are met, approve x1 year.
   If renewal criteria are not met, do not approve.

B. For Pediatric patients, age less than 18 years, growth failure due to pediatric chronic renal insufficiency (CRI)/chronic kidney disease (CKD) prior to renal transplant: Must meet all the following:
   1. Medication is prescribed by an Endocrinologist or Nephrologist.
   2. Patient has not received kidney transplant.

   If renewal criteria are met, approve x1 year.
   If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Growth Hormone Deficiency (GHD) alone or with multiple hormone deficiencies (ex: hypopituitarism), Turner Syndrome, or Prader Willi Syndrome, or as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, or trauma; Pediatric (under 18 years of age) Small for Gestational Age (SGA) with no catch-up growth by 2 years of age; Growth failure due to renal disease]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Growth Hormone Deficiency (GHD) alone or with multiple hormone deficiencies (ex: hypopituitarism), Turner Syndrome, or Prader Willi Syndrome, or as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, or trauma

1. Does the patient have growth hormone deficiency? If yes, must attach chart notes with supporting documentation.

Pediatric (under 18 years of age) Small for Gestational Age (SGA)

1. Is the patient's height 2 or more standard deviations (SD) below the mean height for children of the same age and sex, or less than the second percentile for their age and sex? If yes, must attach chart notes with supporting documentation.

Growth failure due to renal disease

1. Does the patient have CRI/CKD with GHD and awaiting transplant. If yes, must attach chart notes with supporting documentation.

Renewal Review Questions

2. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Small for Gestational Age (SGA) with no catch-up growth by 2 years of age; Growth failure due to renal disease]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Pediatric (under 18 years of age) Small for Gestational Age (SGA)

1. Has the patient's height increased by 2 cm or more from previous year? If yes, must attach chart notes with supporting documentation.
2. Has the patient reached 50th percentile of predicted height? If no, must attach chart notes with supporting documentation.

Growth failure due to renal disease

1. Has the patient received kidney transplant?

RATIONALE

Ensure appropriate use of growth hormones with respect to evidence-based guidelines and direct usage to formulary agents. KPCO generally does not consider frequency of dosing and/or lack of compliance to dosing regimens an indication of medical necessity.

Growth Hormone medications in order of formulary preference (most preferred to least): Omnitrope CARTRIDGE, Genotropin, Zomacton, Norditropin, Nutropin, Saizen, Humatrope, Omnitrope VIAL, Sogroya, Ngenla, Skytrofa.

OMNITROPE CARTRIDGE **[1st line]** is indicated for Pediatric Patients: Treatment of children with growth failure due to growth hormone deficiency (GHD), Prader-Willi Syndrome, Small for Gestational Age, Turner syndrome, and Idiopathic Short Stature. Adult Patients: Treatment of adults with either adult onset or childhood onset GHD.
SAIZEN is indicated for the treatment of pediatric and adult growth hormone deficiency.
SEROSTIM is indicated in the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance with concomitant antiretroviral therapy.

REFERENCES

1. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children – 2003 update. Endocr Pract 2003; 9(1):64-76.
2. Consensus guidelines for the diagnosis and treatment of growth hormone (GH) deficiency in childhood and adolescence: summary statement of the GH Research Society. JCE & M 2000; 85(11):3990-3.
3. Bengtsson B, et al. Treatment of Growth Hormone Deficiency in Adults. JCE & M 2000; 85(3): 933-42.
4. Wilson, T et al. Update of Guidelines for the Use of Growth Hormone in Children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. J Pediatr 2003; 143:314-21.
5. National Kidney Foundation (2000). Clinical practice guidelines for nutrition in chronic renal failure. Available at: www.kidney.org/professionals/kdoqi/guidelines_updates/nut_p10.html. [Accessed July 21, 2009].
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7. Grinspoon S, Mulligan K. Weight loss and wasting in patients infected with human immunodeficiency virus. Clinical Infectious Disease 2003; 36:S69-78.
8. Hintz R, et al. Effect of Growth Hormone Treatment on Adult Height of Children with idiopathic Short Stature. NEJM 1999; 340:502-7.
9. Haffner D, et al. Effect of Growth Hormone Treatment on the Adult Height of Children with Chronic Renal Failure. NEJM 2000; 343:923-30.
10. Sandoz GmbH. Omnitrope package insert. Austria. June 2010.
11. Allen DB, Backeljauw P, Bidlingmaier M, Biller BMK, et al. GH safety workshop position paper: a critical appraisal of recombinant human GH therapy in children and adults. European Journal of Endocrinology (2016) 174 (2). doi:10.1530/EJE-15-0873 (ghresearchsociety.org)

12. Grimberg A, DiVall SA, Polychronakos C, Allen DB, Cohen LE, Quintos JB, Rossi WC, Feudtner C, Murad MH; Drug and Therapeutics Committee and Ethics Committee of the Pediatric Endocrine Society. Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency. Horm Res Paediatr. 2016;86(6):361-397. Doi: 10.1159/000452150.

Creation Date: 11/16/2016
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

SOMATROPIN - NONFORMULARY GHD - GROWTH HORMONE PA GL

Generic	Brand	HICL	GCN	Exception/Other
SOMATROPIN	NUTROPIN AQ	02824	17475, 99320, 27846	NF
SOMATROPIN	NORDITROPIN	02824	24145, 24146, 24147, 25816	NF
SOMATROPIN	HUMATROPE	02824	575, 25957, 25963, 25969	NF
SOMATROPIN	SAIZEN	02824	23695	NF
SOMATROPIN	ZOMACTON	02824	25967, 25955	NF
SOMATROPIN	OMNITROPE VIAL	02824	93215	NF
SOMATROPIN	GENOTROPIN	02824	50177, 50187, 50197, 50207, 21450, 21451, 21452, 21453, 10554, 50217, 21454, 63408	NF

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Review based on diagnosis/indication as outlined below:

A. Growth Hormone Deficiency (GHD), alone or with multiple hormone deficiencies (ex: hypopituitarism), Turner Syndrome, or Prader Willi Syndrome, or as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, or trauma
B. Pediatric (under 18 years of age) Small for Gestational Age (SGA)
C. Growth failure due to renal disease
D. All other indications

A. For treatment of growth hormone deficiency (GHD), alone or with multiple hormone deficiencies (ex: hypopituitarism), Turner Syndrome, or Prader Willi syndrome, or as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, or trauma: Must meet all the following:
   1. Medication is prescribed by an Endocrinologist.
   2. Patient has tried and failed, or has an intolerance or contraindication to Omnitrope cartridges, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

      If initial criteria are met, approve at GPID indefinitely.
      If initial criteria are not met, do not approve.

B. Pediatric patients, age less than 18 years, Small for Gestational Age (SGA): Must meet all the following:
   1. Medication is prescribed by an Endocrinologist.
   2. Patient with no 'catch-up growth' by 2 years of age.
   3. Patient's height is either 2 or more standard deviations (SD) below the mean height for children of the same age and sex, or less than the second percentile for their age and sex.
   4. Patient has tried and failed, or has an intolerance or contraindication to Omnitrope cartridges, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical

characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve at GPID x1 year.
If initial criteria are not met, do not approve.

C. For pediatric patients, less than 18 years of age, with growth failure with pediatric chronic renal insufficiency (CRI)/chronic kidney disease (CKD) prior to renal transplant: Must meet all the following:
   1. Medication is prescribed by an Endocrinologist or a Nephrologist.
   2. Patient has a diagnosis of CRI/CKD with GHD and awaiting transplant.
   3. Patient has tried and failed, or has an intolerance or contraindication to Omnitrope cartridges, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

   If initial criteria are met, approve at GPID x1 year.
   If initial criteria are not met, do not approve.

D. All other indications: The following indications are not covered:
   1. Idiopathic Short Stature (non-GH deficiency)
   2. Athletic Enhancement
   3. Anti-aging
   4. Infertility (female)

RENEWAL CRITERIA: Review based on diagnosis/indication as outlined, A-B below:

A. Pediatric (under 18 years of age) Small for Gestational Age (SGA)
B. Growth failure due to renal disease

A. Pediatric patient, age less than 18 years, Small for Gestational Age (SGA): Must meet all the following:
   1. Medication is prescribed by an Endocrinologist.
   2. Patient's height has increased by 2 cm or more from previous year, or the patient has not yet reached the 50th percentile of predicted height

   If renewal criteria are met, approve x1 year.
   If renewal criteria are not met, do not approve.

B. For Pediatric patients, age less than 18 years, growth failure due to pediatric chronic renal insufficiency (CRI)/chronic kidney disease (CKD) prior to renal transplant: Must meet all the following:

1. Medication is prescribed by an Endocrinologist or Nephrologist.
2. Patient has not received kidney transplant.

If renewal criteria are met, approve x1 year.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Growth Hormone Deficiency (GHD) alone or with multiple hormone deficiencies (ex: hypopituitarism), Turner Syndrome, or Prader Willi Syndrome, or as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, or trauma; Pediatric (under 18 years of age) Small for Gestational Age (SGA) with no catch-up growth by 2 years of age; Growth failure due to renal disease]

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   Growth Hormone Deficiency (GHD) alone or with multiple hormone deficiencies (ex: hypopituitarism), Turner Syndrome, or Prader Willi Syndrome, or as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, or trauma

   1. Does the patient have growth hormone deficiency? If yes, must attach chart notes with supporting documentation.
   2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   3. Is there reasoning why alternatives (Omnitrope cartridges) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

   Pediatric (under 18 years of age) Small for Gestational Age (SGA)

   1. Is the patient's height 2 or more standard deviations (SD) below the mean height for children of the same age and sex, or less than the second percentile for their age and sex? If yes, must attach chart notes with supporting documentation.
   2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   3. Is there reasoning why alternatives (Omnitrope cartridges) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

   Growth failure due to renal disease

   1. Does the patient have CRI/CKD with GHD and awaiting transplant. If yes, must attach chart notes with supporting documentation.
   2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   3. Is there reasoning why alternatives (Omnitrope cartridges) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions

1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Small for Gestational Age (SGA) with no catch-up growth by 2 years of age; Growth failure due to renal disease]

   QUESTIONS BASED ON DIAGNOSIS SELECTED

   Pediatric (under 18 years of age) Small for Gestational Age (SGA)

1. Has the patient's height increased by 2 cm or more from previous year? If yes, must attach chart notes with supporting documentation.
2. Has the patient reached 50th percentile of predicted height? If no, must attach chart notes with supporting documentation.

Growth failure due to renal disease

1. Has the patient received kidney transplant?

RATIONALE

Ensure appropriate use of growth hormones with respect to evidence-based guidelines and direct usage to formulary agents. KPCO generally does not consider frequency of dosing and/or lack of compliance to dosing regimens an indication of medical necessity.

Growth Hormone medications in order of formulary preference (most preferred to least): Omnitrope CARTRIDGE, Genotropin, Zomacton, Norditropin, Nutropin, Saizen, Humatrope, Omnitrope VIAL, Sogroya, Ngenla, Skytrofa.

GENOTROPIN is indicated in the replacement of endogenous growth hormone in adults with growth hormone deficiency in of either adult or child onset. Adult Onset: Patients who have growth hormone deficiency, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, or trauma. Childhood Onset: Patients who were growth hormone deficient during childhood as a result of congenital, genetic, acquired or idiopathic causes. Genotropin is also indicated for pediatric patients for the treatment of inadequate secretion of endogenous growth hormone, growth failure due to Prader-Willi syndrome, growth failure in children born small for gestational age who fail to manifest catch-up growth by the age of 2, for growth failure associated with Turner syndrome in patients with open epiphyses and for idiopathic short stature (ISS).

OMNITROPE CARTRIDGE **[1st line]** is indicated for Pediatric Patients: Treatment of children with growth failure due to growth hormone deficiency (GHD), Prader-Willi Syndrome, Small for Gestational Age, Turner syndrome, and Idiopathic Short Stature. Adult Patients: Treatment of adults with either adult onset or childhood onset GHD.

REFERENCES

1. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children – 2003 update. Endocr Pract 2003; 9(1):64-76.
2. Consensus guidelines for the diagnosis and treatment of growth hormone (GH) deficiency in childhood and adolescence: summary statement of the GH Research Society. JCE & M 2000; 85(11):3990-3.
3. Bengtsson B, et al. Treatment of Growth Hormone Deficiency in Adults. JCE & M 2000; 85(3): 933-42.
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5. National Kidney Foundation (2000). Clinical practice guidelines for nutrition in chronic renal failure. Available at: www.kidney.org/professionals/kdoqi/guidelines_updates/nut_p10.html. [Accessed July 21, 2009].
6. Vance M, Mauras N. Growth hormone therapy in adults and children. NEJM 1999; 341(16):1206-16.
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9. Vetter Pharma-Fertigung GmBH & Co. KG. Genotropin package insert. Ravensburg, Germany. August 2009.
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12. Genentech, Inc. Nutropin package insert. South San Francisco, CA. June 2006.
13. Genentech, Inc. Nutropin AQ package insert. South San Francisco, CA. January 2008.
14. EMD Serono, Inc. Saizen package insert. Rockland, MA. September 2007.
15. Ferring Pharmaceuticals, Inc. Zomacton package insert. Parisppany, NJ. March, 2015.
16. Sandoz GmbH. Omnitrope package insert. Austria. June 2010.
17. Allen DB, Backeljauw P, Bidlingmaier M, Biller BMK, et al. GH safety workshop position paper: a critical appraisal of recombinant human GH therapy in children and adults. European Journal of Endocrinology (2016) 174 (2). doi:10.1530/EJE-15-0873 (ghresearchsociety.org)
18. Grimberg A, DiVall SA, Polychronakos C, Allen DB, Cohen LE, Quintos JB, Rossi WC, Feudtner C, Murad MH; Drug and Therapeutics Committee and Ethics Committee of the Pediatric Endocrine Society. Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency. Horm Res Paediatr. 2016;86(6):361-397. Doi: 10.1159/000452150.

Creation Date: 11/16/2016
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

SOMATROPIN (SEROSTIM)

Generic	Brand	HICL	GPID	Exception/Other
SOMATROPIN	SEROSTIM	02824	63405, 25955, 25960	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Review based on diagnosis/indication as outlined below:

A. HIV/AIDS-wasting syndrome/Cachexia
B. All other indications

A. To treat HIV/AIDS-wasting syndrome/cachexia: Must meet all the following criteria: [New members currently using Growth Hormone use Renewal Criteria below]
   1. Patient has a diagnosis of HIV/AIDS
   2. Medication is prescribed by infectious disease specialists or gastroenterology specialists
   3. Patient is on anti-retroviral therapy for HIV/AIDs
   4. Patient meets one of the following criteria:
      a. 10% unintentional weight loss over 12 months
      b. 7.5% unintentional weight loss over 6 months
      c. 5% body cell mass (BCM) loss within 6 months
      d. In men: BCM less than 35% of total body weight and body mass index (BMI) less than 27kg/m2
      e. In women: BCM less than 23% of total body weight and BMI less than 27kg/m2
      f. BMI less than 20kg/m2
   5. Patient has had an inadequate response or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception: cyproheptadine, dronabinol, testosterone, and megestrol acetate.

If initial criteria are met, approve at GPID x6 months, max daily dose 1 vial.
If initial criteria are not met, do not approve.

B. All other indications: The following indications are not covered:
   1. Idiopathic Short Stature (non-GH deficiency)
   2. Athletic Enhancement
   3. Anti-aging
   4. Infertility (female)

RENEWAL CRITERIA: Review based on diagnosis/indication as outlined below:
1. Medication is prescribed by infectious disease specialist or gastroenterology specialist
2. Patient is on anti-retroviral therapy for HIV/AIDs
3. Patient has shown a clinical benefit as demonstrated by an increase in muscle mass and weight from baseline (weight gain more than 2kg), while on growth hormone replacement

4. Patient has not received more than 48 weeks of therapy. [There is no data supporting more than 48 weeks of therapy.]

If renewal criteria are met, approve at GPID x8 months, max daily dose 1 vial.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Is the patient stable on therapy with Serostim?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Does the patient have a diagnosis of HIV/AIDS?
4. Is the patient on anti-retroviral therapy for HIV/AIDS?
5. Has the patient experienced a 10% or greater unintentional weight loss over 12 months?
6. Has the patient experienced a 7.5% or greater unintentional weight loss over 6 months?
7. Has the patient experienced a 5% body cell mass (BCM) loss within 6 months?
8. If male, does the patient have a BCM less than 35% of total body weight and body mass index (BMI) less than 27kg/m2?
9. If female, does the patient have a BCM less than 23% of total body weight and BMI less than 27kg/m2?
10. Does the patient have a BMI less than 20kg/m2?
11. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
12. Is there reasoning why alternatives (cyproheptadine, dronabinol, testosterone, and megestrol acetate) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions

1. Start date of Serostim therapy (MMDDYY):
2. Is the patient on anti-retroviral therapy for HIV/AIDS?
3. Has the patient shown a clinical benefit demonstrated by an increase in muscle mass and weight from baseline (weight gain more than 2kg) while on growth hormone replacement? If yes, must attach applicable chart notes.

RATIONALE
Ensure appropriate use of growth hormones with respect to evidence-based guidelines and direct usage to formulary agents. KPCO generally does not consider frequency of dosing and/or lack of compliance to dosing regimens an indication of medical necessity.

SEROSTIM is indicated in the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance with concomitant antiretroviral therapy.

REFERENCES
1. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children – 2003 update. Endocr Pract 2003; 9(1):64-76.
2. Grinspoon S, Mulligan K. Weight loss and wasting in patients infected with human immunodeficiency virus. Clinical Infectious Disease 2003; 36:S69-78.
3. Corcoran C, Grinspoon S. Treatments for Wasting in Patients with the Acquired Immunodeficiency Syndrome. NEJM 1999; 340:1740-50.

4. EMD Serono, Inc. Serostim package insert. Rockland, MA. September 2007.

Creation Date: 11/16/2016
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

SONIDEGIB (ODOMZO)

Generic	Brand	HICL	GPID	Comments
SONIDEGIB PHOSPHATE	ODOMZO 200MG CAPSULE	42369	39217	Non-Formulary Preferred for BCC

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA:
Patient is new to KPCO in the past 90 days and stable on therapy.

If new member criteria are met, approve at HICL indefinitely.
If new member criteria are not met, proceed to Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Medication is prescribed by a CPMG or affiliated Dermatologist or Oncologist
2. Patient has a diagnosis of Basal Cell Carcinoma (BCC) and one of the following: metastatic disease, recurrence of BCC following surgery or radiation therapy, locally advanced disease and medication is being used to shrink tumor to allow the patient to become a surgical candidate, or the patient is not a candidate for surgery or radiation therapy

If initial criteria above are met, approve at HICL indefinitely.
If initial criteria above are not met, do not approve.

ePA Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Basal Cell Carcinoma (BCC) with metastatic disease; Recurrence of Basal Cell Carcinoma (BCC) following surgery or radiation therapy; Basal Cell Carcinoma (BCC), locally advanced disease and medication is being used to shrink tumor to allow the patient to become a surgical candidate; Basal Cell Carcinoma (BCC) and the patient is not a candidate for surgery or radiation therapy]

RATIONALE
Per KPCO treatment guidelines
- Sonidegib is the preferred hedgehog inhibitor per KP National guidelines.
- Sonidegib and vismodegib are accepted as equal in terms of efficacy.
- If patient has contraindication to either sonidegib or vismodegib, they would be considered to have a contraindication to the other.
- A patient may have intolerable toxicities with sonidegib that might not occur with vismodegib.
- If a patient has progression of disease with sonidegib, there is no value in trying vismodegib based on currently available data.

FDA APPROVED INDICATIONS
ODOMZO™ (sonidegib) is a hedgehog pathway inhibitor indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

Creation Date: 3/8/2019
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 05/2024

SOTAGLIFLOZIN (INPEFA)

Generic	Brand	HICL	GPID	Comments
SOTAGLIFLOZIN	INPEFA	48976		

GUIDELINES FOR COVERAGE
Must be used for one of the following indications and meet all related criteria as follows:

A. Heart failure
B. DM2 plus CKD plus CV risk factor(s)

A. Heart Failure: Must meet all the following:
   1. 18 years of age or older
   2. Has heart failure (includes HfrEF, HfpEF, HfmrEF, HfimpEF)
   3. eGFR greater than or equal to 25 ml/min
   4. Has contraindications to, is currently using, or has failed all of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. ACE-I or ARB or ARNI (Entresto)
      b. Beta blocker
      c. Aldosterone antagonist (e.g., spironolactone, eplerenone)
      d. Empagliflozin (Jardiance)

If all criteria met, approve at HICL indefinitely, max 1 tablet per day.
If criteria are not met, do not approve.

B. DM2 plus CKD plus CV risk factor(s): Must meet all the following:
   1. 18 years of age or older
   2. Has type 2 diabetes (DM2)
   3. Has chronic kidney disease (CKD) defined as eGFR of at least 25 ml/min but less than 60 mL/min)
   4. Has 1 or more of the following CV risk factors: HF hospitalization in past 2 years, LVEF less than or equal to 40%, left ventricular hypertrophy, coronary artery calcium (CAC) score greater than or equal to 300, NT-proBNP greater than or equal to 400 pg/mL, high sensitivity troponin greater than 15 pg/mL for men or 10 pg/mL for women, hs-CRP greater than 3 mg/L, urinary albumin-to-creatinine ratio greater than or equal to 300 mg/g
   5. Has contraindications to, is currently using or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. ACE-I or ARB
      b. Empagliflozin (Jardiance)

If all criteria met, approve at HICL indefinitely, max 1 tablet per day
If criteria are not met, do not approve.

RATIONALE
Ensure appropriate use consistent with FDA indication.

KPCO Preferred order of agents:
1. Empagliflozin (Jardiance), formulary without PA, is the preferred agent for ASCVD, CKD, and HF due to strength of clinical trial data, range of approved indications, and cost (1/2 tab regimen)
2. Canagliflozin (Invokana), non-formulary with PA, is the 2nd preferred option for ASCVD, CKD and DM2 patients without compelling indications. Due to broad range of indications and cost (1/2 tab regimen).
3. Dapagliflozin (Farxiga), non-formulary with PA, is the 2nd preferred option for HF, and the 3rd preferred option for ASCVD, CKD and DM2 patients without compelling indications due to broad range of indications but at high cost.
4. Ertugliflozin (Steglatro), non-formulary with PA, is least preferred due to high cost, paucity of positive clinical trial data, and lack of additional FDA-approved indications. Specifically, ertugliflozin has been studied in patients with type 2 diabetes and ASCVD and did not improve cardiovascular outcomes while all three other SGLT-2i have demonstrated such benefits in this population.
5. Bexagliflozin (Brenzavvy): non-formulary with PA, is least preferred due to high cost lack of additional FDA-approved indications.
6. Sotagliflozin (Inpefa): non-formulary with PA, is 3rd preferred for HF given shorter history of postmarketing safety data compared to other SGLT2i's approved for HF as well as the need to titrate sotagliflozin dose for when others are fixed-dose regimens. Sotagliflozin (Inpefa) is least preferred for glycemic control due to lack of clinical trial data and FDA-approved indication as well as its high cost.

FDA APPROVED INDICATIONS for SGLT2 Inhibitors
Empagliflozin (Jardiance)
1. Improve glycemic control in patients with DM2
2. Reduce the risk of CV death in pts with DM2 + CVD
3. Reduce risk of CVD death and HF hospitalizations in pts with HF
4. Reduce risk of sustained eGFR decline, ESRD, CV death and hospitalizations in adults with CKD at risk of progression

Canagliflozin (Invokana)
1. Improve glycemic control in patients with DM2
2. Reduce risk of MACE in pts with DM2 + CVD
3. Reduce the risk of ESRD, doubling of creatinine, CV death, or HF hospitalization in pts with DM2 + diabetic nephropathy

Dapagliflozin (Farxiga)
1. Improve glycemic control in patients with DM2
2. Reduce risk of HF hosp in pts with DM2 + CVD/multiple CV RFs
3. Reduce the risk of CV death and HF hosp in patients with HfrEF NYHA II-IV
4. Reduce risk of sustained eGFR decline, ESRD, CV death, and hospitalization for HF in adults with CKD at risk of progression

Ertugliflozin (Steglatro)

1. Improve glycemic control in patients with DM2

Bexagliflozin (Brenzavvy)
1. Improve glycemic control in patients with DM2

Sotagliflozin (Inpefa)
1. Reduce the risk of CV death and HF hosp in pts with heart failure
2. Reduce the risk of CV death and HF hosp in pts with DM2 + CKD + CV RF(s)

REFERENCES
1. Inpefa [Package Insert], Lexicon Pharmaceuticals, Inc.: The Woodlands, TX; 2023
2. Bhatt DL, Szarek M, Steg PG, et al. Sotagliflozin in Patients with Diabetes and Recent Worsening Heart Failure. NEJM. 2021;384:117-28.
3. Bhatt DL, Szarek M, Pitt B, et al. Sotagliflozin in Patients with Diabetes and Chronic Kidney Disease. NEJM. 2021;384:129-139.
4. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. JACC. 2022;145(18):e895–e1032

Creation date: 01/2024
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

WINREVAIR (SOTATERCEPT-CSRK)

Generic	Brand	HICL	GCN	Exception/Other
SOTATERCEPT-CSRK	WINREVAIR	49475	55487, 55485	

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet the following:
1. Patient is new to KPCO within the past 90 days and is currently stable on Winrevair.

