Kaiser Permanente Mid-Atlantic States Region (KPMAS)

Virginia Medicaid

Prior Authorization and Step Therapy Criteria

Effective 07/01/2024

Reference:

1. KPMAS Regional Pharmacy and Therapeutics (P&T) Committee
   P&T Approval/Revision Date: 06/07/2024, 12/01/2023, 10/06/2023, 08/04/2023, 06/02/2023, 04/07/2023, 02/03/2023, 12/06/2022, 10/04/2022, 07/05/2022, 06/07/2022, 04/05/2022; 02/04/2022; 12/3/2021, 05/07/2021, 04/05/2021, 02/05/21, 11/06/20, 9/3/2020; 6/5/2020; 12/6/2019; 10/5/2018

2. DMAS Virginia Medicaid's Preferred Drug List/Common Core Formulary
   https://www.virginiamedicaidpharmacyservices.com/provider/preferred-drug-list/

Table of Contents

Agents to Treat Multiple Sclerosis – Modestly Effective Therapy

Last revised 06/09/2023 (Effective 07/01/2023)

Generic	Brand
PEGINTERFERON BETA-1A	PLEGRIDY SOPN
DIROXIMEL FUMARATE	VUMERITY

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Therapy:

- Member cannot be changed to a preferred drug. (e.g. Avonex, Betaseron, Copaxone, Tecfidera, Kesimpta) Acceptable reasons include: **AND**
  - Allergy to preferred drug.
  - Contraindication to or drug-to-drug interaction with preferred drug.
  - History of unacceptable/toxic side effects to preferred drug.
  - Member's condition is clinically stable; changing to a preferred drug might cause deterioration of the member's condition.
- Member has therapeutic failure of at least two preferred drugs within the same class as appropriate for diagnosis

Additional criteria for Vumerity only:

- Member tried and failed at least one preferred injectable (see above) and Tecfidera
- Member is using for Vumerity's approved indication - treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and/or active secondary progressive disease?

Agents to Treat Multiple Sclerosis – Highly Effective Therapy

Generic	Brand
CLADRIBINE	MAVENCLAD
SIPONIMOD FUMARATE	MAYZENT
OZANIMOD	ZEPOSIA
Prior Authorization Criteria follows the state's criteria (DMAS)	
Length of Authorization: 12 months	

Initial Review Criteria for Mavenclad, Mayzent and Zeposia:

- Member is ≥18 years old AND
- Has had a baseline MRI before initiating the first treatment course, within 3 months prior, AND
- Has at least one of the following diagnoses, AND:
  - Relapsing-remitting Disease (RRMS)
  - Secondary Progressive Disease (SPMS) with relapses
  - Clinically Isolated Syndrome (CIS)
  - Member has had ≥ 1 relapse within the previous two years
  - Member has new and unequivocally enlarging T2 contrast enhancing lesions as evidenced by MRI and has had ≥ 1 relapse in the previous 12 months
- Failed an adequate trial (≥3 months) of, or has a documented allergy or intolerance to, or is not a candidate for other preferred MS agents (e.g., Avonex, Betaseron, Copaxone), AND
- Member is NOT using requested drug therapy in addition to another DMT, AND
- Member has been screened for the presence of tuberculosis according to local guidelines, AND
- Member has been tested for antibodies to the varicella zoster virus (VZV) or received immunization for VZV four weeks prior to beginning therapy, AND
- Member has been evaluated and screened for the presence of hepatitis B and hepatitis C virus (HBV/HCV) prior to initiating treatment, AND

If the authorization is for Mavenclad:

- Lymphocyte count ≥ 800 cells/mL prior to start of therapy, AND
- Women of childbearing age are not pregnant AND that members of reproductive potential use effective contraception during treatment with therapy and for at least six months after the last dose, AND
- Member does not have human immunodeficiency virus (HIV) infection

If the authorization is for Mayzent:

- Member has been tested for CYP2C9 variant status to determine genotyping (required for dosing)
- Attest that member does not have CYP2C9*3/*3 Genotype

If the authorization is for Mayzent or Zeposia specific

- Member obtained a baseline electrocardiogram (ECG), AND
- Member had a baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment, AND
- Attest that the member does NOT have any of the following: AND

- Recent Myocardial Infarction
- Unstable Angina
- Stroke
- Transient Ischemic Attack
- Decompensated Heart Failure with Hospitalization
- Class III/IV Heart Failure within the Previous 6 Months
- Prolonged QTc Interval at Baseline (> 500 msec)
- History of Mobitz Type II second or third-degree atrioventricular block or sick sinus syndrome (unless treated with a functioning pacemaker)

Mayzent™ will NOT be used in combination with the following:

- Moderate or strong CYP3A4 inducers (e.g., modafinil, efavirenz, etc.) in members with a CYP2C9*1/*3 and CYP2C9*2/*3 genotype
- Drug regimens that contain CYP2C9/CY3A4 dual inhibitors (e.g., fluconazole)
- Moderate CYP2C9 inhibitor plus a moderate-to-strong CYP3A4 inhibitor
- Other antineoplastic, immunosuppressive or immunomodulating drugs

Updated Criteria: Zeposia

- Confirmation that Zeposia will not be used in the following circumstances:
- Initiating therapy after previous treatment with alemtuzumab; OR
- In combination with:
- Monoamine oxidase inhibitor (MAOI) (e.g., selegiline, phenelzine, linezolid); OR
- Drugs known to prolong the QT-interval (e.g., fluoroquinolone or macrolide antibiotics, venlafaxine, fluoxetine, quetiapine, ziprasidone, sumatriptan, zolmitriptan), OR
- Strong cytochrome p450 2C8 (CYP2C8) inhibitors (e.g., gemfibrozil) or inducers (e.g., rifampin); OR
- BCRP inhibitors (e.g., cyclosporine, eltrombopag); OR Adrenergic or serotonergic drugs which can increase norepinephrine or serotonin (e.g., opioids, selective serotonin reuptake inhibitors [SSRIs], selective norepinephrine reuptake inhibitors [SNRIs], tricyclics, tyramine); OR
- Foods with large amounts of tyramine (e.g., > 150 mg), such as aged cheeses, cured meats, craft/unfiltered beers, beans); OR
- Other antineoplastic, immunosuppressive or immunomodulating drugs (Note: if there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive effects); AND
- Patient will not receive live vaccines during and at least 4 weeks prior to and 12 weeks after treatment; AND
- Patient does not have an active infection, including clinically important localized infections

Neuromuscular Transmission – Potassium Channel Blocker

Adapted from DMAS Preferred Drug List

Last revised 10/02/2023 (Effective 12/05/2023)

Generic	Brand
DALFAMPRIDINE	AMPYRA

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member has a documented diagnosis of multiple sclerosis (MS), **AND**
- Member has a gait disorder or difficulty walking, **AND**
- Member has documentation of baseline timed 25-foot walk test, **AND**
- Member's renal function estimated (using glomerular filtration rate (eGFR) or creatinine clearance (CrCl) to be >50 mL/min, **AND**
- Member does not have history of seizures
- Member has tried other preferred agents (e.g., Avonex, Betaseron, Copaxone)

Continuation of Therapy:

- Member has current documentation of timed 25-foot walk test

Neuromuscular Transmission – Potassium Channel Blocker (Cont'd)

Last revised: 2/6/2024

Generic	Brand
AMIFAMPRIDINE PHOSPHATE	FIRDAPSE

Prior Authorization Criteria:
Length of Authorization: • Initial: 6 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is a Neurologist, AND • Documented confirmed diagnosis of Lambert-Eaton metabolic syndrome (LEMS) based on clinical, serologic, and electrodiagnostic exam AND • Patient is ≥18 years for Firdapse, AND • Patient is ambulatory, AND • Patient does NOT have a history of seizures or active brain metastases • Forced vital capacity (%FVC) ≥60%
Continuation of Therapy Criteria: • ECG, renal function, and liver function testing completed annually AND • Patient is still ambulatory AND • Patient has NOT developed epileptic seizures AND • Patient is adherent to therapy AND • Patient has documented improvement from baseline

Amyotrophic Lateral Sclerosis Agents

Last Revised 2/6/2024

Generic	Brand	HICL	GSN	Representative NDC
EDARAVONE	RADICAVA ORS STARTER KIT SUSP 105 MG/5 ML	44252	083378	70510232101
EDARAVONE	RADICAVA ORS SUSP 105 MG/5 ML	44252	083378	70510232201

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescriber is a Neurologist,
- AND ALS Functional Rating Scale –Revised (ALSFRS-R) score of 2 points or better on each of the 12 items within past 2 months,
- AND clinical ALS diagnosed by a neurologist with duration of 2 years or less from onset for first symptom,
- AND forced vital capacity (%FVC) ≥ 80% within past 2 months,
- AND patient has had a trial of riluzole

Continuation of Therapy Criteria:

- Documentation of positive clinical response,
- AND specialist follow-up occurred since last review,
- AND patient does not have any of the following:
    - %FVC ≤ 50% and blood gas PaCO2 >45 mmHg
    - Significant clinical decline based on ALSFRS-R and/or %FVC status
    - Non-adherence to follow-up assessments
    - Patient is requiring hospice care

Amyotrophic Lateral Sclerosis Agents (Cont'd)

Last Revised 2/6/2024

Generic	Brand	HICL	GSN	Representative NDC
SODIUM PHENYLBUTYRATE-TAURURSODIOL	RELYVRIO PACK 3-1 GM	48081	083686	73063003503

Prior Authorization Criteria:
Length of Authorization: • Initial: 3 months • Reauthorization: 6 months
Initial Review Criteria: • Prescriber is a Neurologist, • AND clinical ALS diagnosed by a neurologist with duration of 18 months or less from onset for first symptom, • AND forced vital capacity (%FVC) > 60%, • AND patient has had a trial of riluzole • AND patient does not have a tracheostomy
Continuation of Therapy Criteria: • Documentation of positive clinical response, • AND Neurologist follow-up occurred since last review, • AND patient does not have any of the following: o %FVC ≤ 50% and blood gas PaCO2 >45 mmHg o Patient is requiring a tracheotomy or non-invasive ventilation all day o Significant clinical decline based on ALSFRS-R and/or %FVC status o Non-adherence to follow-up assessments o Patient is requiring hospice care

Nuclear Factor Erythroid 2-Rel. Factor 2 Activator

Last Revised 2/6/2024

Generic	Brand	HICL	GSN	Representative NDC
OMAVELOXOLONE	SKYCLARYS CAPS 50 MG	48741	084475	73179025090

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescriber is a Neurologist, Pediatric Neurologist, or Medical Geneticist,
- AND patient is ≥16 years and ≤40 years of age,
- AND patient has diagnosis of Friedreich's ataxia with confirmatory genetic testing,
- AND patient has a modified Friedreich's Ataxia Rating Scale (mFARS) score ≥20 and ≤80,
- AND patient has a left ventricular ejection fraction (LVEF) ≥40%,
- AND patient is using effective contraception, if patient is of childbearing potential

Continuation of Therapy Criteria:

- Documentation of positive clinical response,
- AND specialist follow-up occurred since last review,
- AND documentation of completing the following labs:
  - SCr, if patient has clinically significant renal disease
  - Liver function tests (ALT, AST, bilirubin), BNP, and lipids
- AND patient does not have any of the following:
  - Increase in transaminase levels >5X ULN or >3X ULN with evidence of liver dysfunction
  - Becomes wheelchair bound or non-ambulatory
  - Intolerance to medication
  - Documented non-adherence to medication
  - Pregnancy or breastfeeding

Amyloidosis Agents – Transthyretin (TTR) Suppression

Last Revised 2/6/2024

Generic	Brand
INOTERSEN SODIUM	TEGSEDI

Prior Authorization Criteria:
Length of Authorization: • Initial: 6 months • Reauthorization: 6 months
Initial Review Criteria: • Prescriber is a Neurologist, AND • Patient is ≥18 years, AND • Diagnosis of Neuropathic Heredofamilial Amyloidosis, AND • Documented confirmed transthyretin (TTR) mutation from genetic testing, AND • Patient does not have end stage renal disease (chronic kidney disease Stage 5), AND • Patient has not had a prior liver transplant AND • Patient does not have severe hepatic impairment [alanine transaminase (ALT) >2.5 times the upper limit of normal] and/or cirrhosis, AND • Patient does not have hepatitis B or C infection, human immunodeficiency virus (HIV) infection, or active malignancy, AND • Patient must have documented intolerance or contraindication to Onpattro before being approved for Tegsedi
Continuation of Therapy Criteria: • The following assessments have been performed within the past 6 months: Medical research Council (MRC) strength testing scale (0-5), hand grip strength (with or without dynamometer), and 10-meter walk test (10MWT) and Timed Up and Go (TUG) test, if applicable, AND • Karnofsky performance score ≥30, AND • No significant clinical decline, AND • No development of cardiogenic shock requiring inotropic support, AND • Patient is NOT in hospice care

Anthelmintics

Generic	Brand
MEBENDAZOLE	EMVERM

Prior Authorization Criteria:

Length of Authorization:

- Initial: 1 month
- Reauthorization: N/A; treatment may be repeated in 3 weeks if necessary

Initial Review Criteria:

- Prescriber is an Infectious Disease Specialist, AND
- Diagnosis of *enterobius vermicularis* (pinworm), AND
- Patient has had a trial or contraindication to both pyrantel pamoate and albendazole
    - o Approve treatment as: 100 mg x 1; may repeat in 3 weeks if necessary

-OR-

- Prescriber is an Infectious Disease Specialist, AND
- Confirmed diagnosis of *ascaris lumbricoides* (common roundworm), AND
- Patient has had a trial or contraindication to both pyrantel pamoate and albendazole
    - o Approve treatment as: 100 mg BID x 3 days; may repeat in 3 weeks if necessary