If met, approve at HICL indefinitely.
If not met, review by Initial Criteria.

INITIAL CRITERIA: **Must meet all the following:**
1. Prescriber must be either a pulmonologist or a cardiologist.
2. Patient has a diagnosis of pulmonary arterial hypertension (PAH, WHO Group 1) verified by right heart catheterization.
3. Patient currently has WHO Functional Class II, III or IV symptoms.
4. Patient has tried and failed, has an intolerance to or a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. one phosphodiesterase type 5 (PDE5) inhibitor: sildenafil (Revatio®) or tadalafil (Adcirca®)
   b. one endothelin receptor antagonist (ERA): Bosentan (Tracleer®), Ambrisentan (Letairis®), or macitentan (Opsumit®)

If Initial Criteria are met, approve at HICL indefinitely.
If initial Criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with Winrevair?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Pulmonary Arterial Hypertension (PAH, WHO Group 1) verified by right heart catheterization]
4. Patient's current WHO Functional Class:
5. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
6. Is there reasoning why alternatives (sildenafil tablets or suspension, tadalafil tablets or suspension, bosentan tablets, ambrisentan tablets, macitentan tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Health Plan.

Creation date: 05/2024
Effective date: 06/2024

Reviewed date:
Revised date:

FILSPARI (SPARSENTAN)

Generic	Brand	HICL	GPID	Exception/Other
SPARSENTAN	FILSPARI	48721	53742, 53743	

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA:
1. Patient is new to KPCO within the past 90 days and is stable on sparsentan.

If met, approve indefinitely at HICL.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. The patient is 18 years of age or older.
2. Therapy is prescribed by a nephrologist.
3. The patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN).
4. The patient's diagnosis is confirmed by a biopsy.
5. The patient is at risk of rapid disease progression (e.g., urine protein-to-creatinine ratio (UPCR) 1.5 g/g or greater).
6. The patient has proteinuria of at least 1g/day.
7. The patient has an intolerance or contraindication to, or has failed an ACE inhibitor (e.g. lisinopril) or an ARB (e.g. losartan) after at least 12 weeks of therapy, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.
8. Sparsentan will NOT be used concurrently with an ACE inhibitor (e.g. lisinopril) or an ARB (e.g. losartan), an endothelin receptor antagonist (e.g. ambrisentan), or aliskiren.

If met, approve for 12 months at HICL, max #1 per day.
If not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. The patient has had a reduction in proteinuria or improved or stable kidney function compared to baseline.
2. Sparsentan will not be used concurrently with an ACE inhibitor (e.g. lisinopril), an ARB (e.g. losartan), an endothelin receptor antagonist (e.g. ambrisentan), or aliskiren.

If met, approve for 12 months at HICL, max #1 per day.
If not met, do not approve.

ePA Questions
Initial Review Questions
1. Has the patient had biopsy confirmation of diagnosis IgAN?
2. Is the patient at risk of rapid disease progression (e.g., urine protein-to-creatinine ration (UPCR) 1.5 g/g or greater)? If yes, must attach applicable chart notes.

3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (ACE inhibitors such as lisinopril or ARBs such as losartan) are not suitable? If yes, must list reasoning in the Provider Comment section below or attach applicable chart notes.
5. Will sparsentan (Filspari) be used concurrently with an ACE inhibitor (e.g. lisinopril), an ARB (e.g. losartan), an endothelin receptor antagonist (e.g. ambrisentan), or aliskiren?
6. Current proteinuria lab:
7. Date of proteinuria lab (MMDDYY):

Renewal Review Questions

1. Has the patient had a reduction in proteinuria, or improved or stable kidney function compared to baseline, while using sparsentan (Filspari)?
2. Is sparsentan (Filspari) being used concurrently with an ACE inhibitor (e.g. lisinopril), an ARB (e.g. losartan), an endothelin receptor antagonist (e.g. ambrisentan), or aliskiren?

RATIONALE

Ensure appropriate use consistent with FDA indication.

FDA APPROVED INDICATIONS

FILSPARI (sparsentan): primary immunoglobulin A nephropathy (IgAN)

REFERENCES

Filspari Prescribing Information. San Diego, CA: Travere Therapeutics, Inc.; February 2023.

Creation Date: 11/2023
Effective Date: 12/2024
Reviewed Date: 11/2024
Revised Date: 11/2024

SPIRONOLACTONE (CAROSPIR) ORAL SOLUTION - AGE RESTRICTION CRITERIA

Generic	Brand	HICL	GCN	Exception/Other
SPIRONOLACTONE ORAL SOLUTION	CAROSPIR	02901	15596	

GUIDELINES FOR COVERAGE

INITIAL AND RENEWAL CRITERIA: ONE of the following criteria must be met:
1. Patient is less than or equal to 10 years of age
2. Patient is using an alternative administration route, such as a gastrostomy tube
3. Dose cannot be administered by using halved, whole or combinations of the 25-, 50-, or 100-mg tablets
4. Patient cannot swallow tablets whole, halved, or crushed (with or without mixing in apple sauce)

If any criterion is met, approve x1 year.
If no criteria are met, do not approve.

ePA Questions
1. Is the patient using an alternative administration route, such as a gastrostomy tube? If yes, must attach applicable chart notes.
2. Is the patient unable to swallow tablets whole, halved, or crushed (with or without mixing in applesauce)? If yes, must attach applicable chart notes.

RATIONALE
Per Health Plan

FDA APPROVED INDICATIONS
Edema: Management of edema for cirrhosis of liver when unresponsive to fluid and sodium restriction

Heart failure: To increase survival, manage edema and reduce hospitalization for heart failure in patients with New York Heart Association (NYHA) class III to IV and reduced ejection fraction; usually administered in conjunction with other heart failure therapies

Hypertension: Management of hypertension unresponsive to other therapies. Note: Not recommended for the initial treatment of hypertension (ACC/AHA [Whelton 2017]).

REFERENCES
Per Health Plan

Creation date: 09/26/2018
Effective date: 10/2024
Reviewed date: 09/2024
Revised date: 09/2024

SULOPENEM (ORLYNVAH)

Generic	Brand	HICL	GPID	Comments
SULOPENEM ETZADROXIL AND PROBENECID	ORLYNVAH			Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

B. Urinary tract infection

1. Medication must be prescribed by an Infectious Diseases specialist.
2. Infection is caused by a bacteria susceptible to sulopenem (or other carbapenems - imipenem/cilastatin, meropenem, ertapenem).
3. Infection is caused by a bacteria resistant to the following oral antibiotics
    - Beta-lactams (cephalosporins and penicillins)
    - Fluoroquinolones
    - Nitrofurantoin
    - Sulfamethoxazole / trimethoprim
4. OR the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve x 5 days (one treatment course).
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:

Do not approve.

RATIONALE
Sulopenem etzadroxil and probenecid has only been studied for a 5-day duration of therapy and does not have evidence that a longer course of therapy or an additional course of therapy is more beneficial than a 5-day duration of therapy.

FDA APPROVED INDICATIONS
1. Treatment of uncomplicated urinary tract infections (uUTI) caused by the designated microorganisms Escherichia coli, Klebsiella pneumoniae, or Proteus mirabilis in adult women who have limited or no alternative oral antibacterial treatment options

REFERENCES
1. Orlynvah [package insert]. Chicago, IL: Iterum Therapeutics U.S. Limited; 2024.

Creation Date: 05/2025
Effective Date: 06/2025
Reviewed Date: n/a
Revised Date: n/a

SUVOREXANT (BELSOMRA)

Generic	Brand	HICL	GPID	Comments
SUVOREXANT	BELSOMRA	41333		Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all General Criteria and all Age Criteria in applicable age section

A. **General Criteria for All Requests:** Must meet all the following:
   1. Medication is prescribed by Behavioral Health or Sleep Medicine provider
   2. Patient must be age 18 or older
   3. Diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance
   4. Potential factors contributing to sleep disturbances have been addressed (e.g., inappropriate sleep hygiene, sleep environment issues and co-morbid conditions contributing to insomnia)
   5. Patient has no history of narcolepsy

B. **Age 65 Years or Older:** Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to trazodone
   2. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to ramelteon or OTC melatonin
   3. Trial and failure of, contraindication, or intolerance to lemborexant (Dayvigo)

   If initial criteria are met, approve at HICL indefinitely, max daily dose of 1 tablet.
   If initial criteria are not met, do not approve.

C. **Age Less Than 65 Years:** Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   1. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to trazodone
   2. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to ramelteon or OTC melatonin
   3. Trial and failure of (after at least 2 weeks on therapy), contraindication, or intolerance to at least ONE of the following sedative-hypnotic alternatives: zolpidem (F), zaleplon (NF), eszopiclone (NF)
   4. Trial and failure of, contraindication, or intolerance to lemborexant (Dayvigo)

If initial criteria are met, approve at HICL indefinitely, max daily dose of 1 tablet.
If initial criteria are not met, do not approve.

ePA Questions

1. Have factors that could contribute to sleep disturbances been addressed (e.g., inappropriate sleep hygiene, sleep environment issues and co-morbid conditions contributing to insomnia)?
2. Does the patient have history of narcolepsy?
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (OTC melatonin, trazodone, zolpidem IR tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

FDA APPROVED INDICATIONS

Dayvigo (lemborexant) and Belsomra (suvorexant), and Quviviq (daridorexant) are indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

REFERENCES

Per Health Plan

Creation Date: 03/2021
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

SUZETRIGINE (JOURNAVX)

Generic	Brand	HICL	GPID	Comments
SUZETRIGINE	JOURNAVX	50239		Non-Formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA:

Review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following diagnoses and meet all the diagnosis-specific criteria below:

1. Patient must have had or will undergo abdominoplasty or bunionectomy
2. Patient must be 18 years of age or older.
3. Have a postoperative numeric pain rating scale (NRS) score ≥7 within 48 hours
4. Optimized over-the-counter treatments (e.g., acetaminophen, cold packs, lidocaine patches
5. Be unable to take nonsteroidal anti-inflammatory drugs (NSAIDs)
   - (ie History of stomach ulcer/bleeding, Undergoing coronary artery bypass graft (CABG) surgery, Allergies to the entire NSAID class, History of stroke or myocardial infarction, Taking blood thinners)
6. Not a candidate for opioids due to opioid use disorder (OUD).
7. Patient may not:
   - Have a history of cardiac dysrhythmias within last 2 years requiring anti-arrhythmia treatment(s)
   - Have Chronic kidney disease (CKD) of any degree
   - Have Severe hepatic impairment
   - Be pregnant or breastfeeding
   - Be taking a strong CYP3A4 inhibitor or inducer

If initial criteria are met, approve suzetrigine 50mg x 2 tab loading dose then 1 tab BID for 5 days, 1 time approval.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA:

N/A – Do not approve

ESCALATION CRITERIA:
N/A

RATIONALE
In three randomized controlled trials, suzetrigine was found to be no more effective than low dose hydrocodone/APAP at a cost ~ 90 times higher. Suzetrigine has not been studied outside of acute pain 48 hours status post bunionectomy and abdominoplasty. Suzetrigine has renal and cardiac safety signals that need further investigation. Therefore, it is unclear if long-term blockage of this sodium channel will have unanticipated negative renal or cardiac effects.

FDA APPROVED INDICATIONS

Treatment of moderate to severe acute pain in adults.

REFERENCES

1. Journavx. [Package insert] Boston, MA: Vertex Pharmaceuticals Inc.; 2025.
2. Chou R, Gordon DB, de Leon-Casasola OA, et al. Management of postoperative pain: a clinical practice guideline from the American Pain Society, the American Society of Regional Anesthesia and Pain Medicine, and the American Society of Anesthesiologists' Committee on Regional Anesthesia, Executive Committee, and Administrative Council. *J of Pain*. 2016;17(2):131-157.
3. Dowell D, Ragan KR, Jones CM, et al. CDC clinical practice guideline for prescribing opioids for pain — United States, 2022. *Morbidity and Mortality Weekly Report*. 2022;71.
4. Institute for Clinical and Economic Review (ICER). Draft Evidence Report Suzetrigine for Acute Pain: Effectiveness and Value. https://icer.org/wp-content/uploads/2025/02/ICER_Acute-Pain_Evidence-Report_For-Publication_020525.pdf. Published February 5, 2025. Accessed February 5, 2025.
5. Bertoch T, D'Aunno D, McCoun J, et al. Suzetrigine, a non-opioid NaV1.8 inhibitor for treatment of moderate-to-severe acute pain: two Phase 3 randomized clinical trials. *Anesthesiology*. 2025; https://doi.org/10.1097/ALN.0000000000005460.
6. Hu D, Barajas-Martinez H, Pfeiffer R, et al. Mutations in SCN10A responsible for a large fraction of Brugada syndrome cases. *J Am Coll Cardiol*. 2014;64(1):66–79.
7. Huang Y, Chen XM, Barajas-Martinez H, et al. Common variants in SCN10A gene associated with Brugada syndrome. *Hum Mol Genet*. 2021;31(2):157-165.
8. Suzetrigine. Biomedtracker drug reports. https://www.biomedtracker.com/DrugReport.cfm?DrugID=44822. Accessed February 7, 2025.

Creation Date: 05/2025
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date:

TADALAFIL 20 MG/5 ML SOLUTION - AGE RESTRICTION CRITERIA

Generic	Brand	HICL	GPID	Exception/Other
TADALAFIL 20 MG/5 ML	TADLIQ	24859	52585	Formulary

GUIDELINES FOR COVERAGE

INITIAL AND RENEWAL CRITERIA: ONE of the following criteria must be met:
1. Patient is 10 years old or younger.
2. Patient is using an alternative administration route, such as a gastrostomy tube.
3. Dose cannot be obtained by using half, whole, or combination of the tadalafil tablets (2.5 mg, 5 mg, 10 mg, or 20 mg)
4. Patient cannot swallow tablets whole, halved, or crushed (with or without mixing in applesauce)

If any criterion is met, approve x1 year at GPID.
If no criteria are met, do not approve. May suggest using tablet strengths that can be halved or used in combination, or crushing tadalafil tablets before administration and taking with or without applesauce.

ePA Questions
1. Is the patient using an alternative administration route, such as a gastrostomy tube? If yes, must attach applicable chart notes.
2. Is the patient unable to swallow tablets whole, halved, or crushed (with or without mixing in applesauce)? If yes, must attach applicable chart notes.

RATIONALE
Per Health Plan.

General Clinical Criteria for solutions/suspension
Age is less than or equal to 10 years old
Presence of gastrostomy
Dose does not allow use of halved, whole, or combo of tablet
Dose does not use whole capsule (cannot “cut” capsules in half)
Clinical condition where unable to swallow crushed/opened tablets/capsules (i.e., esophageal stricture)

FDA APPROVAL
1. Treatment of pulmonary arterial hypertension (World Health Organization group 1) to improve exercise ability
2. Treatment of the signs and symptoms of benign prostatic hyperplasia (BPH)
3. Treatment of erectile dysfunction
4. Treatment of erectile dysfunction and the signs and symptoms of BPH

Creation date: 07/2024
Effective date: 08/2024
Reviewed date:
Revised date:

TAFAMIDIS (VYNDAMAX, VYNDAQEL)

Generic	Brand	HICL	GPID	Comments
TAFAMIDIS	VYNDAMAX	45729	46258	
TAFAMIDIS MEGLUMINE	VYNDAQEL	41631	37584	

GUIDELINES FOR COVERAGE

Tafamidis will be approved if ALL the following are met:

1. Patient is aged between 18 and 89 years of age
2. Patient has a diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) documented by positive biopsy demonstrating transthyretin (TTR)-amyloid deposition OR meeting all three of the following:
    a. Diagnosis of heart failure (defined as stage C heart failure (HF) plus New York Heart Association (NYHA class I, II or III), AND either:
        i. Echocardiogram with end-diastolic interventricular septal wall thickness of at least 12mm
        OR
        ii. Cardiac MRI consistent with, or suggestive of, amyloidosis
    b. Pyrophosphate (PYP) scintigraphy cardiac uptake visual score of either:
        i. Grade 2 or 3 using the Perugini Grade 1-3 scoring system
        OR
        ii. Calculated heart-to-contralateral lung (H/CL) ratio of at least 1.5
    c. Absence of a monoclonal gammopathy to rule out light-chain (AL) amyloidosis as determined by meeting the following:
        i. Serum protein electrophoresis (SPEP): no M spike detected, AND
        ii. Kappa/lambda serum free light chains: kappa/lambda free ration within normal limits
        iii. If SPEP and/or kappa lambda serum free light chains are abnormal, serum immunofixation (IFE) is required to be negative (“No monoclonal proteins detected”)
        iv. If results of any of these are unclear such that criteria are not met, a consultation by the Oncology Dept determining that patient does not have AL amyloidosis is adequate to meet this criterion.
3. Patient has medical history of heart failure (HF) with at least 1 of the following:
    a. Hospitalization within the past 2 years for HF
    b. Patient's oral diuretic dose has doubled in the past 6 months AND/OR has received IV diuretics within the past 6 months
4. Patient has glomerular filtration rate (GFR) of at least 25mL/min and is not requiring dialysis
5. Patient has no history of heart or liver transplantation
6. Patient has no implanted cardiac mechanical assist devices
7. Patient's life expectancy is greater than 1 year
8. Tafamidis will not be used concurrently with other ATTR medications including acoramidis (Attruby), inotersen (Tegsedi), or patisiran (Onpattro)

If all the above are met, approve indefinitely.
If any of the above are not met, do not approve.

ePA Questions

1. Does the patient have a diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) documented by positive biopsy demonstrating transthyretin (TTR)-amyloid deposition OR meeting all three of the following:
    A. Diagnosis of heart failure (defined as stage C heart failure (HF) plus New York Heart Association (NYHA class I, II or III), AND either:

a. Echocardiogram with end-diastolic interventricular septal wall thickness of at least 12mm

OR

b. Cardiac MRI consistent with, or suggestive of, amyloidosis

B. Pyrophosphate (PYP) scintigraphy cardiac uptake visual score of either:
   a. Grade 2 or 3 using the Perugini Grade 1-3 scoring system

   OR

   b. Calculated heart-to-contralateral lung (H/CL) ratio of at least 1.5
C. Absence of a monoclonal gammopathy to rule out light-chain (AL) amyloidosis as determined by meeting the following:
   a. Serum protein electrophoresis (SPEP): no M spike detected, AND
   b. Kappa/lambda serum free light chains: kappa/lambda free ration within normal limits
   c. If SPEP and/or kappa lambda serum free light chains are abnormal, serum immunofixation (IFE) is required to be negative ("No monoclonal proteins detected")
   d. If results of any of these are unclear such that criteria are not met, a consultation by the Oncology Dept determining that patient does not have AL amyloidosis is adequate to meet this criterion.

2. Has the patient had prior hospitalization for HF?
3. Has the patient's oral diuretic dose doubled in the past 6 months AND/OR has the patient received IV diuretics within the past 6 months?
4. Is the patient requiring dialysis?
5. Lab: glomerular filtration rate (GFR):
6. Date of GFR Lab (MMDDYY):
7. Has the patient had heart or liver transplant?
8. Does the patient have an implanted cardiac mechanical assist device?
9. Is the patient's life expectancy greater than 1 year?
10. Will the patient use acoramidis (Attruby), inotersen (Tegsedi), or patisiran (Onpattro) concurrently with tafamidis?

RATIONALE
KP Interregional Practice Recommendations for Tafamidis 2019

FDA APPROVED INDICATIONS
Treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization

REFERENCES
1. Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med 2018; 379:1007-1016
2. Vyndaqel and Vyndamax [package insert]. New York, NY: Pfizer Laboratories; revised 4/2020.
3. Damy T, Garcia-Pavia P, Hanna M, et al. Efficacy and safety of tafamidis doses in Transthyretin Cardiomyopathy Clinical Trial (ATTR-ACT) and long-term extension study. Eur J Heart Fail 2020; doi:10.1002/ejhf.2027

Creation Date: 3/2020
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

TASIMELTEON (HETLIOZ)

Generic	Brand	HICL	GPID	Exception/Other
TASIMELTEON	HETLIOZ	40927	36068	Non-Formulary
TASIMELTEON SUSPENSION	HETLIOZ LQ	40927	48937	Non-Formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all of the following:

1. Patient is new to KPCO within the past 90 days.
2. Patient has a diagnosis of Non-24-Hour Sleep Wake Disorder (N24HSWD) or nighttime sleep disturbances in Smith-Magenis syndrome (SMS) and is stable on therapy with tasimelteon (Hetlioz).

If met, approve at HICL 90 days, maximum #1 tablet per day, then review by initial criteria.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following diagnoses and meet all the diagnosis-specific criteria below:

A. Non-24-Hour Sleep Wake Disorder (N24HSWD)
B. Nighttime sleep disturbances in Smith-Magenis syndrome (SMS)

A. Patient has a diagnosis of Non-24-Hour Sleep Wake Disorder (N24HSWD) and must meet all of the following:
   1. Prescribed by a Sleep Specialist (CPMG or affiliated network provider with active referral as necessary)
   2. Patient has tried oral melatonin and ramelteon, if no contraindication to use exists, for at least 1 month without efficacy, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception
   3. Patient has used non-pharmacologic sleep entrainment (alignment of the internal biological clock rhythm to external time cues, such as the natural dark-light cycles) including bright light therapy (in patients with light perception) and/or optimizing sleep therapy

B. Patient has a diagnosis of nighttime sleep disturbances in Smith-Magenis syndrome (SMS) and must meet all of the following:
   1. Prescribed by a Sleep Specialist (CPMG or affiliated network provider with active referral as necessary)
   2. Patient has tried and failed maximally tolerated melatonin therapy, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack

of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

If met, approve indefinitely at HICL with a maximum daily dose of 1 tablet.
If not met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient stable on therapy with tasimelteon?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Non-24-Hour Sleep Wake Disorder (N24HSWD); Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Non-24-Hour Sleep Wake Disorder (N24HSWD)
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (melatonin and ramelteon) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (melatonin) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Promote appropriate utilization of Hetlioz based on FDA approved indication and dosage.

Hetlioz is the first FDA approved treatment for non-24 hour sleep-wake disorder (N24HSWD), a chronic circadian rhythm disorder in which a person's day length is not synchronized with the 24-hour day-night cycle. Hetlioz is a melatonin receptor agonist that has high affinity for MT1 and MT2 receptors in the suprachiasmatic nucleus of the brain, which are thought to synchronize the body's melatonin and cortisol circadian rhythms with the day-night cycle.

The majority of people with N24HSWD are completely blind due to the lack of light information received from the eyes, which normally regulates the 24-hour day-night cycle. Currently there are 1.3 million legally blind people in the United States (US); 130,000 are completely blind and approximately 70% of those people suffer from N24HSWD.

Treatments for N24HSWD are aimed at resynchronizing the patient's internal body clock to the 24-hour day-night cycle. Phototherapy and dietary melatonin are commonly used to help manage symptoms, as there is no permanent cure for the disorder. In sighted patients, exposure to bright light may counteract the tendency for circadian rhythms to delay. It involves 30-120 minutes of exposure to 3,000 to 10,000 lux light intensity upon awakening daily. Use of melatonin may also be successful in advancing a patient’s circadian rhythm; however the dosage and time of administration need to be adjusted on an individual basis.

Aside from Hetlioz, Rozerem (ramelteon) is the only other melatonin receptor agonist approved in the US. However, Rozerem is not indicated for N24HSWD, but rather for the treatment of insomnia characterized by difficulty with sleep onset. Hetlioz offers another option for the treatment of N24HSWD in which there is FDA oversight and regulation, unlike over-the-counter dietary melatonin.

The most frequently reported adverse reactions in patients receiving Hetlioz include headache (17%), alanine aminotransferase increase (10%), nightmare/abnormal dreams (10%), upper respiratory tract infection (7%), and urinary tract infection (7%). In placebo-controlled studies, 6% of patients exposed to Hetlioz discontinued treatment due to an adverse event, compared with 4% of patients who received placebo.

There were no signs or symptoms indicative of abuse potential or physical dependence in clinical studies with Hetlioz. Discontinuation of Hetlioz following chronic administration did not produce withdrawal signs.

DOSE
The recommended dosage of Hetlioz is 20 mg per day taken before bedtime, at the same time every night. Because of individual differences in circadian rhythms, drug effect may not occur for weeks or months. Hetlioz should be taken without food.

FDA APPROVED INDICATIONS
Hetlioz is a melatonin receptor agonist indicated for the treatment of non-24-hour sleep-wake disorder and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients who are 16 years of age and older.