-OR-

- Prescriber is an Infectious Disease Specialist, AND
- Confirmed diagnosis of *trichuris trichiura* (whipworm), AND
- Patient has had a trial or contraindication to albendazole
    - o Approve treatment as: 100 mg BID x 3 days; may repeat in 3 weeks if necessary

-OR-

- Prescriber is an Infectious Disease Specialist, AND
- Confirmed diagnosis of *ancylostoma duodenale* (common hookworm), AND
- Patient has had a trial or contraindication to albendazole
    - o Approve treatment as: 100 mg BID x 3 days; may repeat in 3 weeks if necessary

-OR-

- Prescriber is an Infectious Disease Specialist, AND
- Confirmed diagnosis of *necator americanus* (American hookworm), AND
- Patient has had a trial or contraindication to albendazole
    - o Approve treatment as: 100 mg BID x 3 days; may repeat in 3 weeks if necessary

-OR-

- Prescriber is an Infectious Disease Specialist, AND
- Cystic hydatid disease, AND
- Patient has had treatment failure or contraindication to albendazole
    - o Approve treatment as: 100 mg BID x 3 days; may repeat in 3 weeks if necessary

Notes

- Please approve brand formulation, this is KP-preferred and adjudicates as generic

Anti-Arthritic – Folate Antagonist Agents

Generic	Brand
METHOTREXATE	OTREXUP; RASUVO

Prior Authorization Criteria follows the state's criteria (DMAS)

- **Length of Authorization:**
  6 months initial; 12 months continuation (6 months if using for PsO)

Initial Review Criteria:

- Member has a diagnosis of at least one of the following
  - Rheumatoid Arthritis (RA)
  - Plaque Psoriasis (PsO)
  - Polyarticular juvenile idiopathic arthritis (pJIA)

- Member has an allergy or contraindication to benzoyl alcohol or other preservative contained in generic injectable, AND
- If this is being used for Rheumatoid Arthritis (RA): member had had therapeutic failure to two preferred DMARD agents
- If this is being used for Polyarticular juvenile idiopathic arthritis (pJIA): member has had therapeutic failure to two preferred NSAIDS agents
- If this is being used for Psoriasis: member has had therapeutic failure on a topical psoriasis agent (emollients and/or topical corticosteroids, topical retinoids, topical vitamin D analogs, and topical tacrolimus AND pimecrolimus)

Continuation criteria: member is followed by a physician for monitoring of renal and hepatic function and complete blood counts with differential and platelet count

Anticonvulsant – Cannabinoid Type

Last revised 07.15.2022

Generic	Brand
CANNABIDIOL	EPIDIOLEX SOLN 100 MG/ML

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months
Initial Review Criteria: • Member is ≥1 years? AND • Diagnosed with Epilepsy and recurrent seizures including o Dravet Syndrome, or o Lennox-Gastaut Syndrome, or o Tuberous Sclerosi

Antifibrotic Therapy- Pyridone Analogs

Last revised: 1/29/2024; Effective date: 4/2/2024

Generic	Brand
PIRFENIDONE	ESBRIET

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is a Pulmonologist, • AND if ordering brand Esbriet, patient has tried and failed prior use of pirfenidone (generic Esbriet), • AND patient is a non-smoker, • AND patient is not receiving concomitant treatment with pirfenidone or any CYP1A2 inhibitors (e.g., fluvoxamine, ciprofloxacin), • AND using for one of the following diagnoses: o Idiopathic pulmonary fibrosis (IPF): ▪ NO known cause of interstitial lung disease o OR diagnosis of systemic sclerosis associated with interstitial lung disease (SSc-ILD) with greater than or equal to 10% fibrosis on a chest HRCT scan (conducted within last 12 months)
Continuation of Therapy Criteria: • Patient continues to be under the care of a pulmonologist, • AND hepatic function and spirometry are monitored at least annually, • AND patient continues to meet initial criteria with positive clinical response

Anti-Inflammatory – Interleukin-1 Receptor Antagonist

Generic	Brand
ANAKINRA	KINERET SOSY

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months
Initial Review Criteria: • Medication is being used for Cryopyrin-Associated Periodic Syndromes (CAPS) or treatment of Neonatal-Onset Multisystem Inflammatory Disease OR • Member has diagnosis of one of the following AND o Rheumatoid Arthritis (RA) o Juvenile Idiopathic Arthritis (JIA) • Member had therapeutic failure on oral methotrexate AND • Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND • If this is being used for Rheumatoid arthritis (RA): member tried and failed or had a contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline)

Anti-Inflammatory – Interleukin-1 Receptor Antagonist

Generic	Brand
RILONACEPT	ARCALYST SOLR

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months
Initial Review Criteria: • Medication is being used for: • Cryopyrin-Associated Periodic Syndromes (CAPS) • Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children ≥ 12 years old • Maintenance of remission of deficiency of interleukin-1 receptor antagonist (DIRA) in adults and pediatric patients weighing ≥ 10 kg • Member had therapeutic failure on oral methotrexate • Member had therapeutic failure to one of the preferred agents

Generic	Brand
CERTOLIZUMAB PEGOL	CIMZIA

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member has diagnosis of one of the following AND
  - Rheumatoid Arthritis (RA)
  - Adult Crohn's disease (CD)
  - Psoriatic Arthritis (PsA)
  - Ankylosing Spondylitis (AS)
  - Active Non-radiographic Axial Spondylarthritis (nr-axSpA)
- Member had therapeutic failure on oral methotrexate AND
- Member is not using Cimzia as combination therapy with methotrexate
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND

- If this is being used for Rheumatoid Arthritis (RA):
  - Member tried and failed or have a contraindication, or adverse reaction to methotrexate alone and at least one other DMARD (azathioprine, hydroxychloroquine, leflunomide, sulfasalazine, etc.) AND
- If this is being used for Crohn's disease (CD):
  - Member tried and failed a compliant regimen of oral corticosteroids (for moderate to severe CD) unless contraindicated, or intravenous corticosteroids (for severe and fulminant CD or failure to respond to oral corticosteroids) AND
  - Member tried and failed a compliant regimen of azathioprine or mercaptopurine for three consecutive months, AND
  - Member tried and failed a compliant regimen of parental methotrexate for 3 consecutive months
- If this is being used for Ankylosing Spondylitis (AS):
  - Member tried and failed or have a contraindication, or adverse reaction to at least 2 NSAIDs
- If this is being used for Active Non-radiographic Axial Spondylarthritis (nr-axSpA):
  - Member has objective signs of inflammation, AND
  - Member tried and failed or have a contraindication, or adverse reaction to at least 2 NSAIDs

Anti-Inflammatory – Tumor Necrosis Factor Inhibitor (Cont'd)

Generic	Brand
GOLIMUMAB	SIMPONI

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member has diagnosis of one of the following AND
  - Rheumatoid Arthritis (RA)
  - Psoriatic Arthritis (PsA)
  - Ankylosing Spondylitis (AS)
  - Ulcerative Colitis (UC)
- Member had therapeutic failure on oral methotrexate AND
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND

- If this is being used for Rheumatoid Arthritis (RA):
  - Member tried and failed or have a contraindication, or adverse reaction to methotrexate alone and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline)? AND
  - Simponi is not being used as combination therapy with methotrexate
- If this is being used for Ulcerative Colitis (UC):
  - Member tried and failed a compliant regimen of oral or rectal aminosalicylates (i.e., sulfasalazine or mesalamine) for two consecutive months AND
  - Member tried and failed a compliant regimen of oral corticosteroids (for moderate to severe CD) unless contraindicated, or intravenous corticosteroids (for severe and fulminant CD or failure to respond to oral corticosteroids) AND
  - Member tried and failed a compliant regimen of azathioprine or mercaptopurine for three consecutive months

Anti-inflammatory – Interleukin-1 Beta Blockers

Last revised: 06/07/2024; Effective date: 07/01/2024

Generic	Brand
CANAKINUMAB	ILARIS SOLN

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member has diagnosis of one of the following
  - Cryopyrin-Associated Periodic Syndromes (CAPS)
  - Familial Cold Autoinflammatory Syndrome (FCAS)
  - Muckle-Wells Syndrome (MWS)
  - Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
  - Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
  - Familial Mediterranean Fever (FMF)Member had therapeutic failure on oral methotrexate
  - Active Still's Disease
  - Gout Flares (NSAIDs and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate)

OR

- Member has diagnosis of Juvenile Idiopathic Arthritis (JIA), AND
- Member failed oral methotrexate, AND
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND

OR

- Member is using for Systemic Juvenile Idiopathic Arthritis (SJIA) and is ≥2 years

Anti-Inflammatory – Phosphodiesterase-4 (PDE4) Inhibitor

Generic	Brand
APREMILAST	OTEZLA

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months

Initial Review Criteria
• Member has a diagnosis of one of the following AND
  o Psoriatic arthritis (PsA)
  o Plaque Psoriasis (PsO)
• Member had therapeutic failure on oral methotrexate AND
• Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND
• If this is being used for Plaque Psoriasis:
  o Member had therapeutic failure on a topical psoriasis agent AND
  o Member is not a candidate for phototherapy or systemic therapy

Anti-Narcolepsy, Anti-Cataplexy, Sedative-Type Agent

Generic	Brand
SODIUM OXYBATE	XYREM

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is Pulmonologist (Sleep Specialist) and Neurologist, AND
- Prescriber must enroll in Xyrem Patient Success Program, AND
- Diagnosis of excessive daytime sleepiness in narcolepsy:
- Adequate trial (≥2 months) of a preferred stimulant (methylphenidate, amphetamine salt combination, dextroamphetamine) AND modafinil/armodafinil, unless contraindicated, AND
- Adequate trial of Sunosi (≥2 months) AND Wakix (≥2 months), unless contraindicated OR if patient initiated Xyrem prior to market release of Sunosi and Wakix AND
- Patient is 7 years to 65 years of age, AND
- Patient may NOT be on any sedative-hypnotic agents, opioids, benzodiazepines, or alcohol, AND
- Patient has had adequate trial (≥2 months) of Xywav

- OR –

- Diagnosis of cataplexy due to narcolepsy, AND
- Adequate trial (≥2 months) of at least 2 of the following: TCAs, SSRI, or SNRI or there is a contraindication

Continuation of Therapy Criteria:

- Patient continues to be under the care of a specialist, AND
- Documentation of positive clinical response

Anti-Narcolepsy and Sleep Disorder Therapy

Last revised: 06/07/2024; Effective date: 07/01/2024

Generic	Brand
modafinil	Provigil
armodafinil	Nuvigil
solriamfetol HCl	Sunosi
pitolisant HCl	Wakix

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of authorization: 12 months
Initial Review Criteria:

- Age ≥ 18 years old
- Diagnosis of one of the following:
  - Narcolepsy *(sleep study must be attached)*
  - Excessive daytime sleepiness (EDS) in adult members with narcolepsy
  - Obstructive sleep apnea *(sleep study must be attached)*
  - Sudden onset of weak or paralyzed muscles (cataplexy)
  - Shift work sleep disorder:
    - Documentation of the current shift schedule is required.
    - Assessment that it doesn't occur during another sleep disorder or mental disorder.
    - Assessment that it not due to the direct physiological effects of a medication or a general medical condition.

Additional Criteria for Wakix (pitolisant)

- Member has a baseline daytime sleepiness as measured by a validated scale? (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale); AND
- A mean sleep latency of ≤ 8 minutes AND ≥ 2 sleep onset REM periods (SOREMPs) are found on a mean sleep latency test (MSLT) performed according to standard techniques (A SOREMP [within 15 minutes of sleep onset] on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT); AND
- Either cerebrospinal fluid (CSF) hypocretin-1 concentration has not been measured OR CSF hypocretin-1 concentration measured by immunoreactivity is either > 110 pg/mL OR > 1/3 of mean values obtained in normal subjects with the same standardized assay; AND
- The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal; AND
- Patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for ≥ 3 months; AND
- Patient is not receiving treatment with sedative-hypnotic agents (e.g., zolpidem, eszopiclone, zaleplon, benzodiazepines, barbiturates); AND

- Patient is not using drugs that prolong the QT interval (e.g., quinidine, procainamide, disopyramide, amiodarone, sotalol, ziprasidone, chlorpromazine, thioridazine, moxifloxacin) concomitantly; AND
- Patient is not using histamine-1 (H1) receptor antagonists (e.g., pheniramine maleate, diphenhydramine, promethazine, imipramine, clomipramine, mirtazapine) concomitantly; AND
- Patient does not have a history of prolonged QTc interval (e.g., QTc interval > 450 milliseconds); AND
- Therapy is not being used in patients with severe hepatic impairment (Child-Pugh C); AND
- Patient does not have end-stage renal disease (ESRD) (e.g., eGFR < 15 mL/minute/1.73 m2

For brand Nuvigil or Provigil:

- Member tried and failed the preferred generics for the requested products.

Continuation Criteria:

- Member continues to meet initial criteria, AND
- Member reports a reduction in excessive daytime sleepiness from pre-treatment baseline.
- Member does not report any adverse effects related to treatment.