REFERENCES
1. KPWA Hetlioz prior authorization criteria from 9/2018
2. Hetlioz [Prescribing Information]. Washington, D.C., Vanda Pharmaceuticals, Inc., Jan 2014.
3. FDA News Release on Jan 31, 2014: FDA approves Hetlioz: first treatment for non-24 hour sleepwake disorder in blind individuals. Available online at: http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm384092.html
4. Circadian Sleep Disorders Network. http://www.circadiansleepdisorders.org/index.php

Creation date: 05/2018
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2025

TEDUGLUTIDE (GATTEX)

Generic	Brand	HICL	GPID	SIZE	Exception/Other
TEDUGLUTIDE 5 MG KIT	GATTEX	39890	33927	1	

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Requesting provider is a CPMG or affiliated gastroenterologist.
2. Patient is at least 1 year old with documented short bowel syndrome (SBS).
3. Patient has been dependent on parenteral nutrition (PN) for greater than or equal to 12 months.
4. If the patient is an adult and has a colon, they must have had a colonoscopy in the past 6 months.
5. If the patient is under 18 years of age and has a colon, they must have had a fecal occult blood test in the past 6 months, with a follow up colonoscopy/sigmoidoscopy if unexplained blood was found.
6. Patient has an intolerance or contraindication to, or has failed (after adequate trial of at least 4 weeks) BOTH of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Antisecretory agent (e.g., histamine-2 receptor antagonist, proton pump inhibitor, octreotide, clonidine)
   b. Antimotility agent (e.g., loperamide, diphenoxylate with atropine, opioid such as codeine)

If initial criteria are met, approve x6 months, max 1 vial per day.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Patient is still under the care of a CPMG or an affiliated gastroenterologist.
2. There is documentation demonstrating a decreased need for parenteral support compared to baseline.
3. If the patient is an adult and has a colon, the patient is up to date with screening colonoscopies.
4. If the patient is pediatric and has a colon, the patient is up to date with screening colonoscopies and/or fecal occult blood tests.

If renewal criteria are met, approve x1 year, max 1 vial per day.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Has the patient been on parenteral nutrition (PN) for at least 12 months? If yes, must attach chart notes with supporting documentation.
2. Has the patient had a colonoscopy in the past 6 months? If yes, must attach chart notes with supporting documentation.
3. Has the patient had a fecal occult blood test in the past 6 months? If yes, must attach chart notes with supporting documentation.

4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (histamine-2 receptor antagonist, proton pump inhibitor, clonidine, loperamide, diphenoxylate with atropine) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions

1. Is there a decreased need for parenteral support for this patient compared to baseline? If yes, must attach chart notes with supporting documentation.
2. Is the patient up to date with screening colonoscopies and/or fecal occult blood tests? If yes, must attach chart notes with supporting documentation.

RATIONALE

Teduglutide is a recombinant analog of human glucagon-like peptide-2 (GLP-2) improving the small intestine's ability to absorb fluids, electrolytes and nutrients. Teduglutide 0.05 mg/kg/day and 0.1 mg/kg/day were compared to placebo in a clinical trial (n=84). The lower dose was statistically better than placebo regarding the percent of patients who achieved at least 20% reduction in PN/IVF volume (46% vs 6%, $p<0.01$). The higher dose was not statistically significant compared to placebo. The reason for this variation with the two strengths is unclear but may be due to the strict weaning protocol to which the study subjects were restricted. In a second trial (n=86), teduglutide 0.05 mg/kg/day had a higher percent of patients who achieved at least 20% reduction in PN/IVF volume (63% vs 30%, $p<0.001$) than placebo. Across both of the 6-month trials, two patients treated with teduglutide became completely independent of PN/IVF.

In the cases where TPN cannot be weaned off completely, the clinical significance of TPN volume reduction is unclear.

There are many long-term safety concerns, as teduglutide's mechanism of action promotes cell growth. Long term data is necessary to determine the safety and efficacy of this medication.

FDA APPROVED INDICATIONS

Treatment of adult and pediatric patients 1 year of age and older with short bowel syndrome (SBS) who are dependent on parenteral support.

REFERENCES

1. Kaiser Permanente Drug Information Services, Drug Monograph: Teduglutide (Gattex). May 22, 2013.
2. Kaiser Foundation Health Plan of Washington Group Health Formulary Minutes from Statewide Pharmacy & Therapeutics Committee Meeting: June 12, 2013.
3. KPNW Gattex non-Medicare guideline, 2019.
4. Parrish CR, DiBaise JK. Managing the Adult Patient With Short Bowel Syndrome. Gastroenterol Hepatol (N Y). 2017 Oct;13(10):600-608.

Creation Date:7/25/2018
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

TENAPANOR (IBSRELA)

Generic	Brand	HICL	GPID	Exception/Other
TENAPANOR	IBSRELA	46009	46915	Non-Formulary

GUIDELINES FOR COVERAGE

Must meet all the following:

1. The patient is 18 years of age or older with a diagnosis of IBS-C
2. The patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. at least one bulk-forming laxative (a bulk forming laxative contains psyllium, methylcellulose, or polycarbophil and examples may include Metamucil, Citrucel, FiberCon)
    b. at least one osmotic laxative (an osmotic laxative contains magnesium hydroxide, polyethylene glycol, lactulose, magnesium citrate, or glycerin and examples may include milk of magnesia or Miralax)
    c. lubiprostone
    d. Linzess and/or Trulance

If criteria are met, approve indefinitely at GPID, max 2 tablets per day.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (bulk-forming laxative, osmotic laxative, or others) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Per Plan.

REFERENCES

Per Plan.

Creation date: 3/15/2017
Effective date: 04/2025
Reviewed date: 03/2025
Revised date: 03/2024

TENAPANOR (XPHOZAH)

Generic	Brand	HICL	GPID	Exception/Other
TENAPANOR	XPHOZAH	46009*	54891, 54892	Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of hyperphosphatemia and is currently on dialysis.
2. Patient is 6 years of age or older.
3. Medication is prescribed by a nephrologist.
4. Patient has tried and failed, or has an intolerance or contraindication to one of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    - sevelamer carbonate (generic Renvela)
    - calcium acetate (generic PhosLo)

If initial criteria are met, approve at GPID x1 year, max 2 per day.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Patient's hyperphosphatemia has normalized since starting tenapanor.
2. Patient is actively on dialysis.

If met, approve at GPID x1 year, max 2 per day.
If not met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient currently on dialysis?
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
3. Is there reasoning why alternatives (sevelamer carbonate, calcium acetate) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Is the patient currently on dialysis?
2. Has the patient's phosphate labs normalized since starting tenapanor? If yes, must attach applicable chart notes with supporting documentation.

RATIONALE
In the absence of direct head-to-head studies and similar safety profiles as more preferred therapies, PA is necessary to assure appropriate use of this medication.

Notes
*Tenapanor is branded under two different names with different indications: Xphozah and Ibsrela. Both share the same HICL, and both are restricted to PA. PA criteria are maintained as separate documents specific to each brand and indication.

NDC	Generic Name	Brand Name	Strength	Form	Size	GPID	HICL
73154-0050-60	Tenapanor HCl	Ibsrela	50 mg	Tablet	60	46915	46009
73154-0120-60	Tenapanor HCl	Xphozah	20 mg	Tablet	60	54891	46009
73154-0130-60	Tenapanor HCl	Xphozah	30 mg	Tablet	60	54892	46009

FDA APPROVED INDICATIONS
1. **Hyperphosphatemia in chronic kidney disease, treatment (Xphozah)**: Control of serum phosphorous in adults with chronic kidney disease on hemodialysis. Use as an add-on therapy in patients who have an inadequate response to phosphate binders or who are unable to tolerate phosphate binder therapies.
2. [Irritable bowel syndrome with constipation (Ibsrela): Treatment of irritable bowel syndrome with constipation in adults.]

Creation Date: 07/2024
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: n/a

TERIPARATIDE (FORTEO)

Generic	Brand	HICL	GPID	Comments
TERIPARATIDE	FORTEO		14404, 47023	Non-Formulary (KP pharmacies will dispense BRAND as the preferred product).

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all General Criteria and Drug Specific Criteria below:

A. Osteoporosis:

1. Must be prescribed by an endocrinology or rheumatology provider
2. No history of osteosarcoma
3. Diagnosis of osteoporosis and meets one of the following criteria, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Must be considered very high risk for fracture with one of the following:
      i. T-score of -2.5 or less, and 1 or more fragility fractures
      ii. BMD with t-score of -3.5 or less
      iii. History of multiple vertebral compression fractures
      iv. History of multiple fragility fractures
   b. Decline in BMD by more than 2% at hip or more than 2.5% at spine per year, after at least one year of oral alendronate or risedronate, IV zoledronic acid, or denosumab (Prolia), with at least 75% adherence to therapy
   c. T-score remains or has dropped to <-3.5 after at least one year of oral alendronate or risedronate, IV zoledronic acid, or denosumab (Prolia)
   d. Experienced 2 or more fragility fractures while adherent (at least 75% proportion days covered) to oral alendronate or risedronate, IV zoledronic acid, or denosumab (Prolia) for at least one year
   e. Unable to use alendronate or risedronate and IV zoledronic acid due to contraindications or adverse effects, or unable to use denosumab (Prolia) due to contraindications or adverse effects

If initial criteria are met, approve x2 years at HICL (KP pharmacies will dispense BRAND as the preferred product).
If initial criteria are not met, do not approve.

B. Hypoparathyroidism:

1. Patient must be 18 years of age or older.
2. Medication must be prescribed by an Endocrinologist.
3. Diagnosis of hypoparathyroidism confirmed by BOTH of the following:
   a. Pretreatment low albumin-corrected serum calcium (i.e., ≤ 8.5 mg/dL) confirmed on at least two occasions separated by at least 2 weeks
   b. Pretreatment undetectable or inappropriately low intact parathyroid (PTH) concentration (i.e., < 20 pg/mL), by second- or third-generation immunoassay, on at least two occasions

4. The patient's hypoparathyroidism is NOT due to impaired responsiveness to parathyroid hormone or a history of disease that affects calcium metabolism or calcium-phosphate homeostasis
5. Forteo is not being used to treat acute post-surgical hypoparathyroidism
6. Most recent (within past 30 days) albumin-corrected serum calcium 7.8–10.6 mg/dL
7. Most recent (within past 30 days) serum 25(OH) vitamin D 20–80 ng/mL
8. Patient has had a 12-week trial and failed*, or has an intolerance or contraindication to ALL of the following below, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    - Calcium supplements and active forms of vitamin D (e.g., calcitriol) up to maximally indicated doses^
    - Thiazide diuretic, if hypercalciuria is present [i.e. 24-hour urinary calcium ≥ 250 mg (6.25 mmol)]

**Examples of a "failed" can include large swings in calcium levels, calcium phosphate product cannot be maintained within an acceptable range, high risk of renal complications due to hypercalciuria or calcium containing stones, evidence of renal complications such as nephrolithiasis or having a condition causing poor calcium and vitamin D absorption.*

^Maximum dose shown in table below:

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
calcitriol (Rocaltrol®)	0.25 mcg PO QD initially; dose may be increased at 2- to 4-wk intervals	2 mcg/day
calcium carbonate (Caltrate®, OsCal®, Tums®)	1-3 g PO QD in divided doses	3 g/day
calcium citrate (Cal-Citrate®, Cal-C-Caps®)	1-3 g PO QD in divided doses	3 g/day

If initial criteria are met, approve x 6 months at HICL (KP pharmacies will dispense BRAND as the preferred product).
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
A. Osteoporosis:

1. Must be prescribed by an endocrinology or rheumatology provider
2. Remains high risk for fracture based on current T-score of -2.5 or less or hip or vertebral fracture prior to therapy with Forteo, AND meets one of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy,

diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
a. Chronic glucocorticoid-treated patient (2.5mg or more per day of prednisone or equivalent) and provider indicates is unable to transition to oral alendronate or risedronate, IV zoledronic acid, or denosumab (Prolia)
b. Multiple compression fractures but none while on teriparatide
c. Other high risk fracture condition (i.e., adynamic renal bone disease, elevated P1NP level, severe COPD and compression factures) and provider indicates is unable to transition to oral alendronate or risedronate, IV zoledronic acid, or denosumab (Prolia)

If renewal criteria are met, approve x2 years at HICL (KP pharmacies will dispense BRAND as the preferred product).
If renewal criteria are not met, do not approve.

B. Hypoparathyroidism
1. Documentation of positive clinical response [e.g., albumin-corrected serum calcium level in normal range (approximately 8.3-10.6 mg/dL), independence from conventional therapy (e.g., requiring no active vitamin D, ≤ 600 mg/day of calcium)]

If renewal criteria are met, approve indefinitely at HICL (KP pharmacies will dispense BRAND as the preferred product).
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria]: Osteoporosis; Hypoparathyroidism
QUESTIONS BASED ON DIAGNOSIS SELECTED
Osteoporosis:
1. Is the patient stable on therapy with the requested medication?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
4. Is there a reasoning why alternatives (i.e., oral alendronate, IV zoledronic acid, etc.) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
5. Does the patient have a history of osteosarcoma?
6. Current lowest T-Score: _____ Date (MMDDYY):_____
7. Number of fragility fractures patient has had:
8. Number of vertebral compression fractures the patient has had:

Hypoparathyroidism:
1. Current (within the past 30 days) albumin-corrected serum calcium lab (mg/dL):
2. Date of albumin-corrected serum calcium lab (MMDDYY):
3. Current (within the past 30 days) serum 25 (OH) vitamin D lab (ng/mL):
4. Date of serum 25 (OH) vitamin D lab (MMDDYY):
5. Does the patient have pretreatment low albumin-corrected serum calcium levels (i.e. ≤ 8.5 mg/dL) confirmed on at least two occasions separated by at least 2 weeks?

6. Does the patient have pretreatment undetectable or inappropriately low intact parathyroid (PTH) concentration (i.e. <20 pg/mL) by second or third generation immunoassay, on at least two occasions?
7. Is the patient's hypoparathyroidism due to impaired responsiveness to parathyroid hormone or a history of disease that affects calcium metabolism or calcium-phosphate homeostasis?
8. Does the patient have acute post-surgical hypoparathyroidism?
9. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
10. Is there reasoning why alternatives (such as calcium supplements, active forms of Vitamin D, thiazide diuretics, etc.) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes

Renewal Review Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria]: Osteoporosis; Hypoparathyroidism
QUESTIONS BASED ON DIAGNOSIS SELECTED
Osteoporosis:
1. Has the patient suffered a compression fracture while taking teriparatide (Forteo)?
2. Does the patient have a high-risk fracture condition (i.e., adynamic renal bone disease, elevated P1NP level, severe COPD and compression fractures, etc.)?
3. Did the patient suffer a hip or vertebral fracture prior to therapy with teriparatide (Forteo)?
4. Current lowest T-Score:_____ Date (MMDDYY): _____

Hypoparathyroidism:
1. Current (within the past 30 days) albumin-corrected serum calcium lab (mg/dL):
2. Date of albumin-corrected serum calcium lab (MMDDYY):
3. Does the patient require treatment with active Vitamin D?
4. Does the patient require treatment with calcium supplementation?
5. Has the patient had a positive clinical response to therapy with Teriparatide? If yes, must attach supporting clinical documentation to this request.

RATIONALE
For Osteoporosis:
Initial criteria -
- For initial therapy in patients at high risk, there is some evidence that teriparatide could be started first and then followed by an antiresorptive agent (e.g., bisphosphonate) because the bone formation effects of teriparatide may be reduced if started after treatment with an antiresorptive agent. Criteria would allow for use in patients who are at highest risk for fracture prior to starting alternative therapy.
- Patients with history of fragility fracture and BMD with initial t-score in osteoporosis range (<-2.5) but without severe osteoporosis (<-3.5) are generally managed in primary care with use of IV or oral bisphosphonates, with evidence to support use in fracture risk reduction with treatment duration of up to 6-10 years as long as no significant declines in BMD or multiple fragility fractures while on bisphosphonate therapy. Evidence that transition to anabolic agent after use of bisphosphonates may not have as much of a robust response in BMD improvements compared to initial treatment. Therefore, for patients without severe disease or evidence of bisphosphonate failure, continuation of initial therapy is reasonable.
- Based on the landmark pivotal trials for teriparatide and abaloparatide, there is no clinically significant difference in efficacy or recommended treatment durations between teriparatide and abaloparatide for postmenopausal women with osteoporosis.

- There is no head-to-head comparative trial between teriparatide and abaloparatide. Each agent has only been compared to placebo. When compared to placebo, both have demonstrated comparable BMD improvements and fracture reduction with similar treatment durations for efficacy.
- Given similar efficacy and teriparatide being more cost effective, reasonable to preferentially use teriparatide over abaloparatide.
- Both teriparatide and abaloparatide are viable options for treatment of osteoporosis in those with contraindications or intolerances to bisphosphonates when other alternatives (ex. denosumab or romosozumab would also be contraindicated such as in the case of osteonecrosis of the jaw and atypical femur fractures).

Renewal criteria -
- In November 2020, the FDA removed the 2-year lifetime limitation to treatment with teriparatide due to the risk of osteosarcoma:
  - The osteosarcoma warning was based upon studies in rats that high doses (3x greater than human dosing) administered over most of the rats' lifespan (about 24 months) increased the risk of osteosarcoma.
  - Since the teriparatide clinical trials were happening at that time, the trials were terminated early (~19 months).
  - In the 18 years since teriparatide was approved, no increase in osteosarcoma risk has been reported in studies in animals with bone remodeling similar to that in humans (e.g., monkeys). However osteosarcoma is rare (about 1 in 250,000 adults per year) so would need very large sample sizes.
  - The observed incidence of osteosarcoma during a 15-year post marketing surveillance study was no different than the background incidence rate.
  - Teriparatide has been studied for up to 3 years for the treatment of glucocorticoid-induced osteoporosis.
- Abaloparatide still has 2-year treatment duration in FDA labeling

For Hypoparathyroidism:
PTH-based therapies are an option for patients with chronic hypoparathyroidism who cannot maintain stable serum and urinary calcium levels with calcium and vitamin D treatment.
Palopegteriparatide is a long-acting prodrug of PTH (1-34) FDA approved for treatment of adults with hypoparathyroidism. Teriparatide (Forteo) (PTH [1-34]), the bioactive domain of PTH, is FDA approved for osteoporosis. However, teriparatide has been used extensively long-term, including data from randomized trials, demonstrating effectiveness for the treatment of hypoparathyroidism when compared to calcitriol or conventional therapy. When Natpara, recombinant human PTH(1-84), was recalled in 2019, teriparatide was recommended as an alternative in a joint guidance statement from the American Society for Bone and Mineral Research (ASBMR) and Endocrine Society. It is notable that if teriparatide is used in this clinical scenario, twice daily or even three times daily injections are usually needed.

The goal of PTH-based therapy treatment is to maintain serum calcium within the normal range without the need for active vitamin D (e.g., calcitriol) or therapeutic calcium doses (elemental calcium > 600 mg/day).

FDA APPROVED INDICATIONS
FORTEO (teriparatide)
- **Osteoporosis:** Treatment of osteoporosis in postmenopausal females who are at high risk for fracture (defined as history of osteoporotic fracture or multiple risk factors for fracture); treatment to increase bone mass in males with primary or hypogonadal osteoporosis who are high risk for

fracture; treatment of males and females with glucocorticoid-induced osteoporosis associated with chronic systemic glucocorticoids with a prednisone dosage of ≥5 mg/day (or equivalent) at a high risk for fracture. May also be used in patients who have failed or are intolerant to other available osteoporosis therapy.

OFF-LABEL INDICATION WITH EVIDENCE
FORTEO (teriparatide)

- **Hypoparathyroidism:** Treatment of chronic hypoparathyroidism in adults.

REFERENCES

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2. Tsai JN, Uihlein AV, Lee H, et al. Teriparatide and denosumab, alone or combined, in women with postmenopausal osteoporosis: the DATA study randomized trial. *Lancet* 2013; 382(9886):50–56.
3. Cosman F, Nieves JW, Dempster DW. Treatment sequence matters: anabolic and
4. antiresorptive therapy for osteoporosis. J Bone Miner Res. 2017;32(2):198–202.
5. Miller PD, Lewiecki EM, Krohn K, Schwartz E. Teriparatide: Label changes and identifying patients for long-term use. *Cleveland Clinic Journal of Medicine*. 2021;88(9):489-493. https://www.ccjm.org/content/88/9/489
6. G Puliani et al. Safety and efficacy of PTH 1-34 and 1-84 therapy in chronic hypoparathyroidism: a meta-analysis of prospective trials. J Bone Miner Res 2022; 37:1233. doi:10.1002/jbmr.4566
7. AA Khan et al. Efficacy and safety of parathyroid hormone replacement with TransCon PTH in hypoparathyroidism: 26-week results from the phase 3 PaTHway trial. J Bone Miner Res 2023; 38:14. doi:10.1002/jbmr.4726
8. Rejnmark et al. Palopegteriparatide treatment improves renal function in adults with chronic hypoparathyroidism: 1-year results from the phase 3 PaTHway trial. Adv Ther 2024; 41:2500. doi:10.1007/s12325-024-02843-8
9. Joint American Society for Bone and Mineral Research (ASBMR) - Endocrine Society Guidance on Transitioning Hypoparathyroidism Patients from NATPARA® - Recommendation for Teriparatide (Forteo) https://www.asbmr.org/about/statement-detail/joint-american-society-bone-mineral-research-asbmr
10. Med Lett Drugs Ther. Yorvipath (palopegteriparatide) 2025 Mar 10;67(5100):1-3 doi:10.58347/tml.2025.5100a

Creation Date: 05/2022
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

TESTOSTERONE UNDECANOATE ORAL CAPSULES

Generic	Brand	HICL	GPID	Exception/Other
TESTOSTERONE UNDECANOATE	JATENZO	07304	46152, 46153, 46144	Non-formulary
TESTOSTERONE UNDECANOATE	KYZATREX	07304	52646, 52647, 52648	Non-formulary
TESTOSTERONE UNDECANOATE	TLANDO	07304	52120	Non-formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Must be prescribed by an Endocrinology specialist
2. Patient must be age 18 years or older
3. Patient has a diagnosis of primary hypogonadism or hypogonadotropic hypogonadism with supporting documentation demonstrating serum testosterone concentrations below normal range
4. Patient has persistent signs and symptoms (e.g., depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido) of androgen deficiency prior to treatment
5. Documentation of inadequate response (<400ng/dL total testosterone while adherent to appropriately dosed therapy), intolerance, or contraindication to all the following alternative generic testosterone formulations, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Testosterone cypionate (or enanthate) intramuscular injection*
    b. Testosterone topical gels - 1% and 1.62%
    c. Testosterone transdermal solution (e.g., testosterone 30mg/actuation solution)

If initial criteria are met, approve x2 years at HICL, max 4 capsules per day.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following criteria:
1. Patient's blood pressure is adequately controlled (≤140/90)
2. Patient does NOT have carcinomas of the breast or prostate
3. Patient has shown an adequate response to therapy as demonstrated by testosterone levels of ≥400-600 ng/dL total testosterone, within the most recent year

If renewal criteria are met, approve x2 years at HICL, max 4 capsules per day.
If renewal criteria are not met, do not approve.

* *Documentation of a member having a needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness to injectable products.*

ePA Questions
Initial Review Questions
1. Current serum testosterone lab (ng/dL):

2. Date of serum testosterone lab (MMDDYY):
3. Has the patient experienced persistent signs and symptoms (e.g., depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido) of androgen deficiency?
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Has the patient experienced inadequate response (<400ng/dL total testosterone while adherent to appropriately dosed therapy)? If yes, must attach applicable chart notes.
6. Is there reasoning why alternatives (testosterone cypionate oil for injection (100 mg/mL, 200 mg/mL); testosterone 1.62% (20.25 mg/actuation) gel PUMP) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions

1. Current serum testosterone lab (ng/dL):
2. Date of serum testosterone lab (MMDDYY):
3. Current BP:
4. Date of BP (MMDDYY):
5. Does the patient have carcinomas of the breast or prostate?

FDA APPROVED INDICATIONS:

Testosterone replacement therapy for adult (18 years +) males with primary hypogonadism (congenital or acquire) or hypogonadotropic hypogonadism (congenital or acquired).

REFERENCES

Note: HICL includes injectable vial - Aveed 750mg/3ml as well as all Jatenzo, Tlando, and Kyzatrex strengths

Creation Date: 11/2020
Effective Date: 10/2024
Reviewed Date: 09/2024
Revised Date: 09/2024

TEZACAFTOR/IVACAFTOR (SYMDEKO)

Generic	Brand	HICL	GPID	Exception/Other
TEZACAFTOR/IVACAFTOR	SYMDEKO	44771		

GUIDELINES FOR COVERAGE

Requests for TEZACAFTOR/IVACAFTOR will be approved if ALL the following are met:
1. Prescribed by a pulmonologist
2. Patient has a diagnosis of cystic fibrosis (CF) and
    a. is homozygous for the F508del mutation
    OR
    b. has at least one of mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor (verified by testing) [Consult Symdeko website to check eligibility mutations: https://www.Symdeko.com]
3. Patient is at least 6 years old

If above criteria are met, approve indefinitely, max #2/day
If above criteria are not met, do not approve.

ePA Questions
1. Is the patient homozygous for the F508del mutation? If yes, must attach supporting chart notes.
2. Does the patient have at least one of mutations in the CFTR gene that is responsive to tezacaftor/ivacaftor (verified by testing) [Consult Symdeko website to check eligibility mutations: https://www.Symdeko.com]? If yes, must list the patient's mutation in Provider Comment section below or attach applicable chart notes.

RATIONALE
Ensure appropriate utilization of tezacaftor/ivacaftor. TEZ/IVA (Symdeko) has potential safety advantages over LUM/IVA (Orkambi) including fewer drug-drug interactions and a lower incidence of respiratory adverse effects. TEZ/IVA has not been demonstrated to have improved efficacy compared to LUM/IVA, as there are no head-to-head studies. One study, EXPAND, reported modest improvements in lung function for TEZ/IVA compared to IVA (Kalydeco) for patients ≥12 years with cystic fibrosis who were heterozygous for the F508del mutation and a CFTR mutation associated with residual CFTR function.