Anti-inflammatory – Selective Costimulation Modulator

Generic	Brand
ABATACEPT	ORENCIA

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months

Initial Review Criteria:
• Member has diagnosis of one of the following AND
  o Rheumatoid Arthritis (RA)
  o Juvenile Idiopathic Arthritis (JIA)
• Member had therapeutic failure on oral methotrexate AND
• Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND
• Member tried and failed another DMARD (other than Methotrexate), such as minocycline, hydroxychloroquine, sulfasalazine if using for RA

Anti-psoriatic Agents

Last revised 12.1.2023; Effective 1.1.2024

Generic	Brand
SECUKINUMAB	COSENTYX

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member has diagnosis of at least one of the following, AND
  - Psoriatic arthritis (PsA)
  - Ankylosing Spondylitis (AS)
  - Plaque Psoriasis (PsO)
  - Active Non-Radiographic Spondyloarthritis
  - Active Enthesitis-related arthritis (ERA) in patients 4 years of age and older

- Member had therapeutic failure on oral methotrexate AND
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira), AND
- If this is being used for Plaque Psoriasis: member must have therapeutic failure on a topical psoriasis agent

Anti-psoriatic Agents (Cont'd)

Generic	Brand
TILDRAKIZUMAB-ASMN	ILUMYA
RISANKIZUMAB-RZAA	SKYRIZI
GUSELKUMAB	TREMFYA

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member has diagnosis of one of the following
- Plaque Psoriasis (PsO),
- Psoriatic Arthritis (PsA)
- Member failed oral methotrexate, AND
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND
- Member has had moderate-to-severe plaque psoriasis for at least 6 months AND
    - There is involvement of at least 10% of body surface area (BSA) OR
    - Psoriasis Area and Severity Index (PASI) score 10 or greater OR
    - Incapacitation due to plaque location (e.g., head and neck, palms, soles or genitalia) AND
- Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues) AND
- Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of at least 1 systemic agent (e.g. Immunosuppressives, retinoic acid derivatives, and/or methotrexate) AND
- Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of phototherapy (e.g. Psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol)

Additional criteria for Skyrizi:

- Diagnosis of Crohn's disease
- Patient is ≥ 18 years, AND
- Diagnosis of moderate to severe Crohn's Disease, AND
- Trial and failure of a compliant regimen of oral corticosteroids unless contraindicated or intravenous corticosteroids, AND
- Patient is not receiving risankizumab-rzaa in combinationwith another biologic agent for psoriasis or non-biologic immunomodulator (e.g., upadacitinib)

Anti-psoriatic Agents (Cont'd)

Generic	Brand
BRODALUMAB	SILIQ

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months initial; 12 months continuation

Initial Review Criteria:

- Member has diagnosis of Plaque Psoriasis (PsO), AND
- Member failed oral methotrexate (at least 3 months) unless contraindication or intolerance , AND
- Member had therapeutic failure to both preferred agents (e.g. Enbrel, Humira) AND
- Member has had moderate-to-severe plaque psoriasis AND
    - There is involvement of at least 5% of body surface area (BSA) OR palmoplantar, facial, genital, or severe scalp psoriasis
- Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues) AND
- Member is not receiving Siliq in combination with any of the following:
    - Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Continuation Criteria:

- There is documentation of positive clinical response to Siliq therapy AND
- Member is not receiving Siliq in combination with any of the following:
    - Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Generic	Brand
IXEKIZUMAB	TALTZ

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months initial
Initial Review Criteria: • Member has diagnosis of one of the following, AND: o Plaque Psoriasis (PsO) adults and children 6 years of age or older who are candidates for systemic therapy or phototherapy o Psoriatic Arthritis (PsA) o Ankylosing Spondylitis (AS) o Non-Radiographic spondyloarthritis (nr-axSpA) • Member failed oral methotrexate (at least 3 months) unless contraindication or intolerance, AND • Member had therapeutic failure to one preferred agent (e.g. Enbrel, Humira) AND • Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of at least 2 topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues)

Anti-psoriatic Agents (Cont'd)

Generic	Brand
BIMEKIZUMAB-BKZX	BIMZELX

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months
Review Criteria: • Diagnosis of Plaque Psoriasis (PsO), moderate to severe, adult candidates for systemic therapy or phototherapy • Member has a prior failure on a topical agent. • Member is candidate for systemic therapy or phototherapy.

Arginine Vasopressin (AVP) Receptor Antagonists

Last revised: 10/3/2023

Generic	Brand
TOLVAPTAN	JYNARQUE

Prior Authorization Criteria: (Jynarque)

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Nephrologist, AND
- Patient must be 18 years to 55 years old, AND
- eGFR ≥25 mL/min/1.73 m^2, AND
- Baseline labs completed within 30 days and within normal limits: ALT, AST, bilirubin; and negative pregnancy test (if applicable), AND
- Patient has a diagnosis of typical autosomal dominant polycystic kidney disease (ADPKD) confirmed by one of the following:
    - Ultrasonography:
        - With family history: ≥ 3 cysts (unilateral or bilateral) in patients aged 15-39 years OR ≥ 2 cysts in each kidney in patients aged 40-59 years
        - Without family history: ≥ 10 cysts per kidney

OR

- Magnetic resonance imaging (MRI) or computed tomography (CT) scan:
    - With family history: ≥ 5 cysts per kidney
    - Without family history: ≥ 10 cysts per kidney

-AND -

- High risk of disease progression defined by one of the following:
    - Mayo ADPKD Classification 1C, 1D, or 1E
    - eGFR decline ≥5 mL/min/1.73m2 in one year OR eGFR decline ≥2.5 mL/min/1.73m2 per year over a period of ≥5 years
    - Truncating PKD1 mutation AND PROPKD score >6

Continuation of Therapy Criteria:

- Positive clinical response to tolvaptan, AND
- eGFR >25 mL/min/1.73 m2, AND
- Patient has followed-up with a Nephrologist within the past 12 months

Glucocorticoids

Generic	Brand
DEFLAZACORT	EMFLAZA

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months
Initial Review Criteria: • Member is ≥2 years AND • Prescribed for Duchenne muscular dystrophy (DMD)

Interleukin-5 (IL-5) Receptor Alpha Antagonist, MAB

Last revised: 06/07/2024; Effective date: 07/01/2024

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand
BENRALIZUMAB	FASENRA

Prior Authorization Criteria:
Length of Authorization: • 12 months
Initial Review Criteria: • Diagnosis/documentation of uncontrolled moderate to severe asthma defined as any of the following: • Diagnosis of asthma with an eosinophilic phenotype defined as blood eosinophils ⩾150 cells/μL • ≥2 exacerbations in the past 12 months requiring systemic corticosteroids • ≥1 asthma exacerbation(s) leading to hospitalization in the past 12 months • Requires use of systemic corticosteroids (OCS) for asthma control • Requires use of inhaled corticosteroids • Forced expiratory volume in 1 second (FEV1) • AND patient is ≥12 years • A number of hospitalizations, ER visits, or unscheduled visits to healthcare providers due to asthma • Fasenra (benralizumab) will NOT be used with Dupixent (dupilumab), Cinqair (resilizumab), Nucala (mepolizumab), Xolair (omalizumab), or Tezspire (tezepelumab-ekko).
Continuation of Therapy Criteria • There is no evidence of toxicity to therapy. • Documentation of positive clinical response to Fasenra therapy demonstrated by decrease in one or more of the following: o Use of systemic corticosteroids o Hospitalization, ER visits, unscheduled visits to health care provider o Improvement from baseline in forced expiratory volume in 1 second (FEV1)

Interleukin-6 (IL-6) Receptor Inhibitors (Actemra and Kevzara)

Last revised: 12.01.2023; Effective 1.1.2024

Generic	Brand
TOCILIZUMAB	ACTEMRA
SARILUMAB	KEVZARA

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member has diagnosis of one of the following AND
  - Rheumatoid Arthritis (RA)
  - Systemic Juvenile Idiopathic Arthritis (SJIA)
  - Polyarticular juvenile idiopathic arthritis (pJIA)
- Member had therapeutic failure on oral methotrexate AND
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND

Additional criteria for Actemra:

- Being used for Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis (PJIA) or Systemic Juvenile Idiopathic Arthritis (SJIA):
  - Member tried and failed Methotrexate, OR
  - This medication be used in conjunction with Methotrexate OR
  - Member has a contraindication to Methotrexate (e.g., alcohol abuse, cirrhosis, chronic liver disease, or other contraindication) AND
- Member tried and failed another DMARD (other than Methotrexate), such as azathioprine, d-penicillamine, cyclophosphamide, cyclosporine, gold salts, hydroxychloroquine, leflunomide, sulfasalazine, or tacrolimus

Additional criteria for Kevzara:

- Rheumatoid arthritis (RA)
- Initial review Criteria:
  - ≥18 years old? AND
  - Diagnosis of moderately to severely active rheumatoid arthritis (RA) AND
  - Prescribed by or in consultation with a rheumatologist AND
- History of failure, contraindication, or intolerance to one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Rheumatrex /Trexall (methotrexate), Arava (leflunomide), Azulfidine (sulfasalazine) ANDRenew Criteria
  - The member must not be receiving Kevzara in combination with any of the following:
    - Biologic DMARD (e.g., Enbrel, Humira, Cimzia, Simponi)
    - Janus kinase inhibitor (e.g., Xeljanz, Olumiant)
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
- Polymyalgia Rheumatica (PMR):
- Initial review Criteria:
  - ≥18 years old? AND
  - Diagnosis of Polymyalgia Rheumatica (PMR)-AND
  - Prescribed by or in consultation with a rheumatologist -AND

- History of failure, contraindication, or intolerance to corticosteroids or who cannot tolerate a steroid taper.

- Renew Criteria:
  - Patient is not receiving Kevzara in combination with any of the following:
    - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)

Interleukin-6 (IL-6) Receptor Inhibitors-Enspryng

Generic	Brand
SATRALIZUMAB-MWGE	ENSPRYNG

Prior Authorization Criteria follows DMAS's criteria
Length of Authorization: 12 months
Initial Review Criteria: • Member has diagnosis of Neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive (NMOSD) • Patient has a confirmed diagnosis based on the following: o Patient was found to be seropositive for aquaporin-4 (AQP4) IgG antibodies; AND o Patient has ≥ 1 core clinical characteristic (e.g., optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions); AND • Alternative diagnoses have been excluded (e.g., multiple sclerosis, sarcoidosis, cancer, chronic infection)

Janus Kinase (JAK) Inhibitor

Last Revised 07/15/2022

Generic	Brand
TOFACITINIB CITRATE	XELJANZ XELJANZ XR

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months

Initial Review Criteria:
• Member has diagnosis of one of the following:
  o Rheumatoid Arthritis (RA)
  o Psoriatic arthritis (PsA)
  o Ulcerative Colitis (UC)
  o Ankylosing spondylitis
• Member had therapeutic failure on oral methotrexate AND
• Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND
• If this is being used for Rheumatoid Arthritis (RA) or Psoriatic arthritis (PsO): member had therapeutic failure on or contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline)
• If this is being used for Ulcerative Colitis (UC) OR Ankylosing spondylitis: member had therapeutic failure on, inadequate response or intolerant to TNF blockers

Janus Kinase (JAK) Inhibitor (Cont'd)

Last Revised 12/1/2023

Generic	Brand
BARICITINIB	OLUMIANT
UPADACITINIB	RINVOQ
ABROCITINIB	CIBINQO

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member has diagnosis of Rheumatoid Arthritis (RA)
- Member had therapeutic failure on oral methotrexate AND
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND
- Member is not using in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants such as azathioprine or cyclosporine, AND

Additional criteria for Olumiant:

- Member is ≥18 years, AND
- Member had therapeutic failure on, inadequate response to or intolerant to TNF blockers

Additional criteria for Rinvoq

- ≥18 years, and
    - Diagnosis of psoriatic arthritis
    - Ankylosing spondylitis
    - Ulcerative colitis
    - Non-radiographic axial spondylarthritis
    - Moderate to severe Crohn's Disease
- ≥12 years, and
    - Atopic dermatitis

Additional criteria for Cibinqo:

- ≥12 years, and
- Diagnosis of moderate to severe atopic dermatitis, and
- Documented trial and failure (or contraindication) of 1 topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) and 1 topical calcineurin inhibitor (tacrolimus or pimecrolimus), and
- Inadequate response to a 3-month minimum trial of at least 1 immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.), and
- Inadequate response (or is not a candidate) to a 3-month minimum trial of phototherapy (e.g., psoralens with UVA light [PUVA], UVB, etc.) provided member has reasonable access to photo treatment

Monoclonal Antibodies to Immunoglobulin E (IGE)

Last revised: 06/07/2024; Effective date: 07/01/2024

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand
OMALIZUMAB	XOLAIR

Length of Authorization: 12 months

Initial Review Criteria:

Asthma:

- Diagnosis of severe asthma defined as any of the following:
  - ≥2 exacerbations in the past 12 months requiring systemic corticosteroids
  - ≥1 asthma exacerbation(s) leading to hospitalization in the past 12 months
  - Dependence on daily oral corticosteroids (OCS) for asthma control
- AND patient is ≥6 years,
- AND member weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.),
- AND member has a a positive skin test or in vitro reactivity to a perennial aero - allergen
- AND Member has serum total IgE level, measured before the start of treatment, of either:
  - ⩾ 30 IU/mL and ⩽ 700 IU/mL in patients age ⩾ 12 years; OR
  - ⩾ 30 IU/mL and ⩽ 1300 IU/mL in patients age 6 to 12 years
- AND Xolair will NOT be used with Fasenra (benralizumab), Cinqair (resilizumab), Dupixent (dupilumab), Nucala (mepolizumab), or Tezspire (tezepelumab-ekko)
- AND Xolair will be used for add - on maintenance treatment in members regularly receiving both (unless otherwise contraindicated) of the following:
  - Medium - to high - dose inhaled corticosteroids; AND
  - An additional controller medication (e.g., long - acting beta agonist, leukotriene modifiers)
- Member has at least one of the following:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - A number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV1)

CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP):

- Patient is 18 years of age or older, AND
- Tried and failed at least 8 weeks of intranasal corticosteroid therapy, AND
- Presence of at least 3 of the following indicators for biologic treatment:

[Note: members with a history of sino - nasal surgery are only required to have at least 3 of the indicators]:

- evidence of type 2 inflammation (e.g., tissue eosinophils ⩾10/hpf, blood eosinophils ⩾ 150 cells/μL, or total IgE ⩾ 100 IU/mL)
- required ⩾2 courses of systemic corticosteroids per year or >3 months of low dosecorticosteroids, unless contraindicated.
- disease significantly impairs the patient's quality of life
- there is significant loss of smell