FDA APPROVED INDICATIONS
Cystic fibrosis: Treatment of patients with cystic fibrosis (CF) aged ≥6 years who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence.

REFERENCES
1. Kaiser Permanente Drug Information Services, Drug Monograph: tezacaftor/ivacaftor and ivacaftor (Symdeko). May 2018.
2. Symdeko [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; 2022.

Creation date: 07/2018
Effective date: 08/2024
Reviewed date: 07/2024
Revised date: 07/2023

TEZEPELUMAB (TEZSPIRE)

Generic	Brand	HICL	GCN	COMMENTS
TEZEPELUMAB	TEZSPIRE	47740		Non-Formulary. Pk size: 1.91

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days.
2. Patient has a diagnosis of severe asthma and is stable on therapy.

If met, approve indefinitely, max 1 pen/syringe per 28 days [MDD 0.07].
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Patient has a diagnosis of severe asthma.
2. Patient is 12 years of age or older.
3. Medication is prescribed by an Allergy or Pulmonology specialist.
4. Uncontrolled asthma as evidenced by ANY one of the following:
    - Two or more asthma exacerbations requiring systemic corticosteroids (≥3 days each) in the past 12 months
    - one asthma-related hospitalization in the past 12 months
    - Asthma Control Test (ACT) consistently <20
5. Adherent (≥75% proportion of days covered) to optimized drug therapy (triple drug therapy with high-dose ICS-LABA plus tiotropium (Spiriva Respimat)) for the previous 6 months, OR has contraindications or intolerance to ICS/LABA/tiotropium, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception
6. Patient has tried and failed or has an intolerance or contraindication to benralizumab [PA required] and dupilumab [PA required], or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve indefinitely, max 1 pen/syringe per 28 days [MDD 0.07].
If initial criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with Tezepelumab (Tezspire)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):

3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
4. Is there reasoning why alternatives (Wixela Inhub, Breyna HFA, Spiriva Respimat) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Tezepelumab is no more effective or safe than formulary biologic agents for asthma, benralizumab and dupilumab.

FDA APPROVED INDICATIONS
Add-on maintenance treatment of severe asthma in patients 12 years of age or older.

Creation Date: 05/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: n/a

TOCILIZUMAB (ACTEMRA)

Generic	Brand	HICL	GPID	SIZE	COMMENTS
TOCILIZUMAB	ACTEMRA SYRINGE	36466	35486	0.9	NF – COMM, SF, Fed F - HIX
TOCILIZUMAB	ACTEMRA PEN	36466	45082	0.9	

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on Actemra.
2. Medication is not being used in combination with another biologic for the same indication.
3. Medication is being prescribed by a CPMG or affiliated rheumatologist.
4. Patient has ONE of the following diagnoses:
    a. Rheumatoid Arthritis (RA)
    b. Polymyalgia Rheumatica (PMR)
    c. Giant cell arteritis (GCA)
    d. Polyarticular juvenile idiopathic arthritis (PJIA)
    e. Systemic juvenile idiopathic arthritis (SJIA)
    f. Systemic sclerosis-associated lung disease (SSLD)

If met, approve x1 at GPID; and approve Tyenne (tocilizumab-aazg) indefinitely at HICL, max 4 pens/syringes per 28 days [MDD 0.13].
If not met, Use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications and must meet all indication-specific criteria:

A. Rheumatoid Arthritis (RA)
B. Polymyalgia Rheumatica (PMR)
C. Giant cell arteritis (GCA)
D. Polyarticular juvenile idiopathic arthritis (PJIA)
E. Systemic juvenile idiopathic arthritis (SJIA)
F. Systemic sclerosis-associated lung disease (SSLD)

A. **Rheumatoid Arthritis (RA):** All the following must be met:
1. Patient is 18 years or older, has a diagnosis of RA, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. At least 2 of the following: Methotrexate, Leflunomide, Hydroxychloroquine, Sulfasalazine
    b. At least 1 TNF inhibitor (e.g. infliximab-dyyb (Inflectra) - preferred [F], adalimumab-atto (Amjevita) - preferred [F, PA])
    c. Tocilizumab-aazg (Tyenne)

If criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.13].
If criteria are not met, do not approve.

B. **Polymyalgia Rheumatica (PMR):** All the following must be met:
1. Patient is 18 years or older, has a diagnosis of PMR, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Corticosteroids or cannot tolerate a corticosteroid taper
   b. Methotrexate
   c. Tocilizumab-aazg (Tyenne)

If criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.13].
If criteria are not met, do not approve.

C. **Giant Cell Arteritis (GCA):** All the following must be met:
1. Patient is 18 years or older, has a diagnosis of GCA, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. At least one corticosteroid
   b. Tocilizumab-aazg (Tyenne)

If criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.13].
If criteria are not met, do not approve.

D. **Polyarticular Juvenile Idiopathic Arthritis (PJIA):** All the following must be met:
1. Patient is 2 years or older, has a diagnosis of PJIA, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient with failure, intolerance, or contraindication to at least 1 of the following medications, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same

pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
a. Methotrexate
b. Leflunomide
c. Hydroxychloroquine
d. Sulfasalazine
e. Tocilizumab-aazg (Tyenne)

If criteria are met, approve at HICL indefinitely, max 2 pens/syringes per 28 days [MDD 0.07].
If criteria are not met, do not approve.

E. **Systemic juvenile idiopathic arthritis (SJIA):** All the following must be met:
1. Patient is 2 years or older, has a diagnosis of SJIA, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient with failure, intolerance, or contraindication to at least 1 of the following medications, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Methotrexate
   b. Leflunomide
   c. Hydroxychloroquine
   d. Sulfasalazine
   e. Tocilizumab-aazg (Tyenne)

If criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.13].
If criteria are not met, do not approve.

F. **Systemic sclerosis-associated lung disease (SSLD):** All the following must be met:
1. Patient is 18 years or older, has a diagnosis of SSLD, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient with failure, intolerance, or contraindication to tocilizumab-aazg (Tyenne), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.13].
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions

1. Is the patient stable on therapy with tocilizumab?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Rheumatoid Arthritis (RA); Polymyalgia Rheumatica (PMR); Giant cell arteritis (GCA); Polyarticular juvenile idiopathic arthritis (PJIA) or Systemic juvenile idiopathic arthritis (SJIA); Systemic sclerosis-associated lung disease (SSLD)]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Rheumatoid Arthritis (RA)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); adalimumab-atto) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic for the same indication?

Polymyalgia Rheumatica (PMR)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (corticosteroid; methotrexate 2.5 mg tablets, 25mg/ml vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic for the same indication?

Giant cell arteritis (GCA)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (corticosteroids) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic for the same indication?

Polyarticular Juvenile Idiopathic Arthritis (PJIA) or Systemic Juvenile Idiopathic Arthritis (SJIA)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic for the same indication?

Systemic sclerosis-associated lung disease (SSLD)

1. Is this medication being used in combination with another biologic for the same indication?

FDA APPROVED INDICATIONS

Actemra: RA, GCA, PJIA, SJIA, SSLD
Tyenne: RA, GCA, PJIA, SJIA
Kevzara: RA, PMR

REFERENCES

1. Actemra:
   - Actemra ACTPen: 162 mg/0.9 mL (0.9 mL) Solution Auto-injector, Subcutaneous [preservative free]
   - Actemra 162 mg/0.9 mL (0.9 mL) Solution Prefilled Syringe, Subcutaneous [preservative free]
2. "*Currently stable*" means patient is tolerating well, medication appears to be effective, and provider wishes to continue therapy.
3. Bonelli M, Radner H, Kerschbaumer A, Mrak D, Durechova M, Stieger J, Husic R, Mandl P, Smolen JS, Dejaco C, Aletaha D. Tocilizumab in patients with new onset polymyalgia rheumatica (PMR-SPARE): a phase 2/3 randomised controlled trial. Ann Rheum Dis. 2022 Jun;81(6):838-844. doi: 10.1136/annrheumdis-2021-221126.
4. Assaraf M, Chevet B, Wendling D, Philippe P, Cailliau E, Roux C, Avouac J, Delacour M, Houvenagel E, Sellam J, Cortet B, Henry J, Flipo RM, Devauchelle-Pensec V. Efficacy and management of tocilizumab in polymyalgia rheumatica: results of a multicenter retrospective observational study. Rheumatology (Oxford). 2023 Aug 21:kead426. doi: 10.1093/rheumatology/kead426.
5. Devauchelle-Pensec V, Carvajal-Alegria G, Dernis E, Richez C, Truchetet ME, Wendling D, Toussirot E, Perdriger A, Gottenberg JE, Felten R, Fautrel BJ, Chiche L, Hilliquin P, Le Henaff C, Dervieux B, Direz G, Chary-Valckenaere I, Cornec D, Guellec D, Marhadour T, Nowak E, Saraux A. Effect of Tocilizumab on Disease Activity in Patients With Active Polymyalgia Rheumatica Receiving Glucocorticoid Therapy: A Randomized Clinical Trial. JAMA. 2022 Sep 20;328(11):1053-1062. doi: 10.1001/jama.2022.15459.

Creation Date: 11/2023
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

TOCILIZUMAB (TYENNE)

Generic	Brand	HICL	GPID	SIZE	COMMENTS
TOCILIZUMAB	TYENNE SYRINGE	49425	55374	0.9	Formulary
TOCILIZUMAB	TYENNE PEN INJ	49425	55373	0.9	Formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on tocilizumab.
2. Medication is not being used in combination with another biologic for the same indication.
3. Medication is being prescribed by a CPMG or affiliated rheumatologist.
4. Patient has ONE of the following diagnoses:
    a. Rheumatoid Arthritis (RA)
    b. Polymyalgia Rheumatica (PMR)
    c. Giant cell arteritis (GCA)
    d. Polyarticular juvenile idiopathic arthritis (PJIA)
    e. Systemic juvenile idiopathic arthritis (SJIA)
    f. Systemic sclerosis-associated lung disease (SSLD)

If met, approve indefinitely at HICL, max 4 pens/syringes per 28 days [MDD 0.13].
If not met, Use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications and must meet all indication-specific criteria:

A. Rheumatoid Arthritis (RA)
B. Polymyalgia Rheumatica (PMR)
C. Giant cell arteritis (GCA)
D. Polyarticular juvenile idiopathic arthritis (PJIA)
E. Systemic juvenile idiopathic arthritis (SJIA)
F. Systemic sclerosis-associated lung disease (SSLD)

A. **Rheumatoid Arthritis (RA):** All the following must be met:
1. Patient is 18 years or older, has a diagnosis of RA, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. At least 2 of the following: Methotrexate, Leflunomide, Hydroxychloroquine, Sulfasalazine
    b. At least 1 TNF inhibitor (e.g. infliximab-dyyb (Inflectra) - preferred [F], adalimumab-atto (Amjevita) - preferred [F, PA])

If criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.13].
If criteria are not met, do not approve.

B. **Polymyalgia Rheumatica (PMR):** All the following must be met:
1. Patient is 18 years or older, has a diagnosis of PMR, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient with failure, intolerance, or contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Corticosteroids or cannot tolerate a corticosteroid taper
   b. Methotrexate

If criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.13].
If criteria are not met, do not approve.

C. **Giant Cell Arteritis (GCA):** All the following must be met:
1. Patient is 18 years or older, has a diagnosis of GCA, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient with failure, intolerance, or contraindication to a corticosteroid, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.13].
If criteria are not met, do not approve.

D. **Polyarticular Juvenile Idiopathic Arthritis (PJIA):** All the following must be met:
1. Patient is 2 years or older, has a diagnosis of PJIA, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient with failure, intolerance, or contraindication to at least 1 of the following medications, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. Methotrexate
   b. Leflunomide
   c. Hydroxychloroquine

d. Sulfasalazine

If criteria are met, approve at HICL indefinitely, max 2 pens/syringes per 28 days [MDD 0.07].
If criteria are not met, do not approve.

E. **Systemic juvenile idiopathic arthritis (SJIA):** All the following must be met:
1. Patient is 2 years or older, has a diagnosis of SJIA, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.
3. Patient with failure, intolerance, or contraindication to at least 1 of the following medications, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Methotrexate
    b. Leflunomide
    c. Hydroxychloroquine
    d. Sulfasalazine

If criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.13].
If criteria are not met, do not approve.

F. **Systemic sclerosis-associated lung disease (SSLD):** All the following must be met:
1. Patient is 18 years or older, has a diagnosis of SSLD, and medication is prescribed by a CPMG or affiliated rheumatologist.
2. Medication is not being used in combination with another biologic for the same indication.

If criteria are met, approve at HICL indefinitely, max 4 pens/syringes per 28 days [MDD 0.13].
If criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient stable on therapy with tocilizumab?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Rheumatoid Arthritis (RA); Polymyalgia Rheumatica (PMR); Giant cell arteritis (GCA); Polyarticular juvenile idiopathic arthritis (PJIA) or Systemic juvenile idiopathic arthritis (SJIA); Systemic sclerosis-associated lung disease (SSLD)]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Rheumatoid Arthritis (RA)
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

3. Is this medication being used in combination with another biologic for the same indication?

Polymyalgia Rheumatica (PMR)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (corticosteroid; methotrexate 2.5 mg tablets, 25mg/ml vials) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic for the same indication?

Giant cell arteritis (GCA)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (corticosteroids) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic for the same indication?

Polyarticular Juvenile Idiopathic Arthritis (PJIA) or Systemic Juvenile Idiopathic Arthritis (SJIA)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; hydroxychloroquine 200 mg tablets; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic for the same indication?

Systemic sclerosis-associated lung disease (SSLD)

1. Is this medication being used in combination with another biologic for the same indication?

FDA APPROVED INDICATIONS

Actemra: RA, GCA, PJIA, SJIA, SSLD
Tyenne: RA, GCA, PJIA, SJIA
Kevzara: RA, PMR

REFERENCES

1. “Currently stable” means patient is tolerating well, medication appears to be effective, and provider wishes to continue therapy.
2. Bonelli M, Radner H, Kerschbaumer A, Mrak D, Durechova M, Stieger J, Husic R, Mandl P, Smolen JS, Dejaco C, Aletaha D. Tocilizumab in patients with new onset polymyalgia rheumatica (PMR-SPARE): a phase 2/3 randomised controlled trial. Ann Rheum Dis. 2022 Jun;81(6):838-844. doi: 10.1136/annrheumdis-2021-221126.
3. Assaraf M, Chevet B, Wendling D, Philippe P, Cailliau E, Roux C, Avouac J, Delacour M, Houvenagel E, Sellam J, Cortet B, Henry J, Flipo RM, Devauchelle-Pensec V. Efficacy and management of tocilizumab in polymyalgia rheumatica: results of a multicenter retrospective observational study. Rheumatology (Oxford). 2023 Aug 21:kead426. doi: 10.1093/rheumatology/kead426.
4. Devauchelle-Pensec V, Carvajal-Alegria G, Dernis E, Richez C, Truchetet ME, Wendling D, Toussirot E, Perdriger A, Gottenberg JE, Felten R, Fautrel BJ, Chiche L, Hilliquin P, Le Henaff C,

Dervieux B, Direz G, Chary-Valckenaere I, Cornec D, Guellec D, Marhadour T, Nowak E, Saraux A. Effect of Tocilizumab on Disease Activity in Patients With Active Polymyalgia Rheumatica Receiving Glucocorticoid Therapy: A Randomized Clinical Trial. JAMA. 2022 Sep 20;328(11):1053-1062. doi: 10.1001/jama.2022.15459.

Creation Date: 07/2024
Effective Date: 06/2025
Reviewed Date: 05/2025
Revised Date: 05/2025

TOPICAL ONYCHOMYCOSIS AGENTS

Generic	Brand	HICL	GPID	Comments
CICLOPIROX 8% SOLN	CICLODAN		8040	Nonformulary

GUIDELINES FOR COVERAGE

1. Must have tried and failed, have a contraindication or intolerance to 6 weeks of oral terbinafine tablets for fingernails and 12 weeks of oral terbinafine tablets for toenails, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve at GPID for 48 weeks.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (terbinafine oral tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Per plan.

Creation Date: 07/2022
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

TOPICAL ONYCHOMYCOSIS AGENTS

Generic	Brand	HICL	GPID	Comments
EFINACONAZOLE	JUBLIA		36653	Nonformulary

GUIDELINES FOR COVERAGE

Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Must have tried and failed, have a contraindication or intolerance to 6 weeks of oral terbinafine tablets for fingernails and 12 weeks of oral terbinafine tablets for toenails
2. Must have tried and failed 48 weeks of topical ciclopirox solution
3. Must have tried and failed 48 weeks of topical tavaborole solution
4. Must have mycology labs showing either a positive nail fungal culture or positive PAS staining of nail clipping in formalin

If criteria are met, approve at GPID for 48 weeks.
If criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (terbinafine oral tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Does the patient have mycology labs showing either a positive nail fungal culture or positive PAS staining of nail clipping in formalin? If yes, must attach applicable chart notes with supporting documentation.

RATIONALE

Per plan.

Creation Date: 07/2022
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

TOPICAL ONYCHOMYCOSIS AGENTS

Generic	Brand	HICL	GPID	Comments
TAVABOROLE 5%	KERYDIN		36997	Nonformulary

GUIDELINES FOR COVERAGE
Must meet all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:

1. Must have tried and failed, have a contraindication or intolerance to 6 weeks of oral terbinafine tablets for fingernails and 12 weeks of oral terbinafine tablets for toenails
2. Must have tried and failed 48 weeks of topical ciclopirox solution

If criteria are met, approve at GPID for 48 weeks.
If criteria are not met, do not approve.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (terbinafine oral tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per plan.

Creation Date: 07/2022
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

TOPICAL TRETINOIN COVERAGE RULES

Generic	Brand	HICL	GPID	Exception/Other
TRETINOIN (TOPICAL)		02468, 32888	22874, 31777, 17443, 31776, 44075, 36604, 22881, 22880, 22871, 22882, 22872, 22870	

GUIDELINES FOR COVERAGE

Must meet one of the following criteria:

1. Patient must be age 35 or younger
2. Must have one of the following acne, actinic keratosis or verruca plana diagnoses:
   a) L70.0 - acne vulgaris
   b) L70.1 - acne conglobate
   c) L70.2 - acne varioliformis
   d) L70.3 - acne tropica
   e) L70.5 - acne excoriée
   f) L70.8 - other acne
   g) L70.9 - acne, unspecified
   h) L57.0 - actinic keratosis
   i) B07.8 - verruca plana

If one of the above criteria are met, then approve at HICL-G indefinitely.
If criteria not met, do not approve.

FDA APPROVED INDICATIONS

Topical tretinoin products are FDA approved for acne, wrinkles, hyperpigmentation of skin and roughness of skin. Supported off-label indications include keratosis and ultraviolet-induced change in normal skin. Per CMS guidance all except acne and keratosis are cosmetic indications and are excluded from benefit.

REFERENCES

Topical vitamin A treatment of recalcitrant common warts - PMC (nih.gov)

Creation Date: 01/2023
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

TOPIRAMATE 25 MG/ML SOLUTION - AGE RESTRICTION CRITERIA

Generic	Brand	HICL	GPID	Exception/Other
TOPIRAMATE SOLUTION 25 MG/ML	EPRONTIA		51457	

GUIDELINES FOR COVERAGE

INITIAL AND RENEWAL CRITERIA: ONE of the following criteria must be met:
1. Patient is less than or equal to 10 years old
2. Patient is using an alternative administration route, such as a gastrostomy tube
3. Dose cannot be administered by using half, whole, or combinations of the topiramate tablets or combinations of the topiramate capsules
4. Patient cannot swallow contents of opened capsules or other tablets whole, halved, or crushed (with or without mixing in apple sauce)

If any criterion is met, approve x1 year.
If no criteria are met, do not approve, and suggest either changing to capsules that can be opened and sprinkled on a teaspoonful of soft food or tablet strengths that can be halved or used in combination, or crushing topiramate tablets before administration and taking with or without applesauce.

ePA Questions
1. Is the patient using an alternative administration route, such as a gastrostomy tube? If yes, must attach applicable chart notes.
2. Is the patient unable to swallow tablets/capsules whole, halved, opened or crushed (with or without mixing in applesauce)? If yes, must attach applicable chart notes.

RATIONALE
Per Health Plan.

General Clinical Criteria for solutions/suspension
1. Age is less than or equal to 10 years old
2. Presence of gastrostomy
3. Dose does not allow use of halved, whole or combo of tablet
4. Dose does not use whole capsule (cannot “cut” capsules in half)
5. Clinical condition where unable to swallow crushed/opened tablets/capsules (i.e., esophageal stricture)

FDA APPROVAL
1. Prophylaxis of migraine headache in patients ≥12 years of age
2. Epilepsy: Initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older; adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older.

REFERENCES
Per Health Plan

Creation date: 09/2023
Effective date: 10/2024
Reviewed date: 09/2024
Revised date: 09/2024

TRALOKINUMAB-LDRM (ADBRY)

Generic	Brand	HICL	GPID	SIZE	Other
TRALOKINUMAB-LDRM	ADBRY 150 mg/mL syringe	47741	51749	1	Formulary, Specialty tier
TRALOKINUMAB-LDRM	ADBRY 300 mg/2 mL autoinjector	47741	55922	2	Formulary, Specialty tier

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: All the following must be met:
1. Patient is new to KPCO within the past 90 days and currently stable on tralokinumab (Adbry).
2. Medication is prescribed by a CPMG or an affiliated dermatologist or allergist.
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.

If above criteria are met, approve indefinitely at HICL, max 4 mL per 28 days [MDD: 0.15].
If above criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following indications and meet indication-specific criteria as noted:

A. Patient between 12-17 years of age with moderate to severe atopic dermatitis
B. Patient 18 years of age or older with moderate to severe atopic dermatitis

A. Patient is between 12-17 years of age with moderate to severe atopic dermatitis
   1. Medication is prescribed by a CPMG or an affiliated dermatologist or allergist.
   2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   3. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Patient has experienced an inadequate response, intolerance, or has a contraindication to a topical corticosteroid or topical calcineurin inhibitor.
      b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one**, or contraindication to at least **two** of the following therapies, or the patient is reported as having very high disease activity (greater than 50% BSA) or prior atopic dermatitis biologic or oral JAK inhibitor therapy within the past 4 months making these therapies inappropriate:
         - Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
         - Azathioprine
         - Cyclosporine
         - Methotrexate
         - Mycophenolate

If above criteria are met, approve x1 fill at HICL, max 4 mL per 42 days [MDD: 0.10] (loading dose), then indefinitely at HICL, max 2 mL per 28 days [MDD: 0.08] (maintenance dose).
If above criteria are not met, do not approve.

B. Patient is 18 years of age or older with moderate to severe atopic dermatitis
   1. Medication is prescribed by a CPMG or an affiliated dermatologist or allergist.
   2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   3. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one topical corticosteroid or topical calcineurin inhibitor.
      b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one**, or contraindication to at least **two** of the following therapies, or the patient is reported as being on prior atopic dermatitis biologic or oral JAK inhibitor therapy within the past 4 months making these therapies inappropriate:
         - Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
         - Azathioprine
         - Cyclosporine
         - Methotrexate
         - Mycophenolate

If above criteria are met, approve at HICL x1 fill, max 6 mL per 28 days [MDD: 0.22] (loading dose), then indefinitely at HICL, max 4 mL per 28 days [MDD: 0.15] (maintenance dose).
If above criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with tralokinumab (Adbry)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Percent body surface area (BSA) impacted:
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (topical steroid, tacrolimus ointment, phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy, azathioprine tablets (50 mg), cyclosporine capsules (25 mg, 100 mg), methotrexate 2.5 mg tablets or 25mg/ml vials, mycophenolate mofetil 250 mg capsules or 500 mg tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Health Plan

FDA APPROVED INDICATIONS
Atopic Dermatitis (Moderate to Severe)

REFERENCES

1. Adbry [Prescribing Information]. Madison, NJ: LEO Pharma Inc., June 2024.

Table 3: Relative contraindications of various treatments

Treatment	
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses* (ex: *systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for atopic dermatitis.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities,* active malignancy, *and hypersensitivity*
Mycophenolate	*Hypersensitivity to mycophenolate, active malignancy, pregnancy, breastfeeding, women of childbearing age not using highly effective contraceptive methods. Mycophenolate requires REMS program for females of childbearing age.*

Creation Date: 07/2022
Effective Date: 06/2025
Revised Date: 05/2025
Reviewed Date: 05/2025

TRAMETINIB DIMETHYL SULFOXIDE (MEKINIST)

Generic	Brand	HICL	GPID	Comments
TRAMETINIB	MEKINIST	40361	34726, 34727, 53859	Nonformulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA:
1. Patient is new to KPCO within the past 90 days and is stable on therapy.

   If met, approve based on the following:
   - For adjuvant setting: Approve at HICL for duration needed to complete a total of 12 months of adjuvant treatment, max 3 per day.
   - For unresectable or metastatic setting: Approve at HICL indefinitely, max 3 per day.

   If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
A. Must be prescribed by an oncologist
B. Must meet the diagnosis/drug specific criteria below-
   1. CUTANEOUS MELANOMA (ADJUVANT SETTING)
      a. Must be requested in the adjuvant treatment setting
      b. Must have a BRAF V600 activating mutation positive tumor
      c. Must be requested in combination with dabrafenib (Tafinlar)

      If met, then approve at HICL x 12 months with max daily dose of 3 tablets/day.
      If not met, do not approve.