    - there is comorbid diagnosis of asthma; AND
- The member does not have any of the following:
    - Antrochoanal polyps
    - Nasal septal deviation that would occlude at least one nostril
    - Disease with lack of signs of type 2 inflammation
    - Cystic fibrosis
    - Mucoceles; AND
    - Other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis)? AND
- Physician assessed baseline disease severity utilizing an objective measure/tool, AND
- Therapy is used in combination with intranasal corticosteroids unless patient is unable to tolerate or corticosteroid therapy is contraindicated

Clinical Criteria for IgE‐Mediated Food Allergy:

- Patient is 1 year of age or older, AND
- Prescribing physician is an allergist or immunologist, or an allergist or immunologist has been consulted, AND
- Diagnosis of food allergy as confirmed by:
    - A positive skin prick test under a drop of allergen extract; OR
    - A positive IgE screening ($\geqslant$ kUA/L) to identified foods? AND
    - Member practices allergen avoidance

Continuation of therapy for all indications:

- Member been assessed for toxicity, AND

Severe asthma renewal

- Member has improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Hospitalizations, ER visits, Unscheduled visits to healthcare provider
    - Improvement from baseline in forced expiratory volume in 1 second (FEV1)

CHRONIC IDIOPATHIC URTICARTIA/CHRONIC SPONTANEOUS URTICARIA renewal

- Member has a clinical improvement as documented by an objective clinical evaluation tool (e.g.,UAS7, AAS, DLQI, AE‐QoL, UCT, AECT, CU‐Q2oL, etc.)

CRSwNP renewal

- Improvement of the disease state as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT‐scans and/or an improvement on a disease activity scoring tool [e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sinonasal outcome test‐22 (SNOT‐22), etc.] OR

- There is improvement in at least one of the following response criteria:
    - Reduction in nasal polyp size
    - Reduction in need for systemic corticosteroids
    - Improvement in quality of life
    - Improvement in sense of smell
    - Reduction of impact of comorbidities

IgE-Mediated Food Allergy renewal

- Member is experiencing a clinical response and improvement as attested by the prescriber

Monoclonal Antibody Human Interleukin 12/23 Inhibitor

Generic	Brand
USTEKINUMAB	STELARA

Prior Authorization Criteria follows the state's criteria (DMAS)
• **Length of Authorization:** 12 months

Initial Review Criteria:
• Member has diagnosis of at least one of the following, AND
  o Adult Crohn's disease (CD)
  o Psoriatic arthritis (PsA)
  o Ulcerative Colitis (UC)
  o Plaque Psoriasis (PsO), adult and pediatric patient 6 years of age and older
• Member had therapeutic failure on oral methotrexate AND
• Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira)

Monoclonal Antibody- Interleukin-5 Antagonist

Last revised: 06/07/2024; Effective date: 07/01/2024

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand
MEPOLIZUMAB	NUCALA

Length of Authorization: 12 months

Initial Review Criteria:

Clinical Criteria for Severe Asthma

- Diagnosis of severe asthma AND
- Asthma with an eosinophilic phenotype defined as blood eosinophils ⩾150 cells/μL, AND
  - ≥2 exacerbations in the past 12 months requiring systemic corticosteroids
  - ≥1 asthma exacerbation(s) leading to hospitalization in the past 12 months
- AND patient is ≥ 6 years,
- AND Nucala will NOT be used with Fasenra (benralizumab), Cinqair (resilizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab-ekko)
- ANDNucala is being used as an add‐on maintenance treatment in members regularly receiving both (unless otherwise contraindicated) of the following:
  - Medium‐ to high‐dose inhaled corticosteroids; AND
  - An additional controller medication (e.g., long‐acting beta agonist, leukotriene modifiers)
- AND, member has at least one of the following:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Several hospitalizations (e.g., ER visits, or unscheduled visits to healthcare providers due to condition)
  - Forced expiratory volume in 1 second (FEV1)
- AND if using for eosinophilic asthma documented treatment failure, contraindication or inadequate response to Fasenra AND Xolair

Clinical Criteria for EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS§ (EGPA)

- Patient is ⩾ 6 years, AND
- Diagnosis of EGPA (aka Churg‐Strauss Syndrome), AND
- Blood eosinophils ⩾ 150 cells/μL within 6 weeks of dosing, AND
- Patient has been on stable doses of concomitant oral corticosteroid therapy for at least 4 weeks (i.e., prednisone or prednisolone at a dose of 7.5 mg/day), AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, rate of relapses)

Clinical Criteria for HYPEREOSINOPHILIC SYNDROME (HES):

- Patient is ≥ 12 years, AND
- Diagnosis of HES (without an identifiable non‐hematologic secondary cause (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non‐hematologic malignancy) or FIP1L1‐PDGFRα kinase‐positive HES) for at least 6 months prior to starting treatment, AND
- History of 2 or more HES flares within the previous 12 months (e.g., documented HES‐related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy), AND

- Nucala will this be used in combination with stable doses of at least one other HES therapy, (e.g., oral corticosteroids, immunosuppressive agents, cytotoxic therapy) unless the member cannot tolerate other therapy

Clinical Criteria for CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP)

- Patient is ≥ 18 years, AND
- Member has bilateral symptomatic sino‐nasal polyposis with symptoms lasting at least 8 weeks, AND
- Failure of at least 8 weeks of intranasal corticosteroid therapy AND
- Failure of an adequate trial of the preferred product Xolair

Continuation of Therapy Criteria:

- Patient has been assessed for toxicity

Severe asthma

- Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids,
    - Hospitalizations, ER visits, Unscheduled visits to healthcare provider
    - Improvement from baseline in forced expiratory volume in 1 second (FEV1)

EGPA

- Member has disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced in one or more of the following:
    - Member is in remission [defined as a Birmingham Vasculitis Activity Score (BVAS) score=0 and a prednisone/prednisolone daily dose of ⩽ 7.5 mg]
    - Decrease in maintenance dose of systemic corticosteroids.
    - Improvement in BVAS score compared to baseline.
    - Improvement in asthma symptoms or asthma exacerbations
    - Improvement in duration of remission or decrease in the rate of relapses

HES

- Member has a disease response as indicated by a decrease in HES flares from baseline (Note: An HES flare is defined as worsening of clinical signs and symptoms of HES or increasing eosinophils (on at least 2 occasions), resulting in the need to increase oral corticosteroids or increase/add cytotoxic or immunosuppressive HES therapy.)