   2. CUTANEOUS MELANOMA (UNRESECTABLE OR METASTATIC SETTING)
      a. Must be requested in unresectable or metastatic (advanced) setting
      b. Must have a BRAF V600 activating mutation positive tumor
      c. Must be requested in combination with dabrafenib (Tafinlar)
      d. Must have confirmed brain metastasis OR patient has tried and is unable to tolerate vemurafenib (Zelboraf) and/or cobimetinib (Cotellic) due to unacceptable toxicities despite adequate dose reductions OR patient has previously demonstrated clinical benefit from any BRAF/MEK targeted therapy and may benefit from rechallenge after other (non BRAF/MEK) therapies

      If met, approve at HICL indefinitely, max 3 tablets/day.
      If not met, do not approve. Use specific notations below for denial as applicable:
      - If criteria 2.c. is not met, deny noting that trametinib must be used in combination with dabrafenib.
      - If criteria 2.d. is not met, deny noting the patient must use cobimetinib (in combination with vemurafenib).

   3. NON-SMALL CELL LUNG CANCER
      a. Must be requested in the unresectable or metastatic setting
      b. Must have BRAF V600E mutation positive tumor

      If met, approve at HICL indefinitely, max 3 per day.

If not met, do not approve.

4. THYROID CANCER
   a. Must be requested in the locally advanced or metastatic setting
   b. Must have anaplastic thyroid cancer
   c. Must have BRAF V600E mutation positive tumor

   If met, approve at HICL indefinitely, max 3 per day.
   If not met, do not approve.

5. SOLID TUMORS
   a. Must be requested in the unresectable or metastatic setting
   b. Must have BRAF V600E mutation positive tumor
   c. Must have progressed through prior treatment and have no satisfactory alternative treatment options

   If met, approve at HICL indefinitely, max 3 per day.
   If not met, do not approve.

6. OVARIAN CANCER
   a. Must have low-grade serous carcinoma
   b. Must have recurrent disease

   If met, approve at HICL indefinitely, max 3 per day.
   If not met, do not approve.

RENEWAL CRITERIA
1. Request for continued coverage is in the unresectable or metastatic setting only. [No indication for treatment beyond 12 months in the adjuvant setting]
2. Patient's disease has not progressed since treatment initiation OR treating provider believes patient is deriving significant clinical benefit to justify treatment continuation
   Note that provider does NOT need to prove lack of progression via imaging, a clinical evaluation suffices

   If met, approve at HICL indefinitely, max 3 per day.
   If not met, do not approve.

RATIONALE
FDA labeling
Steering use toward preferred products

FDA APPROVED INDICATIONS
Melanoma (adjuvant, unresectable/metastatic), NSCLC (metastatic), anaplastic thyroid cancer (locally advanced, metastatic), solid tumors (unresectable, metastatic) with BRAF V600 activating mutations

REFERENCES
Package insert

Creation Date: 03/2020
Effective Date: 02/2025

Reviewed Date: 01/2025
Revised Date: 01/2025

ORENITRAM (TREPROSTINIL)

Generic	Brand	HICL	GCN	Exception/Other
TREPROSTINIL	ORENITRAM	40827		

GUIDELINES FOR COVERAGE:

NEW MEMBER CRITERIA: Must meet the following:
1. Patient is new to KPCO within the past 90 days and is currently stable on Orenitram

If met, approve indefinitely at HICL.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Prescriber must be either a pulmonologist or a cardiologist
2. Patient has a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) verified by right heart catheterization
3. Patient currently has WHO Functional Class II, III or IV symptoms
4. Patient has tried and failed or has an intolerance to or a contraindication to all the following or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   a. One phosphodiesterase type 5 (PDE5) inhibitor: Sildenafil (Revatio®) or Tadalafil (Adcirca®)
   b. One endothelin receptor antagonist (ERA): Bosentan (Tracleer®), Ambrisentan (Letairis®), or macitentan (Opsumit®)

If Initial Criteria are met, approve indefinitely at HICL.
If Initial Criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with 761yary761ram?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Pulmonary Arterial Hypertension (PAH, WHO Group 1) verified by right heart catheterization]
4. Patient's current WHO Functional Class:
5. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
6. Is there reasoning why alternatives (sildenafil tablets or suspension, tadalafil tablets or suspension, bosentan tablets, ambrisentan tablets, macitentan tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Ensure appropriate use consistent with FDA indication.

FDA APPROVED INDICATIONS

Treatment of pulmonary arterial hypertension (PAH) (WHO Group I) verified by right heart catheterization to reduce risks of disease progression and hospitalization.

REFERENCES

1. Orenitram (treprostinil) [prescribing information]. Research Triangle Park, NC: United Therapeutics Corp; October 2019.

Creation Date: 8/18/2020
Effective Date: 06/2024
Reviewed Date: 05/2024
Revised Date: 05/2024

TREPROSTINIL (TYVASO)

Generic	Brand	HICL	GCN	Exception/Other
TREPROSTINIL SOLUTION FOR INHALATION	TYVASO	36541	27492	
TREPROSTINIL DRY POWDER FOR INHALATION	TYVASO DPI	36541	52362, 52387, 52382, 52376, 52377, 52378	

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet the following:
1. Patient is new to KPCO within the past 90 days and is currently stable on Tyvaso or Tyvaso DPI

If met, approve indefinitely at HICL.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must have one of the following indications and meet indication-specific criteria as noted:

A. Pulmonary Arterial Hypertension (PAH) (WHO Group 1)
B. Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD) (WHO Group 3)

A. Pulmonary Arterial Hypertension (PAH) (WHO Group 1): Must meet all the following:
1. Prescriber must be a cardiologist or a pulmonologist.
2. Patient has a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) verified by right heart catheterization.
3. Patient currently has WHO Functional Class II, III or IV symptoms.
4. Patient has tried and failed, or has an intolerance to, or a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. One phosphodiesterase type 5 (PDE5) inhibitor: sildenafil (Revatio®) or tadalafil (Adcirca®)
    b. One endothelin receptor antagonist (ERA): Bosentan (Tracleer®), Ambrisentan (Letairis®), or macitentan (Opsumit®)
    c. Orenitram (treprostinil oral tablet)

If criteria are met, approve indefinitely at HICL.
If criteria are not met, do not approve.

B. Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD) (WHO Group 3): Must meet all the following:
1. Prescriber must be a pulmonologist or a cardiologist.
2. Patient has a diagnosis of pulmonary hypertension associated with interstitial lung disease (WHO Group 3) verified by right heart catheterization.

If criteria are met, approve indefinitely at HICL.
If criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with Tyvaso or Tyvaso DPI?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Pulmonary Arterial Hypertension (PAH, WHO Group 1) verified by right heart catheterization; Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD) (WHO Group 3) verified by right heart catheterization]
   QUESTIONS BASED ON DIAGNOSIS SELECTED
   Pulmonary Arterial Hypertension (PAH, WHO Group 1) verified by right heart catheterization
   1. Patient's current WHO Functional Class:
   2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
   3. Is there reasoning why alternatives (sildenafil tablets or suspension, tadalafil tablets or suspension, bosentan tablets, ambrisentan tablets, macitentan tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Ensure appropriate use consistent with FDA indication(s).

FDA APPROVED INDICATIONS
- TYVASO (solution for inhalation)
  - Treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to reduce risks of disease progression and hospitalization.
- TYVASO DPI (dry powder for inhalation)
  - Treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to reduce risks of disease progression and hospitalization.
  - Treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3).

REFERENCES
1. Tyvaso (treprostinil solution for inhalation) [prescribing information]. Research Triangle Park, NC: United Therapeutics Corp; May 2022.
2. Tyvaso DPI (treprostinil dry powder for inhalation) [prescribing information]. Research Triangle Park, NC: United Therapeutics Corp; June 2023.

Creation Date: 11/2023
Effective Date: 06/2024
Reviewed Date: 05/2024
Revised Date: 05/2024

TROFINETIDE (DAYBUE)

Generic	Brand	HICL	GCN	COMMENTS
TROFINETIDE 200 MG/ML SOLN	DAYBUE SOLN	48773	53839	Non-Formulary

GUIDELINES FOR COVERAGE
Must meet all the following:
1. Medication is prescribed by a neurologist or medical geneticist.
2. The patient is 2 years of age or older.
3. The patient has a diagnosis of Rett syndrome confirmed by genetic testing showing disease-causing mutation in the MECP2 gene.

If met, approve indefinitely, max daily dose: 120 mL.
If not met, do not approve.

ePA Questions
1. Does the patient have a diagnosis of Rett syndrome confirmed by genetic testing showing disease-causing mutation in the MECP2 gene? If yes, must attach supporting documentation.

RATIONALE
Ensure appropriate use consistent with FDA indication.

FDA APPROVED INDICATIONS
Rett syndrome: Treatment of Rett syndrome in adults and pediatric patients ≥2 years of age.

REFERENCES
Daybue (trofinetide) [prescribing information]. San Diego, CA: Acadia Pharmaceuticals Inc; March 2023.

Creation Date: 11/2023
Effective Date: 12/2024
Reviewed Date: 11/2024
Revised Date:

TUCATINIB (TUKYSA) - QUANTITY LIMIT RESTRICTION

Generic	Brand	HICL	GPID	Exception/Other
TUCATINIB	TUKYSA	46459	47929, 47931	Max 4 tabs per day, per strength

QUANTITY LIMIT rules:

- **Maximum 4 tablets per day per strength**
- **If patient requires a dose that exceeds 4 tablets per day, two separate prescriptions must be used (one for each strength) to result in desired dose**

RATIONALE

- Tukysa comes in 50mg (bottle of #60) and 150mg (bottles of #60 or #120) that must be dispensed in original bottle due to a desiccant required for stability.
- Tukysa 150mg cost less per mg than the 50mg.
- Packaging does not align with the typical 21-day treatment cycle creating a potential safety issue as patients may take therapy without recommended follow up.

Creation Date: 11/2021
Effective Date: 10/2024
Reviewed Date: 09/2024
Revised Date: 09/2024

UBROGEPANT (UBRELVY)

Generic	Brand	HICL	GPID	Comments
UBROGEPANT	UBRELVY	46273	47477, 47478	Oral CGRP antagonist; "Gepant" for acute tx

GUIDELINES FOR COVERAGE
Must meet all the following:
1. Prescribed for acute treatment of migraine with or without aura
2. Patient must be age 18 or older
3. Patient with failure of (after at least one month of therapy), intolerance to, or contraindication to, at least one triptan, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If criteria are met, approve indefinitely at HICL, max 10 tablets per 30 days [MDD 0.34].
If criteria are not met, do not approve.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (sumatriptan tablets, rizatriptan tablets, rizatriptan ODT, eletriptan tablets, naratriptan tablets, sumatriptan nasal spray (5 mg/act, 20 mg/act), sumatriptan succinate injectable 6 mg/0.5 mL) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Available triptan/ergotamine options:

Generic	Brand	Formulations available
Almotriptan	Axert	Tablet
Eletriptan	Relpax	Tablet
Frovatriptan	Frova	Tablet
Naratriptan	Amerge	Tablet
Rizatriptan	Maxalt/Maxalt MLT	Tablet, ODT
Sumatriptan	Imitrex, Sumavel, Onzetra, Zembrace	Tablet, nasal spray, injection
Zolmitriptan	Zomig/Zomig ZMT	Tablet, ODT, nasal spray
Ergotamine	Ergomar	Sublingual
Ergotamine/caffeine	Cafergot	Tablet, suppository
Dihydroergotamine	Migranal, Trudhesa D.H.E.	Nasal spray, injection

ODT=orally disintegrating tablet

True contraindications to triptan class

- Ischemic coronary artery disease including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina)
- History of stroke or transient ischemic attack
- Peripheral vascular disease
- Ischemic bowel disease
- Uncontrolled hypertension
- Hemiplegic or basilar migraine
- Wolff-Parkinson-White syndrome

Quantity Limits for Novel Oral Migraine Treatment

Medication	Dosage Strength	Maximum quantity limit for 30 days	Notes
Acute migraine indication			
Ubrogepant (Ubrelvy)	50 mg, 100 mg	10	Tablet splitting of the 100 mg tablet has been approved and should be recommended for all patients prescribed to take a dose of 50 mg at onset of migraine
Rimegepant (Nurtec ODT)	75 mg	8	Tablet splitting n/a
Zavegepant (Zavzpret)	10 mg	6	Available as a ready-to-use, unit-dose disposable nasal spray device that contains 10 mg of zavegepant. Each carton contains 6 nasal spray units.
Lasmiditan (Reyvow)	50 mg, 100 mg	8	Tablet splitting NOT approved Approved doses to take at onset of migraine are 50 mg, 100 mg, or 200 mg, however, only 50 mg and 100 mg tablet strengths are available
Preventive migraine indication			
Atogepant (Qulipta)	10 mg, 30 mg, 60 mg	30	Tablet splitting of the 60 mg tablet has been approved and should be recommended for all patients prescribed 30 mg daily
Rimegepant (Nurtec ODT)	75 mg	16	Tablet splitting n/a

CGRP-Directed Migraine Medications

Generic (Brand)	Route CGRP "class"	Acute Migraine Approval	Preventive Migraine Approval
Eptinezumab (Vyepti)	IV, CGRP-mAb	X	100 mg or 300 mg Q 3 mo
Erenumab (Aimovig)	SC, CGRP-mAb	X	70 mg or 140 mg Q mo

Fremanezumab (Ajovy)	SC, CGRP-mAb	X	225 mg Q 769yary, OR 675 mg Q 3 mo
Galcanezumab (Emgality)	SC, CGRP-mAb	X	240 mg loading dose, then 120 mg Q mo
Atogepant (Qulipta)	Oral, CGRP antagonist "gepant"	X	10 mg, 30 mg or 60 mg daily
Rimegepant (Nurtec ODT)	Orally disintegrating tablet, CGRP antagonist "gepant"	75 mg at onset do NOT repeat dose	75 mg every OTHER day
Ubrogepant (Ubrelvy)	Oral, CGRP antagonist "gepant"	50 mg or 100 mg at onset, may repeat in 2 hours	X
Zavegepant (Zavzpret)	Intranasal, CGRP antagonist "gepant"	10 mg at onset do NOT repeat dose	X

RATIONALE

Acute migraine indication

At this time, there is a lack of compelling data for ubrogepant, rimegepant, or lasmiditan to replace triptans as the gold standard for acute migraine treatment, considering cost and familiarity [1]. The 2019 AHS update briefly mentions role of emerging acute therapies as these options were not approved until about one year after its publication AHS [2]. Reiterated is the role for these novel treatment options, which do not result in constriction of blood vessels, for patients with vascular-related contraindications to triptans. Also acknowledged is the higher cost of these new agents compared to the generic availability of oral triptans and recommendation for ubrogepant, rimegepant, or lasmiditan to be used only in patients who have contraindications to triptans or who have failed to respond or tolerate at least two oral triptans. Patients should treat at least 2 migraine attacks before a provider makes a determination on efficacy and tolerability.

A comparative analysis of ubrogepant, lasmiditan, and rimegepant was performed by the Institute of Clinical and Economic Review (ICER) to assess the effectiveness and safety of these medications. [3] In comparison to placebo, ubrogepant [odds ratio (OR) 2.12], rimegepant [OR 2.11], and lasmiditan [OR 3.01] showed higher odds of achieving pain freedom at 2 hours. The analysis did not demonstrate statistically significant differences among the medications in pain freedom at two hours, absence of the most bothersome symptoms at two hours, and no disability at two hours in comparison to one another. On the other hand, in comparing triptans and ubrogepant, sumatriptan [OR 4.09] and eletriptan [OR 5.6] have shown to have higher odds of pain freedom at two hours than ubrogepant.

With regards to safety, nausea was the most common adverse effect seen with the use of ubrogepant. For single migraine attacks, ubrogepant and rimegepant had similar odds of experiencing any adverse event compared to triptans and placebo, but ubrogepant [OR 5.10] had lower odds for treatment-emergent adverse events compared to lasmiditan. Also, the risk of medication overuse headaches, which is present with triptans, is unknown with repeated use of ubrogepant and rimegepant.

In terms of cost per quality-adjusted life year (QALY) gained threshold, ubrogepant is considered cost effective at $40,000 per QALY gained. Ubrogepant has similar QALY values compared to rimegepant. Comparing ubrogepant and triptans, the cost of ubrogepant is substantially greater than triptans and has less QALYs than sumatriptan and eletriptan.

If choosing a one of these new acute medication options, pharmacokinetics and characteristics of a patient's migraine attacks should be kept in mind. Lasmiditan has pharmacokinetic characteristic similar to faster-acting triptans and most closely similar to almotriptan and eletriptan in regard to onset of action, time to maximum concentration, and half-life. Ubrogepant and rimegepant have slower onsets of action but longer half-lives which may be helpful for patients experiencing migraine recurrence. Dosing recommendations should also be considered when using these new medications including if a dose can be repeated in 2 hours, dose adjustments with other disease states, and potential for drug interactions (Table 1).

As the only gepant medication supplied in a non-oral formulation, zavegepant 10 mg nasal spray could be particularly useful in patients with characteristics associated with guideline-based recommendations for non-oral therapies, including headache attacks with severe nausea or vomiting or rapidly escalating headache pain, as well as for patients in whom oral forms are associated with inadequate response, slow onset of action, or poor tolerability. Additional trials are needed to provide evidence for the long-term safety and consistency of effect over time.

Using triptans as part of a combination therapy regimen can be useful (although possibly underutilized in clinical practice) and careful selection of agents to combine can achieve synergistic pharmacokinetic effects. For example, in patients needing a quick onset of action to relieve the migraine pain but also a longer duration to avoid migraine recurrence, a fast-acting triptan (e.g. nasal spray, injectable, or faster-acting oral) can be combined with a long-acting NSAID. Effectiveness and safety of combining gepants or lasmiditan with other acute therapies is less defined. Pertaining to other acute migraine medications that could be utilized, study protocols for phase 3 clinical trials differed slightly, but all included specific recommendations for what patients could or could not take within 24 hours or 48 hours after the initial dose of the study medication. Due to the potential for duplicating mechanisms, it appears logical to avoid the combination of lasmiditan with a triptan, but there may be a role for combining lasmiditan with an analgesic and/or antiemetic if needed. While gepants and triptans do not appear to directly have overlapping mechanisms, they do both target the trigeminovascular system, and thus the utility in combining a gepant with a triptan remains unclear. Given the slower onset of gepants, there may be clinical situations where combining a gepant with a faster acting NSAID could be beneficial. Overall, more data is needed.

More real-world utilization and long-term safety and efficacy data is needed for these new acute medication options, but the development of these therapy options fills a long-standing gap in therapy for patients with multiple trials and failures of triptans or those with contraindications to this class.

FDA APPROVED INDICATIONS

Ubrogepant: Acute treatment of migraine with or without aura in adults

REFERENCES

1. Moreno-Ajona D, Pérez-Rodríguez A, Goadsby PJ. Gepants, calcitonin-gene-related peptide receptor antagonists: what could be their role in migraine treatment? Curr Opin Neurol. 2020;33(3):309-315.
2. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache. 2019;59(1):1-18.
3. Atlas S, Touchette D, Agboola F, et al. Acute Treatments for Migraine: Effectiveness and Value. Institute for Clinical and Economic Review. February 25, 2020. Available at: icer-review.org/wp-content/uploads/2019/06/ICER_Acute-Migraine_Final-Evidence-Report_updated_030320.pdf. Accessed August 27, 2020.
4. Ashina M. Migraine. N Engl J Med 2020;383:1866-76.

5. Yang CP, Liang CS, Chang CM, et al. Comparison of new pharmacologic agents with triptans for treatment of migraine: a systematic review and meta-analysis. JAMA Netw Open. 2021;4(10):e2128544.

Creation Date: 08/2020
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

NON-PREFERRED USTEKINUMAB PA GL

Generic	Brand	HICL	GPID	Exception/Other
USTEKINUMAB	STELARA	36187		NF- Comm, Hx, Fed; F- SF
USTEKINUMAB-AUUB	WEZLANA	49290		NF
USTEKINUMAB-STBA	STEQEYMA	50109		NF
USTEKINUMAB-AEKN	SELARSDI	49526		NF
USTEKINUMAB-TTWE	PYZCHIVA	49730		NF
USTEKINUMAB-SRLF	IMULDOSA			NF
USTEKINUMAB-AAUZ	OTULFI	49894		NF

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:
1. Patient is new to KPCO within the past 90 days and is stable on therapy.
2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
3. Patient has one of the following indications and medication is prescribed by the appropriate specialist as noted:
   a. Patient has a diagnosis of psoriatic arthritis (PsA) and requested medication is being prescribed by a CPMG or affiliated rheumatologist.
   b. Patient has a diagnosis of psoriasis and requested medication is being prescribed by a CPMG or affiliated dermatologist.
   c. Patient has a diagnosis of ulcerative colitis, Crohn's Disease or IBD-unclassified and requested medication is being prescribed by a CPMG or affiliated gastroenterologist.
4. Patient has tried and failed, or has an intolerance or contraindication to Yesintek, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

If met, approve indefinitely, with the following quantity limits based on indication:
- PsA: max 1 syringe per 84 days [max qty: 1, min ds: 84]
- Psoriasis: max 1 syringe per 84 days [max qty: 1, min ds: 84]
- Ulcerative Colitis or Crohn's Disease: 1 syringe per 56 days [max qty: 1, min ds: 56]

If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria:

A. Psoriatic Arthritis (PsA)
B. Psoriasis
C. Crohn's Disease, Ulcerative Colitis, or IBD-Unclassified

A. Psoriatic Arthritis: All the following must be met:
   1. Patient has a diagnosis of PsA.
   2. Medication is prescribed by a rheumatologist.

3. Patient is 6 years of age or older.
4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
5. Patient has experienced an inadequate response, intolerance, or has a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. At least 2 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, sulfasalazine, or leflunomide
    b. At least 1 TNF inhibitor (e.g., infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F, PA])
    c. Yesintek

If initial criteria are met, approve at HICL x 1 month, max 1 syringe per 28 days (loading dose) [max qty: 1, min ds: 28], then 1 syringe per 84 days (maintenance dose) indefinitely [max qty: 1, min ds: 84].
If initial criteria are not met, do not approve.

B. Psoriasis: All the following must be met:
    1. Patient has a diagnosis of moderate to severe psoriasis.
    2. Medication is prescribed by a dermatologist.
    3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
    4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
        a. Patient has experienced an inadequate response, intolerance, or has a contraindication to a topical corticosteroid or topical calcineurin inhibitor (pimecrolimus, tacrolimus), or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate
        b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one** or contraindication to at least **two** of the following therapies, or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate: Acitretin, Cyclosporine, Methotrexate, Apremilast (Otezla), Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy

c. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one TNF inhibitor (adalimumab (Amjevita) - preferred [F, PA], infliximab (Inflectra)-preferred [F])
d. Patient has experienced an inadequate response, intolerance, or has a contraindication to Yesintek

If initial criteria are met, approve at HICL x 1 month, max 1 syringe per 28 days (loading dose) [max qty: 1, min ds: 28], then 1 syringe per 84 days (maintenance dose) indefinitely [max qty: 1, min ds: 84].
If initial criteria are not met, do not approve.

C. Crohn's Disease, Ulcerative Colitis, or IBD-Unclassified: All the following must be met:
1. Patient has a diagnosis of Crohn's Disease, Ulcerative Colitis, or IBD-Unclassified.
2. Medication is prescribed by a gastroenterologist.
3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
4. Patient has experienced an inadequate response, intolerance, or has a contraindication to all of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
a. at least 1 TNF inhibitor (e.g. adalimumab (Amjevita) - preferred [F, PA], infliximab (Inflectra)-preferred [F], or certolizumab (Cimzia) [NF, PA])
b. Yesintek

If initial criteria are met, approve indefinitely, max 1 syringe per 56 days [max qty: 1, min ds: 56].
If initial criteria are not met, do not approve.

ESCALATION CRITERIA/QTY LIMIT OVERRIDES: Patient must meet New Member or Initial Criteria prior to review for Quantity Overrides. Escalation Criteria review only the quantities authorized upon PA approval.

A. Patient diagnosis of Ulcerative Colitis, Crohn's disease or IBD-Unclassified:
1. For requests to start on escalated frequencies (1 syringe per less than 56 days):
Patient must have objective signs of persistent or worsening disease activity as demonstrated by at least one of the following:
a. Colonoscopy or imaging with persistent or worsening activity compared to baseline
b. Fecal calprotectin greater than 150 [only if patient had an elevated fecal calprotectin prior to medication initiation]
c. C-reactive protein greater than 2 [only if patient had an elevated C-reactive protein prior to medication initiation]

If met, approve at HICL x1 year, max 1 syringe per 28 days [max qty: 1, min ds: 28].
If not met, deny and offer maximum 1 syringe per 56 days indefinitely [max qty: 1, min ds: 56].

2. For requests to continue escalated frequencies (1 syringe per less than 56 days):

Patient must have been assessed by a gastroenterologist in the last 1 year, and the gastroenterologist evaluated if the frequency can be de-escalated and determined that the escalated frequency continues to be medically necessary.

If met, approve at HICL x2 years, max 1 syringe per 28 days [max qty: 1, min ds: 28].
If not met, deny and offer max 1 syringe per 56 days indefinitely [max qty: 1, min ds: 56].

ePA Questions
Initial Review Questions

1. Is the patient stable on therapy with ustekinumab?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Psoriatic Arthritis (PsA), Psoriasis, Crohn's Disease or Unclassified IBD with Crohn's Features, Ulcerative Colitis or Unclassified IBD with Ulcerative Colitis Features]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Psoriatic Arthritis (PsA)

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

Psoriasis

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (tacrolimus ointment, acitretin capsules (10 mg, 25 mg), cyclosporine capsules (25 mg, 100 mg), methotrexate tablets (2.5 mg) or injection (25 mg/mL), Otezla tablets, Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?
4. Current BSA (%):
5. Date of BSA assessment (MMDDYY):

Crohn’s Disease or Unclassified IBD with Crohn’s Features

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

Ulcerative Colitis or Unclassified IBD with Ulcerative Colitis Features

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

RATIONALE

"Stable on therapy" means patient is tolerating well, medication appears to be effective, and provider wishes to continue therapy.

Trial and failure of 2 DMARDs is required, as the DMARD classification is not representative of a specific pharmacological class and these medications are pharmacologically unrelated in terms of mechanism of action.

FDA APPROVED INDICATIONS

1. Treatment of patients 6 years of age or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
2. Treatment of patients 6 years of age with active psoriatic arthritis, with or without concurrent methotrexate.
3. Treatment of moderately to severely active Crohn disease in adults
4. Treatment of moderately to severely active ulcerative colitis in adults
5. Treatment of refractory inflammatory bowel disease in children and adolescents ≥12 years old (off label)

Treatment	Relative Contraindications for Psoriasis
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses (ex: systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for psoriasis.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities, active malignancy, and hypersensitivity*
Acitretin	*Women of child potential (cannot consider pregnancy up to 3 years after completion of treatment), pregnancy, lactation, severe hepatic or renal dysfunction, chronically abnormal elevated lipid values, and hypersensitivity*

Creation date: 09/26/2018
Effective date: 06/2025
Revised date: 05/2025
Reviewed date: 05/2025

YESINTEK (USTEKINUMAB-KFCE)

Generic	Brand	HICL	GPID	Exception/Other
USTEKINUMAB-KFCE	YESINTEK	50041		Formulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet all the following:

1. Patient is new to KPCO within the past 90 days and is stable on therapy
2. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
3. Patient has one of the following indications and medication is prescribed by the appropriate specialist as noted:
   a. Patient has a diagnosis of psoriatic arthritis (PsA) and requested medication is being prescribed by a CPMG or affiliated rheumatologist.
   b. Patient has a diagnosis of psoriasis and requested medication is being prescribed by a CPMG or affiliated dermatologist.
   c. Patient has a diagnosis of ulcerative colitis, Crohn's Disease or IBD-unclassified and requested medication is being prescribed by a CPMG or affiliated gastroenterologist.

If met, approve indefinitely at HICL.
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must have one of the following indications, and must meet all indication-specific criteria:

A. Psoriatic Arthritis (PsA)
B. Psoriasis
C. Crohn's Disease, Ulcerative Colitis, or IBD-Unclassified

A. Psoriatic Arthritis: All the following must be met:
   1. Patient has a diagnosis of PsA.
   2. Medication is prescribed by a rheumatologist.
   3. Patient is 6 years of age or older.
   4. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   5. Patient has experienced an inadequate response, intolerance, or has a contraindication to all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. At least 2 of the following medications, or the patient has documented high disease activity in which these medications would not be suitable treatment: methotrexate, sulfasalazine, or leflunomide
      b. At least 1 TNF inhibitor (e.g., infliximab-dyyb (Inflectra)-preferred [F], adalimumab-atto (Amjevita)-preferred [F])

If initial criteria are met, approve indefinitely at HICL.
If initial criteria are not met, do not approve.

B. Psoriasis: All the following must be met:
   1. Patient has a diagnosis of moderate to severe psoriasis.
   2. Medication is prescribed by a dermatologist.
   3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.
   4. Meets all the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. Patient has experienced an inadequate response, intolerance, or has a contraindication to a topical corticosteroid or topical calcineurin inhibitor (pimecrolimus, tacrolimus), or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate
      b. Patient has experienced an inadequate response (after at least 2 months) or intolerance to at least **one** or contraindication to at least **two** of the following therapies, or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis), disease affecting critical areas (ex: genitals, face), or prior biologic therapy within the past 4 months, making these therapies inappropriate: Acitretin, Cyclosporine, Methotrexate, Apremilast (Otezla), Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy
      c. Patient has experienced an inadequate response, intolerance, or has a contraindication to at least one TNF inhibitor (adalimumab (Amjevita) - preferred [F], infliximab (Inflectra)-preferred [F]), or the patient is reported as having very high disease activity (ex: > 50% BSA, erythrodermic, pustular psoriasis)

If initial criteria are met, approve indefinitely at HICL.
If initial criteria are not met, do not approve.

C. Crohn's Disease, Ulcerative Colitis or IBD-Unclassified: All the following must be met:
   1. Patient has a diagnosis of Crohn's Disease, Ulcerative Colitis or IBD-Unclassified
   2. Medication is prescribed by a gastroenterologist.
   3. Medication is not being used in combination with another biologic or advanced small molecule for the same indication.

If initial criteria are met, approve indefinitely.
If initial criteria are not met, do not approve.

ESCALATION CRITERIA/QTY LIMIT OVERRIDES:
For patients previously approved for ustekinumab with quantity limits now requesting dose escalation, remove the quantity limit from approval.

ePA Questions
Initial Review Questions
1. Is the patient stable on therapy with ustekinumab (Yesintek)?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Psoriatic Arthritis (PsA), Psoriasis, Crohn's Disease or Unclassified IBD with Crohn's Features, Ulcerative Colitis or Unclassified IBD with Ulcerative Colitis Features]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Psoriatic Arthritis (PsA)
1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (methotrexate 2.5 mg tablets, 25mg/ml vials; sulfasalazine 500 mg tablets, 500 mg enteric coated tablets; leflunomide tablets (10 mg, 20 mg); adalimumab-atto (Amjevita)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

Psoriasis
1. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (tacrolimus ointment, acitretin capsules (10 mg, 25 mg), cyclosporine capsules (25 mg, 100 mg), methotrexate tablets (2.5 mg) or injection (25 mg/mL), Otezla tablets, Phototherapy or narrow-band short wave ultraviolet B (NB-UVB) light therapy, adalimumab-atto (Amjevita)) are not suitable? If yes, you must list reasoning in the Provider Comment section below or attach applicable chart notes.
3. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?
4. Current BSA (%):
5. Date of BSA assessment (MMDDYY):

Crohn's Disease or Unclassified IBD with Crohn's Features
1. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

Ulcerative Colitis or Unclassified IBD with Ulcerative Colitis Features
1. Is this medication being used in combination with another biologic or advanced small molecule for the same indication?

RATIONALE
"Stable on therapy" means patient is tolerating well, medication appears to be effective, and provider wishes to continue therapy.

Trial and failure of 2 DMARDs is required, as the DMARD classification is not representative of a specific pharmacological class and these medications are pharmacologically unrelated in terms of mechanism of action.

FDA APPROVED INDICATIONS
1. Treatment of patients 6 years of age or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

2. Treatment of patients 6 years of age with active psoriatic arthritis, with or without concurrent methotrexate.
3. Treatment of moderately to severely active Crohn disease in adults
4. Treatment of moderately to severely active ulcerative colitis in adults
5. Treatment of refractory inflammatory bowel disease in children and adolescents ≥2 years old (off label)

Treatment	Relative Contraindications for Psoriasis
Phototherapy or NVU-UB	*Past/current melanoma or non-melanoma skin cancer, concomitant cyclosporine, predominant symptoms on genitals or face, type I skin (highly sensitive skin), erythroderma, preexisting photodermatoses (ex: systemic lupus, porphyria)*
Cyclosporine	*Uncontrolled hypertension, impaired renal function, prior PUVA or radiation therapy, drug hypersensitivity, and malignancy. Due to side effect profile, cyclosporine is not used chronically for psoriasis.*
Methotrexate	*Pregnancy, breastfeeding, actively trying to conceive, alcoholism or history of heavy alcohol use, chronic liver disease, immunodeficiency syndrome, preexisting blood dyscrasias, persistent liver or renal abnormalities, active malignancy, and hypersensitivity*
Acitretin	*Women of child potential (cannot consider pregnancy up to 3 years after completion of treatment), pregnancy, lactation, severe hepatic or renal dysfunction, chronically abnormal elevated lipid values, and hypersensitivity*

Creation date: 09/26/2018
Effective date: 06/2025
Revised date: 05/2025
Reviewed date: 05/2025

VAGINAL ESTROGEN CREAM

Generic	Brand	HICL	GPID	Comments
CONJUGATED ESTROGENS VAGINAL CREAM	PREMARIN VAGINAL CREAM		28410	

GUIDELINES FOR COVERAGE

Patient has tried and failed, or has a contraindication or intolerance to, estradiol vaginal cream (Estrace) and/or estradiol vaginal tablet (Yuvafem), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or likely will cause an adverse reaction or harm; ii) based on supporting clinical documentation provided, the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and a received step therapy exception.

If met, approve indefinitely at GPID.
If not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (estradiol vaginal cream) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

- Current practice guidelines, including those from the North American Menopause Society, state that vaginal estrogen is safe and effective for most patients. These guidelines do not make preference for one vaginal product over another.
- A Cochrane 2016 systematic review of 19 randomized trials including over 4000 patients investigated local estrogen treatment and found that creams, tablets/inserts, and rings were all similarly effective in relieving symptoms of vaginal atrophy.
- KPCO preferred, formulary vaginal estrogen treatment is estradiol vaginal cream (Estrace) for all patients, including those with a history of breast cancer who fail lifestyle modifications and non-hormonal treatment options.

FDA APPROVED INDICATIONS

Vulvar and vaginal atrophy associated with menopause: Treatment of moderate to severe vulvar and vaginal atrophy associated with menopause

Note: The International Society for the Study of Women's Sexual Health and The North American Menopause Society have endorsed the term genitourinary syndrome of menopause (GSM) as new terminology for vulvovaginal atrophy. The term GSM encompasses all genital and urinary signs and symptoms associated with a loss of estrogen due to menopause.

REFERENCES

1. Per Health Plan
2. North American Menopause Society (NAMS), Genitourinary Syndrome of Menopause, 2020
3. Suckling JA, Kennedy R, Lethaby A, Roberts H. Local oestrogen for vaginal atrophy in postmenopausal women. Cochrane Database of Systematic Reviews 2006, Issue 4
4. KPCO FAQ: Management of Urogenital Symptoms in Women with a History of Breast Cancer

Creation Date: 05/2022
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 05/2024

VAGINAL ESTROGEN RING

Generic	Brand	HICL	GPID	Comments
ESTRADIOL VAGINAL RING	ESTRING		10773	

GUIDELINES FOR COVERAGE

Must meet ONE of the following:

1. Patient has tried and failed, or has a contraindication or intolerance to estradiol vaginal cream (Estrace) and/or estradiol vaginal tablet (Yuvafem), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or likely will cause an adverse reaction or harm; ii) based on supporting clinical documentation provided, the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and a received step therapy exception.
2. Patient is physically or mentally unable to apply or insert vaginal estrogen cream/tablet.

If either criterion is met, approve indefinitely at GPID.
If none of the criteria are met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (estradiol vaginal cream) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

- Current practice guidelines, including those from the North American Menopause Society, state that vaginal estrogen is safe and effective for most patients. These guidelines do not make preference for one vaginal product over another.
- A Cochrane 2016 systematic review of 19 randomized trials including over 4000 patients investigated local estrogen treatment and found that creams, tablets/inserts, and rings were all similarly effective in relieving symptoms of vaginal atrophy.
- KPCO preferred, formulary vaginal estrogen treatment is estradiol vaginal cream (Estrace) for all patients, including those with a history of breast cancer who fail lifestyle modifications and non-hormonal treatment options.

FDA APPROVED INDICATIONS

Vulvar and vaginal atrophy associated with menopause: Treatment of moderate to severe vulvar and vaginal atrophy associated with menopause

Note: The International Society for the Study of Women's Sexual Health and The North American Menopause Society have endorsed the term genitourinary syndrome of menopause (GSM) as new terminology for vulvovaginal atrophy. The term GSM encompasses all genital and urinary signs and symptoms associated with a loss of estrogen due to menopause.

REFERENCES

1. Per Health Plan
2. North American Menopause Society (NAMS), Genitourinary Syndrome of Menopause, 2020
3. Suckling JA, Kennedy R, Lethaby A, Roberts H. Local oestrogen for vaginal atrophy in postmenopausal women. Cochrane Database of Systematic Reviews 2006, Issue 4
4. KPCO FAQ: Management of Urogenital Symptoms in Women with a History of Breast Cancer

Creation Date: 05/2022
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 05/2024

VAGINAL ESTROGEN TABLET

Generic	Brand	HICL	GPID	Comments
ESTRADIOL VAGINAL TABLET	YUVAFEM		28107	

GUIDELINES FOR COVERAGE

Patient has tried and failed, or has a contraindication or intolerance to estradiol vaginal cream (Estrace), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or likely will cause an adverse reaction or harm; ii) based on supporting clinical documentation provided, the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and a received step therapy exception.

If met, approve indefinitely at GPID.
If not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (estradiol vaginal cream) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

- Current practice guidelines, including those from the North American Menopause Society, state that vaginal estrogen is safe and effective for most patients. These guidelines do not make preference for one vaginal product over another.
- A Cochrane 2016 systematic review of 19 randomized trials including over 4000 patients investigated local estrogen treatment and found that creams, tablets/inserts, and rings were all similarly effective in relieving symptoms of vaginal atrophy.
- KPCO preferred, formulary vaginal estrogen treatment is estradiol vaginal cream (Estrace) for all patients, including those with a history of breast cancer who fail lifestyle modifications and non-hormonal treatment options.

FDA APPROVED INDICATIONS

Vulvar and vaginal atrophy associated with menopause: Treatment of moderate to severe vulvar and vaginal atrophy associated with menopause

Note: The International Society for the Study of Women's Sexual Health and The North American Menopause Society have endorsed the term genitourinary syndrome of menopause (GSM) as new terminology for vulvovaginal atrophy. The term GSM encompasses all genital and urinary signs and symptoms associated with a loss of estrogen due to menopause.

REFERENCES

1. Per Health Plan
2. North American Menopause Society (NAMS), Genitourinary Syndrome of Menopause, 2020

3. Suckling JA, Kennedy R, Lethaby A, Roberts H. Local oestrogen for vaginal atrophy in postmenopausal women. Cochrane Database of Systematic Reviews 2006, Issue 4
4. KPCO FAQ: Management of Urogenital Symptoms in Women with a History of Breast Cancer

Creation Date: 05/2022
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 05/2024

VAMOROLONE (AGAMREE)

Generic	Brand	HICL	GPID	COMMENTS
VAMOROLONE	AGAMREE	49283		Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: All the following must be met:
1. Patient is at least 2 years old.
2. Patient has a diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by genetic testing.
3. Medication is prescribed by a neurologist.
4. Patient has tried deflazacort [NF, PA required] for at least 6 months, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve at HICL indefinitely.
If initial criteria are not met, do not approve.

ePA Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Duchenne Muscular Dystrophy (DMD) confirmed by genetic testing]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

RATIONALE
Prednisone is recommended as the first-line corticosteroid for use in patients with DMD. Prednisone and deflazacort are considered comparable in efficacy with regards to improving muscle strength and function in patients with DMD.

The American Academy of Neurology guideline on corticosteroid treatment in DMD that was reaffirmed in 2022, states the following (Gloss 2016):
- Prednisone, offered as an intervention for patients with DMD, should be used to improve strength and pulmonary function (Level B).
- Deflazacort, offered as an intervention for patients with DMD, may be used to improve strength and timed motor function and delay the age at loss of ambulation by 1.4 to 2.5 years (Level C).
- Vamorolone is not included.

The efficacy of vamorolone appears comparable to standard-of-care corticosteroids (i.e. prednisone and deflazacort), and the safety and tolerability data from the VISION-DMD trial suggest vamorolone may offer reduced side effects compared to prednisone (Guglieri 2022). However, long-term safety profile of vamorolone in real-world settings has not been established.

FDA APPROVED INDICATIONS
Treatment of Duchenne muscular dystrophy (DMD) in patients 2 years and older

REFERENCES

Guglieri M, Bushby K, McDermott MP, et al. Effect of Different Corticosteroid Dosing Regimens on Clinical Outcomes in Boys With Duchenne Muscular Dystrophy: A Randomized Clinical Trial. JAMA. 2022 Apr 19;327(15):1456-1468.

Gloss D, Moxley RT, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy. Neurology. 2016;86(5):465-472.

Creation Date: 05/2024
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date:

VERICIGUAT (VERQUVO)

Generic	Brand	HICL	GCN	Exception/Other
VERICIGUAT	VERQUVO	47075		

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA: Must meet the following:
1. Patient is new to KPCO within the past 90 days and is currently stable on Verquvo.

If met, approve at HICL indefinitely.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following criteria:
1. Medication is prescribed by a CPMG or affiliated cardiologist.
2. Not currently taking PDE-5 inhibitor (e.g., tadalafil, sildenafil, vardenafil) or another soluble guanyl cyclase (sGC) stimulator (e.g., riociguat).
3. Patient has a diagnosis of heart failure with previous or current LVEF less than or equal to 45%.
4. Has contraindications to, is currently using, or has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   i. ARNI (Entresto)
   ii. Beta blocker
   iii. Aldosterone antagonist (e.g., spironolactone, eplerenone)
   iv. SGLT2 inhibitor

If criteria are met, approve at HICL indefinitely.
If criteria are not met, do not approve.

ePA Questions
1. Is the patient stable on therapy with Verquvo?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Is the patient taking a PDE-5 inhibitor (e.g., tadalafil, sildenafil, vardenafil) or another soluble guanyl cyclase (sGC) stimulator (e.g., riociguat)?
4. Does the patient have previous or current LVEF 45% or less?
5. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
6. Is there reasoning why alternatives (Entresto tablets; spironolactone tablets; atenolol tablets, metoprolol IR/ER tablets, bisoprolol tablets, carvedilol tablets, labetalol tablets, acebutolol capsules, propranolol ER capsules (60 mg, 80 mg, 120 mg, 160 mg) or IR tablets; Jardiance tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Creation Date: 07/2021

Effective Date: 06/2024
Reviewed Date:05/2024
Revised Date: 05/2024

VIBEGRON (GEMTESA)

Generic	Brand	HICL	GPID	Exception/Other
VIBEGRON	GEMTESA TABLETS	47040	49009	Nonformulary with max daily dose of 1/day

GUIDELINES FOR COVERAGE
Must have one of the following diagnoses and meet all the diagnosis-specific criteria:

A. OVERACTIVE BLADDER AND MYASTHENIA GRAVIS
B. OVERACTIVE BLADDER WITHOUT MYASTHENIA GRAVIS

A. PATIENTS WITH A DIAGNOSIS OF OVERACTIVE BLADDER AND MYASTHENIA GRAVIS: Must meet all of the following criteria:
   1. Patient has a diagnosis of overactive bladder, urge incontinence, urgency, urinary frequency or bladder spasm.
   2. Patient has a diagnosis of myasthenia gravis.
   3. Patient has failed mirabegron (Myrbetriq), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

   If criteria are met, approve at HICL indefinitely, max daily dose of 1 tablet.
   If criteria are not met, do not approve.

B. PATIENTS WITH A DIAGNOSIS OF OVERACTIVE BLADDER WITHOUT A DIAGNOSIS OF MYASTHENIA GRAVIS: Must meet all the following criteria:
   1. Patient has a diagnosis of overactive bladder, urge incontinence, urgency, urinary frequency or bladder spasm.
   2. Patient has failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) is/(are) contraindicated or will likely cause an adverse reaction or harm; ii) the required drug(s) is/(are) ineffective based on known clinical characteristics of the patient or drug(s); iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
      a. At least one anticholinergic [listed in preferential order]: oxybutynin IR/ER, solifenacin, trospium IR and tolterodine IR/ER
      b. mirabegron (Myrbetriq)

   If criteria are met, approve at HICL indefinitely, max daily dose of 1 tablet.
   If criteria are not met, do not approve.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (trospium 20 mg tablets, solifenacin (5 mg, 10 mg), oxybutynin IR (5 mg) or ER (5 mg, 10 mg, 15 mg) tablets, OTC* oxybutynin patches (Oxytrol)) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per Health Plan.
- An adequate response is defined as one less episode of frequency or incontinence per day after an adequate trial of 4-6 weeks. Patients with a diagnosis of myasthenia gravis should avoid the use of anticholinergic agents.
- Preferred formulary agents, in order: oxybutynin ER, oxybutynin IR, solifenacin, trospium IR and oxybutynin syrup.
- Oral oxybutynin is not preferred in patients with dementia or cognitive impairment. Darifenacin is a preferred non-formulary option for patients with history of cognitive issues after solifenacin and trospium IR.
- Preferred nonformulary agents in order: tolterodine IR, tolterodine ER, darifenacin, fesoterodine, trospium ER, mirabegron and vibegron, Oxybutynin gel (Gelnique) and oxybutynin patch (Oxytrol) are excluded from coverage.
- Mirabegron granules are FDA approved for pediatric patients 3 to 17 years of age for neurogenic detrusor overactivity. Both oxybutynin (ER formulation) and solifenacin are FDA approved for neurogenic detrusor overactivity.

FDA APPROVED INDICATIONS
See individual medication.

REFERENCES

Creation Date: 9/26/2019
Effective Date: 10/2024
Reviewed Date: 09/2024
Revised Date: 09/2024

VILOXAZINE (QELBREE)

Generic	Brand	HICL	GPID	Exception/Other
VILOXAZINE	QELBREE	07345		

GUIDELINES FOR COVERAGE

Must meet all the following:

1. Patient is at least 6 years of age.
2. Patient has a diagnosis of ADHD or ADD.
3. Patient has failed or has a contraindication to atomoxetine, has difficulty swallowing oral capsules, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If initial criteria are met, approve indefinitely, max daily dose (MDD) of 3.
If initial criteria are not met, do not approve.

ePA Questions

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (atomoxetine capsules) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE

Viloxazine is a Brand non-stimulant (SNRI) treatment option for ADHD in patients 6 years and older. Atomoxetine represents a generic, non-stimulant (SNRI) treatment option for the same diagnosis and age group without significant differences in efficacy or safety. As such, trial of atomoxetine should be required prior to viloxazine approval/trial. The only exception will be for patients unable to swallow capsules whole as atomoxetine capsules should not be opened (atomoxetine is an ocular irritant) whereas viloxazine capsules may be opened and contents sprinkled on applesauce or pudding for consumption.

FDA APPROVED INDICATIONS

Viloxazine is indicated for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older.

REFERENCES

1. Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc; Dec 2023.
2. Wolraich ML. et. al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. Oct. 2019, 144 (4) 2019-2528.

Creation Date: 6/7/2023
Effective Date: 08/2024
Reviewed Date: 07/2024
Revised Date: 07/2024

VISMODEGIB (ERIVEDGE)

Generic	Brand	HICL	GPID	Comments
VISMODEGIB	ERIVEDGE 150MG CAPSULE	38455	31307	Non-Formulary Nonpreferred for BCC

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA:
Patient is new to KPCO in the past 90 days and stable on therapy.

If new member criteria are met, approve indefinitely.
If new member criteria are not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Medication is prescribed by a CPMG or affiliated Dermatologist or Oncologist
2. Patient has a diagnosis of Basal Cell Carcinoma (BCC) and one of the following: metastatic disease, recurrence of BCC following surgery or radiation therapy, locally advanced disease and medication is being used to shrink tumor to allow the patient to become a surgical candidate, or the patient is not a candidate for surgery or radiation therapy
3. Must meet all of the following or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug is contraindicated or likely will cause an adverse reaction or harm; ii) based on supporting clinical documentation provided, the required drug is ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and a received step therapy exception:
    a. Patient has failed sonidegib (Odomzo) due to intolerability even after appropriate dose reductions
    b. Patient's disease has not progressed on sonidegib (Odomzo)

If initial criteria are met, approve at HICL indefinitely.
If initial criteria are not met, do not approve.

ePA Questions
1. Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Basal Cell Carcinoma (BCC) with metastatic disease; Recurrence of Basal Cell Carcinoma (BCC) following surgery or radiation therapy; Basal Cell Carcinoma (BCC), locally advanced disease and medication is being used to shrink tumor to allow the patient to become a surgical candidate; Basal Cell Carcinoma (BCC) and the patient is not a candidate for surgery or radiation therapy]
2. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

RATIONALE
Per KPCO treatment guidelines
- Sonidegib is the preferred hedgehog inhibitor per KP National guidelines.
- Sonidegib and vismodegib are accepted as equal in terms of efficacy.
- If patient has contraindication to either sonidegib or vismodegib, they would be considered to have a contraindication to the other.

- A patient may have intolerable toxicities with sonidegib that might not occur with vismodegib.
- If a patient has progression of disease with sonidegib, there is no value in trying vismodegib based on currently available data.

FDA APPROVED INDICATIONS
ODOMZO™ (sonidegib) is a hedgehog pathway inhibitor indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

ERIVEDGE™ (vismodegib) is a hedgehog pathway inhibitor indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and not candidates for radiation.

Creation Date: 3/8/2019
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 05/2024

VMAT2-INHIBITORS
DEUTETRABENAZINE (AUSTEDO)

Generic	Brand	HICL	GPID	Comments
DEUTETRABENAZINE	AUSTEDO	44192		Nonformulary
DEUTETRABENAZINE	AUSTEDO XR	44192		Nonformulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

1. Patient is 18 years or older
2. Prescribed by Psychiatrist or Neurologist
3. Must meet the diagnosis/drug specific criteria below:
   a. For Tardive Dyskinesia
      i. Patient must have a diagnosis of tardive dyskinesia, neuroleptic induced tardive dyskinesia or orofacial dyskinesia
      ii. Patient must have Abnormal Involuntary Movement Scale (AIMS) score of at least 6
      iii. Patient has had persistent symptoms of tardive dyskinesia despite trial of dose reduction or discontinuation of [suspected] offending medication or the patient is not a candidate for dose reduction or discontinuation of [suspected] offending medication
      iv. Patient has had persistent symptoms of tardive dyskinesia despite discontinuation of anticholinergics or is not a candidate for discontinuation of anticholinergics
      v. Patient has an intolerance to, contraindication to, or failed a 12-week trial of tetrabenazine, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

   If initial criteria are met, approve indefinitely at HICL with the following quantity limit of a max daily dose of 4 tablets.
   If initial criteria are not met, do not approve.

   b. For Chorea associated with Huntington's Disease
      i. Diagnosis of Huntington's Disease must be confirmed by genetic testing
      ii. Patient must have a diagnosis of Chorea associated with Huntington's Disease
      iii. Patient has a contraindication to, intolerance to, or failed a 12-week trial of tetrabenazine, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

   If initial criteria are met, approve indefinitely at HICL with the following quantity limit of a max daily dose of 4 tablets.

If initial criteria are not met, do not approve.

Medication	Dosage Strengths	Maximum Dose	Quantity Limit for 30 Days
Deutetrabenazine	6 mg, 9 mg, 12 mg	48 mg	#120 tablets
Deutetrabenazine XR	6 mg, 9 mg, 12 mg, 24 mg, 30 mg, 36 mg, 42 mg, 48 mg	48 mg	#30 tablets*

*4 – week titration kit [28 tabs total of 12 mg, 18mg, 24 mg and 30 mg XR tabs (7 of each strength)] available for therapy initiation

RATIONALE

For Tardive Dyskinesia

When treating tardive dyskinesia (TD), guidelines recommend to first evaluate whether dopamine receptor blockers (e.g., antipsychotics, metoclopramide) or anticholinergics (e.g., benztropine, trihexyphenidyl) can be discontinued, dose reduced, or changed as these agents contribute to or may worsen TD. Notably, anticholinergics may be mistakenly prescribed for TD treatment. In general, if a patient is taking a first-generation antipsychotic, changing to a second-generation antipsychotic (SGA) with a lower risk can be considered. If the patient is already taking an SGA, changing to either quetiapine or clozapine is largely considered in clinical practice, though a 2018 meta-analysis also supports changing to aripiprazole or olanzapine. Even with these changes, distressing and disabling TD may persist requiring the use of adjunctive treatment strategies.

If adjustment of the existing medication regimen described above is clinically inappropriate or failed, then adjunctive therapies for TD management can be considered. Tetrabenazine, deutetrabenazine, and valbenazine are all vesicular monoamine transporter 2 (VMAT2) inhibitors. VMAT2 inhibitors have been studied for treatment of moderate-severe TD. Although tetrabenazine has only been approved in the US for the symptomatic management of chorea associated with Huntington's disease, it is reasonable to consider a trial prior to deutetrabenazine and valbenazine as:

- Tetrabenazine is approved for TD management in other countries (e.g., United Kingdom).
- Tetrabenazine has been used off-label with success for the symptomatic management of other hyperkinetic movement disorders including tardive dyskinesia.
- Clinical experience suggests that the drug is effective in TD, including in some severe and/or refractory cases.
- Based on American Academy of Neurology (AAN) guidelines, tetrabenazine is possibly effective and may be considered in the treatment of patients with TD.
- While deutetrabenazine and valbenazine are established as effective for the treatment of TD per AAN guidelines, there are no randomized controlled trials of tetrabenazine for TD nor are there head-to-head studies comparing tetrabenazine to any other active treatment, including deutetrabenazine to valbenazine.
- Tetrabenazine remains the most cost-effective VMAT2 inhibitor option for tardive dyskinesia without known quantifiable comparisons in safety and efficacy relative to deutetrabenazine and valbenazine.
- The only known advantage of deutetrabenazine over tetrabenazine is the need for less frequent dosing (BID instead of TID) at the higher end of the dosing range.

All VMAT2 inhibitors should be used with caution in patients with active suicidal ideation or untreated depression. While tetrabenazine and deutetrabenazine have boxed warnings for depression and suicidality, this is specific to their indication for chorea treatment. Patients with Huntington’s disease have a higher risk of depression and suicidality at baseline. In a large longitudinal prospective observational study, tetrabenazine treatment was not found to be associated with an increased risk of

depression and suicidality. Even though deutetrabenazine and valbenazine lack this boxed warning for increased depression and suicidality when used for TD, clinical trials have excluded patients with a significant risk of suicidal behavior so no comparisons can be made for differences in depression or suicidality risk amongst VMAT2 inhibitors at this time.

For Chorea associated with Huntington's Disease
According to the American Academy of Neurology (AAN) guidelines on the treatment of chorea of Huntington's disease (2012), if Huntington's disease chorea requires treatment, clinicians should prescribe tetrabenazine (≤ 100 mg/day), amantadine (300 to 400 mg/day), or riluzole (200 mg/day) [Level B] for varying degrees of expected benefit. Deutetrabenazine is not addressed in the guidelines.

FDA APPROVED INDICATIONS

Deutetrabenazine:	Treatment of patients with tardive dyskinesia and chorea associated with Huntington's Disease
Valbenazine:	Treatment of patients with tardive dyskinesia and chorea associated with Huntington's Disease

APPENDIX A. Antipsychotics

First-generation antipsychotics	Second-generation antipsychotics
Chlorpromazine	Aripiprazole
Fluphenazine	Asenapine
Haloperidol	Brexpiprazole
Loxapine	Cariprazine
Molindone	Clozapine
Perphenazine	Iloperidone
Pimozide	Lumateperone
Thioridazine	Lurasidone
Thiothixene	Olanzapine
Trifluoperazine	Paliperidone
	Quetiapine
	Risperidone
	Ziprasidone

APPENDIX B. Anticholinergics commonly prescribed by psychiatry and neurology for drug-induced movement disorders.

- Benztropine
- Diphenhydramine
- Hydroxyzine
- Trihexyphenidyl

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1. Tetrabenazine monograph. Facts and Comparisons online. (www.fco-factsandcomparisons-com.kaiserpermanente.idm.oclc.org), Wolters Kluwer Health, St. Louis, MO. Last updated 5/15/21.
2. Sweetman S (Ed), Martindale: The Complete Drug Reference. London: The Royal Pharmaceutical Society of Great Britain. Electronic version, IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ (cited: *5/19/21*).
3. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: treatment of tardive syndromes: report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology.* 2013;81(5):463-469. doi: 10.1212/WNL.0b013e31829d86b6
4. Austedo [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; August 2017.

5. Ingrezza [prescribing information]. San Diego, CA: Neurocrine Biosciences, Inc.; April 2017.
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Creation Date: 5/28/21
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

VMAT2-INHIBITORS
VALBENAZINE (INGREZZA)

Generic	Brand	HICL	GPID	Comments
VALBENAZINE TOSYLATE	INGREZZA	44202		Nonformulary

GUIDELINES FOR COVERAGE

NEW MEMBER CRITERIA:
1. Patient is new to KPCO with the past 90 days and is stable on therapy valbenazine (Ingrezza)

If met, approve indefinitely at HICL, max 1 per day.
If not met, review by Initial Criteria.

INITIAL CRITERIA: Must meet all the following:
1. Patient is 18 years or older
2. Prescribed by a Psychiatrist or Neurologist
3. Must meet the diagnosis/drug specific criteria below:
   a. For Tardive Dyskinesia
      i. Patient must have a diagnosis of tardive dyskinesia, neuroleptic induced tardive dyskinesia or orofacial dyskinesia
      ii. Patient must have Abnormal Involuntary Movement Scale (AIMS) score of at least 6
      iii. Patient has had persistent symptoms of tardive dyskinesia despite trial of dose reduction or discontinuation of [suspected] offending medication or the patient is not a candidate for dose reduction or discontinuation of [suspected] offending medication
      iv. Patient has had persistent symptoms of tardive dyskinesia despite discontinuation of anticholinergics or is not a candidate for discontinuation of anticholinergics
      v. Patient has an intolerance to, contraindication to, or failed a 12-week trial of tetrabenazine, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

      If initial criteria are met, approve indefinitely at HICL with the following quantity limit of a max daily dose of 1 capsule.
      If initial criteria are not met, do not approve.

   b. For Chorea associated with Huntington's Disease
      i. Diagnosis of Huntington's Disease must be confirmed by genetic testing
      ii. Patient must have a diagnosis of Chorea associated with Huntington's Disease
      iii. Patient has a contraindication to, intolerance to, or failed a 12-week trial of tetrabenazine, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is

stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception

If initial criteria are met, approve indefinitely at HICL with the following quantity limit of a max daily dose of 1 capsule.
If initial criteria are not met, do not approve.

Medication	Dosage Strengths	Maximum Dose	Quantity Limit for 30 Days
Valbenazine	40 mg, 60 mg, 80 mg	80 mg	#30 capsules

RATIONALE

For New Member Criteria

Valbenazine does not have any guidance re: tetrabenazine dose equivalencies or switching strategies so if new member is stable and their cost share is affordable, valbenazine continuation versus switching to tetrabenazine is recommended to minimize risk for uncontrolled abnormal movement related disability.

For Tardive Dyskinesia

When treating tardive dyskinesia (TD), guidelines recommend to first evaluate whether dopamine receptor blockers (e.g., antipsychotics, metoclopramide) or anticholinergics (e.g., benztropine, trihexyphenidyl) can be discontinued, dose reduced, or changed as these agents contribute to or may worsen TD. Notably, anticholinergics may be mistakenly prescribed for TD treatment. In general, if a patient is taking a first-generation antipsychotic, changing to a second-generation antipsychotic (SGA) with a lower risk can be considered. If the patient is already taking an SGA, changing to either quetiapine or clozapine is largely considered in clinical practice, though a 2018 meta-analysis also supports changing to aripiprazole or olanzapine. Even with these changes, distressing and disabling TD may persist requiring the use of adjunctive treatment strategies.

If adjustment of the existing medication regimen described above is clinically inappropriate or failed, then adjunctive therapies for TD management can be considered. Tetrabenazine, deutetrabenazine, and valbenazine are all vesicular monoamine transporter 2 (VMAT2) inhibitors. VMAT2 inhibitors have been studied for treatment of moderate-severe TD. Although tetrabenazine has only been approved in the US for the symptomatic management of chorea associated with Huntington's disease, it is reasonable to consider a trial prior to deutetrabenazine and valbenazine as:

- Tetrabenazine is approved for TD management in other countries (e.g., United Kingdom).
- Tetrabenazine has been used off-label with success for the symptomatic management of other hyperkinetic movement disorders including tardive dyskinesia.
- Clinical experience suggests that the drug is effective in TD, including in some severe and/or refractory cases.
- Based on American Academy of Neurology (AAN) guidelines, tetrabenazine is possibly effective and may be considered in the treatment of patients with TD.
- While deutetrabenazine and valbenazine are established as effective for the treatment of TD per AAN guidelines, there are no randomized controlled trials of tetrabenazine for TD nor are there head-to-head studies comparing tetrabenazine to any other active treatment, including deutetrabenazine to valbenazine.
- Tetrabenazine remains the most cost-effective VMAT2 inhibitor option for tardive dyskinesia without known quantifiable comparisons in safety and efficacy relative to deutetrabenazine and valbenazine.
- The only known advantage of deutetrabenazine over tetrabenazine is the need for less frequent dosing (BID instead of TID) at the higher end of the dosing range.

All VMAT2 inhibitors should be used with caution in patients with active suicidal ideation or untreated depression. While tetrabenazine and deutetrabenazine have boxed warnings for depression and suicidality, this is specific to their indication for chorea treatment. Patients with Huntington's disease have a higher risk of depression and suicidality at baseline. In a large longitudinal prospective observational study, tetrabenazine treatment was not found to be associated with an increased risk of depression and suicidality. Even though deutetrabenazine and valbenazine lack this boxed warning for increased depression and suicidality when used for TD, clinical trials have excluded patients with a significant risk of suicidal behavior so no comparisons can be made for differences in depression or suicidality risk amongst VMAT2 inhibitors at this time.

For Chorea associated with Huntington's Disease
According to the American Academy of Neurology (AAN) guidelines on the treatment of chorea of Huntington's disease (2012), if Huntington's disease chorea requires treatment, clinicians should prescribe tetrabenazine (≤ 100 mg/day), amantadine (300 to 400 mg/day), or riluzole (200 mg/day) [Level B] for varying degrees of expected benefit. Deutetrabenazine is not addressed in the guidelines.

FDA APPROVED INDICATIONS

Deutetrabenazine:	Treatment of patients with tardive dyskinesia and chorea associated with Huntington's Disease
Valbenazine:	Treatment of patients with tardive dyskinesia and chorea associated with Huntington's Disease

APPENDIX A. Antipsychotics

First-generation antipsychotics	Second-generation antipsychotics
Chlorpromazine	Aripiprazole
Fluphenazine	Asenapine
Haloperidol	Brexpiprazole
Loxapine	Cariprazine
Molindone	Clozapine
Perphenazine	Iloperidone
Pimozide	Lumateperone
Thioridazine	Lurasidone
Thiothixene	Olanzapine
Trifluoperazine	Paliperidone
	Quetiapine
	Risperidone
	Ziprasidone

APPENDIX B. Anticholinergics commonly prescribed by psychiatry and neurology for drug-induced movement disorders.

- Benztropine
- Diphenhydramine
- Hydroxyzine
- Trihexyphenidyl

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16. Armstrong MJ, Miyasaki JM. Evidence-based guideline: pharmacologic treatment of chorea in Huntington disease: report of the guideline development subcommittee of the American Academy of Neurology. Neurology. 2012;79:597-603. (last reaffirmed 2015)

Creation Date: 5/28/21
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (ALYFTREK)

Generic	Brand	HICL	GPID	Comments
VANZACAFTOR/ TEZACAFTOR/ DEUTIVACAFTOR	ALYFTREK	50120		

GUIDELINES FOR COVERAGE

Requests for TEZACAFTOR/IVACAFTOR/DEUTIVACAFTOR will be approved if ALL the following are met:

1. Prescribed by a pulmonologist
2. Patient is at least 6 years old
3. At least one responsive mutation (per most recent Alyftrek Prescribing Information) in the cystic fibrosis (CF) transmembrane conductance regulator (CFTR) gene (verified by testing)
4. Patient has received prior treatment with elexacaftor/tezacaftor/ivacaftor (Trikafta) or has a mutation that is not responsive to elexacaftor/tezacaftor/ivacaftor, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If all above criteria are met, approve indefinitely, for VANZACAFTOR 4 MG/TEZACAFTOR 20 MG/DEUTIVACAFTOR 50 MG TABLET – max #3 tablets per day; for VANZACAFTOR 10 MG/TEZACAFTOR 50 MG/DEUTIVACAFTOR 125 MG TABLET – max #2 tablets/day.
If criteria are not met, do not approve.

ePA Questions

1. Does the patient have at least one responsive mutation, per the most recent Alyftrek Prescribing information, in the cystic fibrosis transmembrane conductance regulator (CFTR) gene? If yes, must attach supporting chart notes.
2. Has the patient failed other treatments for this indication? If yes, you must list the medication, strength, dates of treatment, and reason for discontinuation in the Provider Comment section below or attach applicable chart notes.

RATIONALE

Per Health Plan.

FDA APPROVED INDICATIONS

Treatment of cystic fibrosis (CF) in patients 6 years and older who have at least one F508del mutation or another responsive mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of at least one F508del mutation or other responsive mutations in the CFTR gene.

Limitations of use: Efficacy and safety have not been established in patients with CF other than those with at least one F508del mutation or other responsive mutation.

REFERENCES

1. Per Health Plan.

2. Alyftrek [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; 2024.

Creation date: 05/2025
Effective date: 06/2025
Reviewed date: n/a
Revised date: n/a

LUPKYNIS (VOCLOSPORIN)

Generic	Brand	HICL	GPID	Exception/Other
VOCLOSPORIN	LUPKYNIS	47077	49037	Nonformulary

GUIDELINES FOR COVERAGE:

NEW MEMBER CRITERIA:
Patient is new to KPCO within the past 90 days, has a diagnosis of lupus nephritis (LN), and is currently stable on voclosporin (Lupkynis) in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil (Cellcept) or mycophenolic acid (Myfortic) and systemic corticosteroids).

If met, approve x 6 months, max 6 capsules per day.
If not met, use Initial Criteria for review.

INITIAL CRITERIA: Must meet all the following:
1. Patient must be age 18 or older
2. Have a diagnosis of lupus nephritis (LN)
3. Must be prescribed by CPMG or affiliated Rheumatologist or Nephrologist
4. Patient has tried and failed all the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - Monotherapy with one of the following: mycophenolate mofetil (Cellcept), mycophenolic acid (Myfortic), or cyclophosphamide (Cytoxan) (PO or IV)
   - Combination treatment with one of the following regimens:
     - (mycophenolate mofetil or mycophenolic acid) + tacrolimus
     - (mycophenolate mofetil, mycophenolic acid, or cyclophosphamide (Cytoxan PO or IV)) + belimumab (Benlysta SQ or IV)

If initial criteria above are met, approve x 6 months, max 6 capsules per day.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following:
1. Patient's Lupus Nephritis has been assessed by Rheumatologist and/or Nephrologist in the past year
2. Voclosporin (Lupkynis) is being used in combination with a background immunosuppressive therapy regimen [e.g., mycophenolate mofetil (Cellcept) or mycophenolic acid (Myfortic) and systemic corticosteroids]
3. Documentation of a positive clinical response to therapy, i.e., patient has shown improvement in renal response from baseline laboratory values (eGFR) or proteinuria (urine protein: creatinine ratio) and/or clinical parameters (such as fluid retention, use of rescue drug, glucocorticoid use)

If renewal criteria are met, approve x 6 months, max 6 capsules per day.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Is the patient stable on therapy?
2. For patients noted stable on therapy, start date of therapy (MMDDYY):
3. Is the patient, or will the patient be taking this medication in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil (Cellcept) or mycophenolic acid (Myfortic) and systemic corticosteroids)? If yes, must list the medication, in Provider Comment section below or attach applicable chart notes.
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
5. Is there reasoning why alternatives (tacrolimus tablets; mycophenolate mofetil 250 mg capsules or 500 mg tablets) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions
1. Has the patient's Lupus Nephritis has been assessed by Rheumatologist and/or Nephrologist in the past year?
2. Is the requested medication being used in combination with a background immunosuppressive therapy regimen [e.g., mycophenolate mofetil (Cellcept) or mycophenolic acid (Myfortic) and systemic corticosteroids]?
3. Is there documentation of a positive clinical response to therapy, i.e., patient has shown improvement in renal response from baseline laboratory values (eGFR) or proteinuria (urine protein: creatinine ratio) and/or clinical parameters (such as fluid retention, use of rescue drug, glucocorticoid use)? If yes, please attach applicable chart notes.

FDA APPROVED INDICATIONS
Voclosporin (Lupkynis) is a calcineurin-inhibitor immunosuppressant indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis.

REFERENCES
Currently stable on medication means patient is tolerating well, appears to be effective and provider wishes to continue

Creation Date: 09/2021
Effective Date: 10/2024
Reviewed Date: 09/2024
Revised Date: 09/2024

VONOPRAZAN (VOQUEZNA)

Generic	Brand	HICL	GPID	Comments
VONOPRAZAN TABLETS	VOQUEZNA	48007	53199, 52309	Non-formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must have one of the following diagnoses and meet all the diagnosis-specific criteria below:

A. Erosive esophagitis
B. Non-erosive gastroesophageal reflux disease (GERD)
C. H. pylori infection

A. Erosive esophagitis: Must meet all the following:

1. Patient has a diagnosis of erosive esophagitis confirmed by endoscopy (e.g., Los Angeles Classification of Reflux Esophagitis Grade A-D).
2. Patient is 18 years of age or older.
3. Medication is prescribed by a gastroenterology provider.
4. Patient has failed an 8-week trial of at least 1 proton pump inhibitor at twice daily dosing, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If met, approve x 8 weeks at HICL, max 1 tablet per day.
If not met, do not approve.

B. Non-erosive gastroesophageal reflux disease (GERD): Must meet all the following:

1. Patient has a diagnosis of GERD without erosive esophagitis on endoscopy.
2. Patient is 18 years of age or older.
3. Medication is prescribed by a gastroenterology provider.
4. Patient has 4 or more days of heartburn per week.
5. Patient has failed all of the following, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    - 2-week trial of at least 1 histamine type-2 receptor antagonist at twice daily dosing
    - 8-week trial of at least 1 proton pump inhibitor at twice daily dosing

If met, approve x 4 weeks at HICL, max 1 tablet per day.
If not met, do not approve.

C. H. pylori infection: Must meet all the following:

1. Patient has a diagnosis of H. pylori infection.
2. Patient is 18 years of age or older.
3. Medication is prescribed by a gastroenterology provider.
4. Patient has failed TWO of the following treatment regimens for H. pylori infection, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
   - bismuth quadruple therapy (Omeprazole, Bismuth subsalicylate, Doxycycline or Tetracycline, Metronidazole)
   - levofloxacin triple therapy (Omeprazole, Levofloxacin, Amoxicillin)
   - concomitant therapy (Omeprazole, Clarithromycin, Amoxicillin, Metronidazole)
   - clarithromycin triple therapy (Omeprazole, Clarithromycin, Amoxicillin or Metronidazole)
   - rifabutin triple therapy (Omeprazole, Rifabutin [NF], Amoxicillin)

   If met, approve x 2 weeks at HICL, max 2 tablets per day.
   If not met, do not approve.

RENEWAL CRITERIA: Must have one of the following diagnoses and meet all the diagnosis-specific criteria below:

A. Erosive esophagitis
B. Non-erosive gastroesophageal reflux disease (GERD)
C. H. pylori infection

A. Erosive esophagitis: Must meet all the following:
1. Patient has a diagnosis of erosive esophagitis as confirmed by endoscopy (e.g., Los Angeles Classification of Reflux Esophagitis Grade A-D).
2. Medication is prescribed by a gastroenterology provider.
3. Patient has achieved and maintained clinical response while on Voquezna.

   If met, approve x 6 months at HICL, max 1 tablet per day.
   If not met, do not approve.

B. Non-erosive gastroesophageal reflux disease (GERD): Prior authorization will not be renewed for this indication.

C. H. pylori infection: Prior authorization will not be renewed for this indication.

ePA Questions
Initial Review Questions
Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Erosive esophagitis; Non-erosive gastroesophageal reflux disease (GERD); H. pylori infection]

QUESTIONS BASED ON DIAGNOSIS SELECTED
Erosive esophagitis

3. Does the patient have a diagnosis of erosive esophagitis confirmed by endoscopy (e.g., Los Angeles Classification of Reflux Esophagitis Grade A-D)? If yes, must attach chart notes with supporting documentation.
4. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

Non-erosive gastroesophageal reflux disease (GERD)

1. Does the patient have a diagnosis of non-erosive esophagitis confirmed by endoscopy? If yes, must attach chart notes with supporting documentation.
2. Days of heartburn per week:
3. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dosing, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

H. pylori infection

1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dosing, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.

Renewal Review Questions

Diagnosis associated with this request: [check boxes for all diagnoses listed in criteria: Erosive esophagitis; Non-erosive gastroesophageal reflux disease (GERD); H. pylori infection]

QUESTIONS BASED ON DIAGNOSIS SELECTED

Erosive esophagitis

1. Does the patient have a diagnosis of erosive esophagitis confirmed by endoscopy (e.g., Los Angeles Classification of Reflux Esophagitis Grade A-D)? If yes, must attach chart notes with supporting documentation.
2. Has the patient achieved and maintained clinical response while on vonoprazan (Voquezna)?

RATIONALE

The approval of vonoprazan for the treatment of all grades of EE is based on results of the PHALCON-EE study, which compared vonoprazan to lansoprazole in the healing and maintenance of EE. Vonoprazan met the primary endpoint of noninferiority to lansoprazole 30 mg once daily in the healing phase and 15 mg once daily in the maintenance phase. Vonoprazan also demonstrated superior healing rates (by a difference of 17.6%) compared to lansoprazole 30 mg once daily in patients with moderate to severe disease (Los Angeles Grade C/D) at Week 2 and improved maintenance rates of healed EE compared to lansoprazole 15 mg once daily in all randomized patients through Week 24 as preplanned secondary endpoints. The rates of adverse events were comparable. It is unclear whether PHALCON-EE would have shown similar results with a more potent PPI comparator, a twice-daily PPI comparator, or a higher PPI dose in the maintenance phase. Vonoprazan provides an alternative treatment option for patients with EE who do not respond to lower-cost, generic, first-line PPI therapy at twice daily dosing for at least 8 weeks. Prior authorization will also ensure patients have a diagnosis of erosive esophagitis as confirmed by endoscopy. Renewal will require achievement and/or maintenance of clinical response while on vonoprazan. A quantity limit of 1 tablet per day has been applied given the 10 mg and 20 mg tablets are the same acquisition cost.

FDA APPROVED INDICATIONS

For healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
To maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
For the relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults.

In combination with amoxicillin and clarithromycin for the treatment of H. pylori infection in adults.
In combination with amoxicillin for the treatment of H. pylori infection in adults.

REFERENCES

1. IPD Analytics. Rx Brief: Voquezna (vonoprazan). November 2023.
2. MedImpact. Standard Commercial Drug Formulary Prior Authorization Guidelines: Vonoprazan.
3. Voquezna [Prescribing Information]. Buffalo Grove, IL: Phathom Pharmaceuticals, Inc. May 2024.

Creation Date: 07/2024
Effective Date: 10/2024
Reviewed Date: 09/2024
Revised Date: 09/2024

VOSORITIDE (VOXZOGO)

Generic	Brand	HICL	GPID	Comments
VOSORITIDE	VOXZOGO	47677		Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Prescriber must be a Pediatric Endocrinologist or Geneticist
2. Bone age is either females less than 14 or males less than 16
3. Diagnosis of achondroplasia documented and genetic testing confirming FGFR3 mutation associated with achondroplasia

If initial criteria are met, approve at HICL x 12 months.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA: Must meet all the following criteria:
1. Individual's condition responded while on therapy (example: improved limb proportion/anthropometric criteria) as provided by pediatric endocrinologist or geneticist
2. Open epiphyses or bone age is either females less than 14 or males less than 16

If renewal criteria are met, approve at HICL x 12 months.
If renewal criteria are not met, do not approve.

ePA Questions
Initial Review Questions
1. Current bone age of the patient:
2. Has the patient completed genetic testing that confirms FGFR3 mutation associated with achondroplasia?

Renewal Review Questions
1. Current bone age of the patient:
2. Has the patient's condition improved while on therapy?

REFERENCES
Specialty drug to be dispensed by Accredo Specialty Pharmacy, Memphis, TN

Creation Date: 05/2022
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 11/2023

ZAVEGEPANT (ZAVZPRET)

Generic	Brand	HICL	GPID	Comments
ZAVEGEPANT	ZAVZPRET	48771	53837	Intranasal CGRP antagonist; "Gepant" for acute tx

GUIDELINES FOR COVERAGE
Must meet all the following:
1. Prescribed for acute treatment of migraine with or without aura
2. Patient must be age 18 or older
3. Patient meets the following step therapy requirements, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception:
    a. Patient with failure of (after at least one month of therapy), intolerance to, or contraindication to, at least one triptan
    b. Patient with failure of (after at least one month of therapy), intolerance to, or contraindication to, dihydroergotamine nasal spray (Migranal preferred)
    c. Patient with failure of (after at least one month of therapy), intolerance to, or contraindication to, ubrogepant (Ubrelvy) and/or Rimegepant (Nurtec ODT)

If criteria are met, approve indefinitely at HICL, max 1 carton containing 6 single use nasal spray units per 30 days [MDD 0.2].
If criteria are not met, do not approve.

ePA Questions
1. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
2. Is there reasoning why alternatives (sumatriptan tablets, rizatriptan tablets, rizatriptan ODT, eletriptan tablets, naratriptan tablets, sumatriptan nasal spray (5 mg/act, 20 mg/act), sumatriptan succinate injectable 6 mg/0.5 mL) are not suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

Available triptan/ergotamine options:

Generic	Brand	Formulations available
Almotriptan	Axert	Tablet
Eletriptan	Relpax	Tablet
Frovatriptan	Frova	Tablet
Naratriptan	Amerge	Tablet
Rizatriptan	Maxalt/Maxalt MLT	Tablet, ODT
Sumatriptan	Imitrex, Sumavel, Onzetra, Zembrace	Tablet, nasal spray, injection
Zolmitriptan	Zomig/Zomig ZMT	Tablet, ODT, nasal spray
Ergotamine	Ergomar	Sublingual
Ergotamine/caffeine	Cafergot	Tablet, suppository

Dihydroergotamine	Migranal, Trudhesa D.H.E.	Nasal spray, injection

ODT=orally disintegrating tablet

True contraindications to triptan class
- Ischemic coronary artery disease including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina)
- History of stroke or transient ischemic attack
- Peripheral vascular disease
- Ischemic bowel disease
- Uncontrolled hypertension
- Hemiplegic or basilar migraine
- Wolff-Parkinson-White syndrome

Quantity Limits for Novel Oral Migraine Treatment

Medication	Dosage Strength	Maximum quantity limit for 30 days	Notes
Acute migraine indication			
Ubrogepant (Ubrelvy)	50 mg, 100 mg	10	Tablet splitting of the 100 mg tablet has been approved and should be recommended for all patients prescribed to take a dose of 50 mg at onset of migraine
Rimegepant (Nurtec ODT)	75 mg	8	Tablet splitting n/a
Zavegepant (Zavzpret)	10 mg	6	Available as a ready-to-use, unit-dose disposable nasal spray device that contains 10 mg of zavegepant. Each carton contains 6 nasal spray units.
Lasmiditan (Reyvow)	50 mg, 100 mg	8	Tablet splitting NOT approved Approved doses to take at onset of migraine are 50 mg, 100 mg, or 200 mg, however, only 50 mg and 100 mg tablet strengths are available
Preventive migraine indication			
Atogepant (Qulipta)	10 mg, 30 mg, 60 mg	30	Tablet splitting of the 60 mg tablet has been approved and should be recommended for all patients prescribed 30 mg daily
Rimegepant (Nurtec ODT)	75 mg	16	Tablet splitting n/a

CGRP-Directed Migraine Medications

Generic (Brand)	Route CGRP "class"	Acute Migraine Approval	Preventive Migraine Approval
Eptinezumab (Vyepti)	IV, CGRP-mAb	X	100 mg or 300 mg Q 3 mo
Erenumab (Aimovig)	SC, CGRP-mAb	X	70 mg or 140 mg Q mo
Fremanezumab (Ajovy)	SC, CGRP-mAb	X	225 mg Q mo, OR 675 mg Q 3 mo
Galcanezumab (Emgality)	SC, CGRP-mAb	X	240 mg loading dose, then 120 mg Q mo
Atogepant (Qulipta)	Oral, CGRP antagonist "gepant"	X	10 mg, 30 mg or 60 mg daily
Rimegepant (Nurtec ODT)	Orally disintegrating tablet, CGRP antagonist "gepant"	75 mg at onset do NOT repeat dose	75 mg every OTHER day
Ubrogepant (Ubrelvy)	Oral, CGRP antagonist "gepant"	50 mg or 100 mg at onset, may repeat in 2 hours	X
Zavegepant (Zavzpret)	Intranasal, CGRP antagonist "gepant"	10 mg at onset do NOT repeat dose	X

RATIONALE

Acute migraine indication

At this time, there is a lack of compelling data for ubrogepant, rimegepant, or lasmiditan to replace triptans as the gold standard for acute migraine treatment, considering cost and familiarity [1]. The 2019 AHS update briefly mentions role of emerging acute therapies as these options were not approved until about one year after its publication AHS [2]. Reiterated is the role for these novel treatment options, which do not result in constriction of blood vessels, for patients with vascular-related contraindications to triptans. Also acknowledged is the higher cost of these new agents compared to the generic availability of oral triptans and recommendation for ubrogepant, rimegepant, or lasmiditan to be used only in patients who have contraindications to triptans or who have failed to respond or tolerate at least two oral triptans. Patients should treat at least 2 migraine attacks before a provider makes a determination on efficacy and tolerability.

A comparative analysis of ubrogepant, lasmiditan, and rimegepant was performed by the Institute of Clinical and Economic Review (ICER) to assess the effectiveness and safety of these medications. [3] In comparison to placebo, ubrogepant [odds ratio (OR) 2.12], rimegepant [OR 2.11], and lasmiditan [OR 3.01] showed higher odds of achieving pain freedom at 2 hours. The analysis did not demonstrate statistically significant differences among the medications in pain freedom at two hours, absence of the most bothersome symptoms at two hours, and no disability at two hours in comparison to one another. On the other hand, in comparing triptans and ubrogepant, sumatriptan [OR 4.09] and eletriptan [OR 5.6] have shown to have higher odds of pain freedom at two hours than ubrogepant.

With regards to safety, nausea was the most common adverse effect seen with the use of ubrogepant. For single migraine attacks, ubrogepant and rimegepant had similar odds of experiencing any adverse event compared to triptans and placebo, but ubrogepant [OR 5.10] had lower odds for treatment-emergent adverse events compared to lasmiditan. Also, the risk of medication overuse headaches, which is present with triptans, is unknown with repeated use of ubrogepant and rimegepant.

In terms of cost per quality-adjusted life year (QALY) gained threshold, ubrogepant is considered cost effective at $40,000 per QALY gained. Ubrogepant has similar QALY values compared to rimegepant. Comparing ubrogepant and triptans, the cost of ubrogepant is substantially greater than triptans and has less QALYs than sumatriptan and eletriptan.

If choosing one of these new acute medication options, pharmacokinetics and characteristics of a patient's migraine attacks should be kept in mind. Lasmiditan has pharmacokinetic characteristic similar to faster-acting triptans and most closely similar to almotriptan and eletriptan in regard to onset of action, time to maximum concentration, and half-life. Ubrogepant and rimegepant have slower onsets of action but longer half-lives which may be helpful for patients experiencing migraine recurrence. Dosing recommendations should also be considered when using these new medications including if a dose can be repeated in 2 hours, dose adjustments with other disease states, and potential for drug interactions (Table 1).

As the only gepant medication supplied in a non-oral formulation, zavegepant 10 mg nasal spray could be particularly useful in patients with characteristics associated with guideline-based recommendations for non-oral therapies, including headache attacks with severe nausea or vomiting or rapidly escalating headache pain, as well as for patients in whom oral forms are associated with inadequate response, slow onset of action, or poor tolerability. Additional trials are needed to provide evidence for the long-term safety and consistency of effect over time.

Using triptans as part of a combination therapy regimen can be useful (although possibly underutilized in clinical practice) and careful selection of agents to combine can achieve synergistic pharmacokinetic effects. For example, in patients needing a quick onset of action to relieve the migraine pain but also a longer duration to avoid migraine recurrence, a fast acting triptan (e.g. nasal spray, injectable, or faster-acting oral) can be combined with a long-acting NSAID. Effectiveness and safety of combining gepants or lasmiditan with other acute therapies is less defined. Pertaining to other acute migraine medications that could be utilized, study protocols for phase 3 clinical trials differed slightly, but all included specific recommendations for what patients could or could not take within 24 hours or 48 hours after the initial dose of the study medication. Due to the potential for duplicating mechanisms, it appears logical to avoid the combination of lasmiditan with a triptan, but there may be a role for combining lasmiditan with an analgesic and/or antiemetic if needed. While gepants and triptans do not appear to directly have overlapping mechanisms, they do both target the trigeminovascular system, and thus the utility in combining a gepant with a triptan remains unclear. Given the slower onset of gepants, there may be clinical situations where combining a gepant with a faster acting NSAID could be beneficial. Overall, more data is needed.

More real-world utilization and long-term safety and efficacy data is needed for these new acute medication options, but the development of these therapy options fills a long-standing gap in therapy for patients with multiple trials and failures of triptans or those with contraindications to this class.

FDA APPROVED INDICATIONS

Zavegepant: Acute treatment of migraine with or without aura in adults

REFERENCES

1. Moreno-Ajona D, Pérez-Rodríguez A, Goadsby PJ. Gepants, calcitonin-gene-related peptide receptor antagonists: what could be their role in migraine treatment? Curr Opin Neurol. 2020;33(3):309-315.

2. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache. 2019;59(1):1-18.
3. Atlas S, Touchette D, Agboola F, et al. Acute Treatments for Migraine: Effectiveness and Value. Institute for Clinical and Economic Review. February 25, 2020. Available at: icer-review.org/wp-content/uploads/2019/06/ICER_Acute-Migraine_Final-Evidence-Report_updated_030320.pdf. Accessed August 27, 2020.
4. Ashina M. Migraine. N Engl J Med 2020;383:1866-76.
5. Yang CP, Liang CS, Chang CM, et al. Comparison of new pharmacologic agents with triptans for treatment of migraine: a systematic review and meta-analysis. JAMA Netw Open. 2021;4(10):e2128544.

Creation Date: 08/2020
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

ZILUCOPLAN (ZILBRYSQ)

Generic	Brand	HICL	GPID	COMMENTS
ZILUCOPLAN	ZILBRYSQ	49273		

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:

A. General criteria for all neurology-related requests: Must meet all the following:
   1. The patient is 18 years or older
   2. Prescribed by a neurologist
   3. Positive serologic test for anti-acetylcholine receptor (AChR) antibodies[§]
   4. Patient must have a diagnosis of Generalized Myasthenia Gravis (gMG)
   5. No history of thymic neoplasms or a thymectomy within 12 months prior to treatment initiation
   6. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
   7. Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score of at least 6 at baseline
   8. Patient is currently taking chronic corticosteroid with pyridostigmine as prescribed unless there is an intolerance or contraindication to one or both
   9. The patient has tried and failed, or has contraindication to, all of the following therapies, or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception
      a. ONE nonsteroidal immunosuppressive therapy (NSIST): azathioprine[¥], cyclophosphamide[¥], mycophenolate mofetil[¥], cyclosporine[¥], methotrexate[¥]
      b. TWO biologic therapies: rituximab or its biosimilar, chronic IVIG, efgartigimod (Vyvgart) [requires authorization], efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) [requires authorization], ravulizumab (Ultomiris) [requires authorization]

If met, approve at HICL x indefinitely.
If not met, do not approve.

ePA Questions
Initial Review Questions
1. Does the patient have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies?
2. Does the patient have history in the last 12 months of thymic neoplasms or a thymectomy?
3. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of this patient (1-5):
4. Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) score prior to treatment with zilucoplan:
5. Date of MG-ADL score:
6. Has the patient failed other treatments for this indication? If yes, must list the medication, strength, dates of treatment, and reason for discontinuation in Provider Comment section below or attach applicable chart notes.
7. Is there reasoning why alternatives (chronic corticosteroid with pyridostigmine, azathioprine tablets (50 mg), cyclosporine capsules (25 mg, 100 mg), methotrexate 2.5 mg tablets or 25mg/ml vials, mycophenolate mofetil 250 mg capsules or 500 mg tablets, cyclophosphamide capsules) are not

suitable? If yes, must list reasoning in Provider Comment section below or attach applicable chart notes.

RATIONALE
Treatment – Refractory Myasthenia Gravis
Summary of current biological therapies for gMG.

- Complement C5 inhibitors:
  - Eculizumab (Soliris) for IV infusion– approved 2017
  - Ravulizumab (Ultomiris) for IV infusion – approved 4/2022
  - Zilucoplan (Zilbrysq) for SC self-administration – approved 10/2023
- FcRn inhibitors (aka neonatal Fc receptor inhibitors- halts IgG recycling):
  - Efgartigimod (Vyvgart) for IV infusion – approved 12/2021
  - Efgartigimod and Hyaluronidase (Vyvgart-Hytrulo for SC injection by health care professional) – approved 12/2021
  - Rozanolixizumab (Rystiggo) (for SC infusion by health care professional) – approved 6/2023

Both 2020 treatment guidelines, lack of comparative clinical trial data, and side effect profile indicate that zilucoplan and other complement inhibitors should be used as 3rd line treatments, specifically when first and second-line therapies fail. Though low utilization is expected, given its high cost, exceedingly judicious prescribing with the guidance of PA guidelines is warranted. The KP ETSP treatment guidelines recommend that rituximab +/- oral immunosuppressants be used prior to the newer agents. Off-label use of rituximab is supported by a CMS-approved Compendia resource. LexiComp categorizes off-label rituximab for use in Myasthenia Gravis (refractory) with level of evidence [B,G] and Micromedex categorizes off-label use of rituximab for Myasthenia Gravis (refractory); Strength of recommendation Adult, Class1. Strength of evidence, Adult Category B (all affirmed November 25, 2024).

FDA APPROVED INDICATIONS:
Generalized Myasthenia gravis

APPENDIX
[¥] Peer-Reviewed Evidence-Based and CMS Compendia Approved Therapies: rituximab, azathioprine, mycophenolate

[§]Positive antibody status does NOT include anti-muscle-specific receptor tyrosine kinase (MuSK) or anti-low-density lipoprotein receptor-related protein (LRP4) antibodies.

REFERENCES
1. Zilbrysq subcutaneous injection [prescribing information]. Symra, GA: UCB: October 2023.
2. National Institute of Neurological Disorders and Stroke (NINDS). Myasthenia Gravis Fact Sheet. National Institutes of Health (NIH) Publication No. 17-768. Publication last updated: March 2020. Available at: https://www.ninds.nih.gov/sites/default/files/migratedocuments/myasthenia_gravis_e_march_2020_508c.pdf. Accessed on February 12, 2024.
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87:419–425.
4. Howard JF, Bresch S, Genge A, et al on behalf of the RAISE study team. Safety and efficacy of zilucoplan in patients with generalized myasthenia gravis (RAISE): a randomized, double-blind, placebo-controlled, phase 3 study. Lancet Neurology. 2023;22:395-406.

5. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. Neurology. 2021;96(3):114-122.

Creation Date: 03/2024
Effective Date: 02/2025
Reviewed Date: 01/2025
Revised Date: 01/2025

ZOLMITRIPTAN NASAL SPRAY - STEP THERAPY

Generic	Brand	HICL	GPID	Exception/Other
ZOLMITRIPTAN NASAL SPRAY	ZOMIG		18972	Generic - Formulary

Step Therapy Criteria

Patient has tried and failed, or had an intolerance/allergy to any sumatriptan product (oral, nasal or injection - HICL 12779), or the provider has submitted justification and supporting clinical documentation that states one of the following: i) the required drug(s) will likely cause an adverse reaction or harm; ii) the required drug(s) is/are ineffective based on known clinical characteristics of the patient or drug; iii) the patient has tried and failed the required drug(s) or another drug in the same pharmacological class or with the same mechanism of action, and the use of the drug was discontinued due to lack of efficacy, diminished effect or an adverse event; iv) the patient is stable on the requested drug after undergoing step therapy or after having sought and received a step therapy exception.

If met, override restriction only for generic zolmitriptan nasal spray at GPID-g indefinitely
If not met, do not approve.

RATIONALE
Per Health Plan

REFERENCE
Note: this product does have a quantity limit per fill applied to it. The claims will look for the quantity limit first and if that is met will begin the step therapy look back for HICL 12779 in the claim history.

Since Zomig nasal spray is available as a generic, the brand will remain non-formulary.

Creation date: 01/2022
Effective date: 02/2025
Reviewed date: 01/2025
Revised date: 01/2025

ZONISAMIDE 100 MG/5 ML SUSPENSION - AGE RESTRICTION CRITERIA

Generic	Brand	HICL	GPID	Exception/Other
ZONISAMIDE SUSPENSION 100 MG/5 ML	ZONISADE		52582	

GUIDELINES FOR COVERAGE

INITIAL AND RENEWAL CRITERIA: ONE of the following criteria must be met:
1. Patient is less than or equal to 10 years old.
2. Patient is using an alternative administration route, such as a gastrostomy tube.
3. Dose cannot be administered by using any combinations of the zonisamide capsules.
4. Patient cannot swallow capsules.

If any criterion is met, approve x1 year.
If no criteria are met, do not approve, and suggest changing to capsule strengths that can be used in combination to achieve desired dose.

ePA Questions
1. Is the patient using an alternative administration route, such as a gastrostomy tube? If yes, must attach applicable chart notes.
2. Is the patient unable to swallow tablets/capsules whole? If yes, must attach applicable chart notes.

RATIONALE
Per Health Plan.

General Clinical Criteria for solutions/suspension
1. Age is less than or equal to 10 years old
2. Presence of gastrostomy
3. Dose does not allow use of halved, whole or combo of tablet
4. Dose does not use whole capsule (cannot “cut” capsules in half)
5. Clinical condition where unable to swallow crushed/opened tablets/capsules (i.e., esophageal stricture)

FDA APPROVAL
1. Adjunctive therapy in the treatment of focal (partial) onset seizures in patients 16 years of age or older

REFERENCES
Administration: Pediatric
Oral: May be administered without regard to meals.
Capsule: Swallow capsule whole; do not crush, chew, or break capsule.

Creation date: 09/2023
Effective date: 10/2024
Reviewed date: 09/2024
Revised date: 09/2024

ZURANOLONE (ZURZUVAE)

Generic	Brand	HICL	GPID	Exception/Other
ZURANOLONE	ZURZUVAE	49127	43601, 45723, 48261	Non-Formulary

GUIDELINES FOR COVERAGE

INITIAL CRITERIA: Must meet all the following:
1. Patient must be between 18 and 45 years of age.
2. Patient has a diagnosis of postpartum depression (PPD).
3. Moderately severe to severe depression which correlates to a Patient Health Questionnaire-9 (PHQ-9) score of at least 15.
4. Treatment initiated within 12 months postpartum.
5. Patient must not have active psychosis, bipolar disorder, schizophrenia, schizoaffective disorder, or alcohol or drug use disorders.
6. Patient must not have received a full 14-day course of past treatment in current episode of PPD (typically conceptualized as onset no earlier than third trimester of pregnancy and up to 12 months postpartum)

If initial criteria are met, approve at HICL x 2 weeks only.
If initial criteria are not met, do not approve.

RENEWAL CRITERIA:
This drug is not eligible for renewal. Zuranolone use beyond 14 days in a single treatment course for PPD has not been studied and is not recommended.

ePA Questions
1. Current Patient Health Questionnaire-9 (PHQ-9) score:
2. Date of completion of Current PHQ-9 (MMDDYY):
3. How many months postpartum is this patient?
4. Does the patient have any of the following (Check all that apply):
    a. active psychosis
    b. bipolar disorder
    c. schizophrenia
    d. schizoaffective disorder
    e. alcohol or drug use disorders
5. Has the patient completed a 14-day course of zuranolone treatment at any time during this episode of PPD?

RATIONALE
Criteria for drug approval closely matches clinical trial criteria and KP emerging therapeutics strategy program (ETSP) interregional practice recommendations. A full course of treatment is defined as a 14-d course of zuranolone at any dose.

Zuranolone is the only FDA approved *oral* treatment option for postpartum depression. Zuranolone offers a novel mechanism of action as a neuroactive steroid that is fast acting (e.g. symptom improvement noted as early as Day 3) with a 14-d treatment course yielding lasting effects up to 4 weeks after last zuranolone dose (has not been studied longer). However, zuranolone, should not be used if pregnant, caution warranted if breastfeeding*, has a boxed warning regarding impaired ability to

drive or engage in other potentially hazardous activities due to CNS depressant effects for up to 12 hours after administration during the 14-day treatment course**, must be taken with 400-1,000 calories, has clinically significant interactions with CYP3A4 inducers and inhibitors, and is not known to treat other comorbid psychiatric conditions (e.g. GAD, PTSD) or depressive illness e.g. bipolar depression. Zuranolone has not been studied head-to-head with traditional treatment options. Updated ACOG guidelines for the treatment of depression during pregnancy and postpartum recommend off-label SSRIs as first line with serotonin norepinephrine reuptake inhibitors as reasonable alternatives for moderate-severe PPD. For milder PPD symptoms, cognitive behavioral therapy has been shown to be effective.

*Data suggests <1% zuranolone enters breastmilk. The boxed warning re: CNS depressant effects and impaired driving ability urges caution even with small amount of infant exposure and risk/benefit discussion of various infant feeding options. Conversely, many antidepressants are considered safe in breastfeeding.

**Clinical trials suggest zuranolone is generally well-tolerated with common adverse events reported as somnolence, dizziness, and sedation. 1 patient receiving zuranolone 30mg dose experienced a confusional state. It does have the associated boxed warning re: impaired driving ability and CNS depressant effects.

FDA APPROVED INDICATIONS
Depression, postpartum. Treatment of postpartum depression in adults.

REFERENCES
1. ACOG clinical practice guideline: treatment and management of mental health conditions during pregnancy and postpartum. Obstetrics and Gynecology; June 2023:141(5):1262-1288.
2. ETSP Interregional Practice Recommendations: Brexanolone (Zulresso) and Zuranolone (Zurzuvae) for Treatment of Postpartum Depression. November 2023.
3. Zurzuvae. Package Insert. Biogen MA Inc. November, 1, 2023.
4. Deligiannidis KM, et al. Effect of zuranolone vs placebo in postpartum depression. JAMA Psychiatry. 2021;78(9):951-959.
5. Deligiannidis KM, et al. Effect of zuranolone on concurrent anxiety and insomnia symptoms in women with postpartum depression. J Clin Psychiatry. 2023;84(1):22m14475.
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Creation Date: 03/2024
Effective Date: 04/2025
Reviewed Date: 03/2025
Revised Date: 03/2025

KAISER PERMANENTE

KAISER COLORADO HMO MR GUIDELINES

INDEX

A

B

C

D

E

F

G

H

I

J

K

L

M

N

O

P

Q

R

S

T

U

V

W

X

Y

Z