CRSwNP

- Member has disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT‐scans and/or an improvement on a disease activity scoring tool [e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sinonasal outcome test‐22 (SNOT‐22), etc.], OR
    - Member has improvement in at least one of the following response criteria:
    - Reduction in nasal polyp size
    - Reduction in need for systemic corticosteroids
    - Improvement in quality of life
    - Improvement in sense of smell
    - Reduction of impact of comorbidities

Respiratory Tract Agents-(Miscellaneous)-THYMIC STROMAL LYMPHOPOIETIN (TSLP) INHIBITORS (Tezspire)

Last revised 06/04/2024; Effective date: 07/01//2024

Generic	Brand
TEZEPELUMAB-EKKO	Tezspire

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member is ≥ 12 years of age.
- Member has a diagnosis of severe asthma
- Coadministration with another monoclonal antibody will be avoided (e.g., omalizumab, mepolizumab, reslizumab, benralizumab, dupilumab), **AND**
- Therapy is being used as an add-on maintenance treatment in members regularly receiving **both** (unless otherwise contraindicated) of the following:
    - Medium- to high-dose inhaled corticosteroids; **AND**
    - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers)
- Member had two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) or one exacerbation resulting in a hospitalization, AND
- Member has at least one of the following for assessment of clinical status:
    - Use of systemic corticosteroids
    - Use of inhaled corticosteroids
    - Several hospitalizations (e.g., ER visits, or unscheduled visits to healthcare provider due to condition)
    - Forced expiratory volume in 1 second (FEV_1), **AND**
- Member tried and failed an adequate trial of the 2 different preferred products (Fasenra® and Xolair®), or have an intolerance to a preferred agents, OR
- Member lacks an eosinophilic phenotype with blood eosinophils ≥150 cells/Ml, AND
- Member lacks a serum IgE level < 30 IU/mL

Continuation of Therapy Criteria:

- Member has been assessed for toxicity, **AND**
- **M**ember has improvement in asthma symptoms or asthma exacerbations as evidenced by a decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Hospitalizations
    - ER visits
    - Unscheduled visits to healthcare provider
    - Improvement from baseline in forced expiratory volume in 1 second (FEV_1)

Pulmonary Fibrosis- Systemic Enzyme Inhibitors

Last revised: 1/29/2024; Effective date: 4/2/2024

Generic	Brand
NINTEDANIB ESYLATE	OFEV

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist,
- AND patient is a non-smoker,
- AND patient is not receiving concomitant treatment with pirfenidone or any CYP3A4 inducers,
- AND pregnancy has been excluded in patients of reproductive potential prior to starting treatment, and patient has been provided with contraceptive counseling on the risks of taking nintedanib if the patient were to become pregnant,
- AND using for one of the following diagnoses:
    - Idiopathic pulmonary fibrosis (IPF):
        - NO known cause of interstitial lung disease
        - AND patient has tried and failed prior use of pirfenidone (generic Esbriet)
    - OR diagnosis of progressive pulmonary fibrosis
    - OR diagnosis of systemic sclerosis associated with interstitial lung disease (SSc-ILD) with greater than or equal to 10% fibrosis on a chest HRCT scan (conducted within last 12 months)

Continuation of Therapy Criteria:

- Patient continues to be under the care of a pulmonologist,
- AND hepatic function and spirometry are monitored at least annually,
- AND patient continues to meet initial criteria with positive clinical response

Antibiotics, Inhaled (Tobi Podhaler) – Step Therapy (ST)

Generic	Brand
TOBRAMYCIN	TOBI PODHALER

*representative list

Step Therapy Criteria:

Adapted from DMAS Preferred Drug List– Step Therapy (ST)

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Patient must be ≥ 6 years old
- Must provide a clinical reason as to why one of the preferred tobramycin inhalation nebulizer solutions cannot be used

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Antiemetic Agents (Cannabinoid Derivatives)

Generic	Brand
DRONABINOL	MARINOL, SYNDROS
NABILONE	CESAMET

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Patient must have diagnosis of HIV or Cancer (FDA-approved age indication)
- Non-preferred agents must have documented trial and treatment failure with dronabinol (generic) prior to approval

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Antimigraine

Last revised 06/07/2024 Effective07/01/2024

Generic	Brand
ERENUMAB-AOOE	AIMOVIG
FREMANEZUMAB-VFRM	AJOVY
GALCANEZUMAB-GNLM	EMGALITY
LASMIDTAN	REYVOW
UBROGEPANT	UBRELVY
RIMEGEPANT SULFATE	NURTEC
ATOGEPANT	QULIPTA
DIHYDROERGOTAMINE MESYLATE	TRUDHESA
ZAVEGEPANT	ZAVZEPRET

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 6 months
- Reauthorization: 1 year

Initial Review Criteria:

- Patient must be 18 years old or older

For preventative treatment of migraine:

- Preferred agents are Aimovig, Ajovy, Emgality 120 mg, and Nurtec ODT, Qulipta
- Diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria, AND
- Patient has ≥ 4 migraine days per month for at least 3 months, AND
- Tried and failed a ≥ 1-month trial of any 2 of the following oral generic medications:
    - Antidepressants (e.g., amitriptyline, venlafaxine)
    - Beta blockers (e.g., propranolol, metoprolol, timolol, atenolol)
    - Anti-epileptics (e.g., valproate, topiramate)
    - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan)
- For the non-preferred agents, Emgality 100 mg the above criteria apply and non-formulary exception is required,(trial and failure of two preferred agents) .

For acute treatment of migraine:

- Preferred Nurtec ODT and Ubrelvy require trial of 2 generic triptans
- Non-preferred Reyvow and Trudhesa must meet the following criteria:
    - Diagnosis of migraine with or without aura, AND
    - Trial and failure, or has contraindications to, two preferred triptans, AND
    - Non-formulary exception is required for using the non-preferred product.
    - Additional criteria for Trudhesa (dihydroergotamine mesylate) only:
        - Completion of cardiovascular evaluation prior to initiation of Trudhesa

For Episodic Cluster Headache:

- Diagnosis of episodic cluster headache, AND
- Patient experienced at least two cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months, AND
- Medication requested will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines, AND
- Trial and failure (or has contraindications to) of at least one formulary preferred therapy for cluster headache

Continuation of Therapy Criteria:

- Patient demonstrates a significant decrease in the number, frequency, and/or intensity of headache

Weight Loss Drugs

Revised 06/07/2024 ; Effective 07/01/2024

Generic	Brand
ORLISTAT	XENICAL
BENZPHETAMINE HCL	DIDREX, REGIMEX
PHENTERMINE HCL	ADIPEX-P, OBY-CAP, LOMAIRA
DIETHYLPROPION HCL	DIETHYLPROPION HCL
PHENDIMETRAZINE TARTRATE	BONTRIL PDM, BONTRIL SLOW-RELEASE
PHENTERMINE HCL-TOPIRAMATE	QSYMIA
NALTREXONE HCL-BUPROPION HCL	CONTRAVE ER
LIRAGLUTIDE	SAXENDA
SEMAGLUTIDE	WEGOVY
SETMELANOTIDE ACETATE	IMCIVREE
TIRZEPATIDE	ZEPBOUND

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial:
  - 3 months: Benzphetamine, diethylpropion, phendimetrazine, phentermine, Qsymia, Contrave
  - 4 months: Saxenda, Imcivree
  - 6 months: Wegovy, Zepbound, Xenical/Alli

Initial Review Criteria:

- Body Mass Index (BMI) Requirements:
  - BMI ≥ 30, if no applicable risk factors
  - BMI ≥ 27, with 2 or more of the following risk factors:
    - Coronary heart disease
    - Dyslipidemia
    - Hypertension
    - Sleep apnea
    - Type 2 Diabetes
- Pediatric Patients

  Imcivree
  - BMI ≥ 30 or ≥ 95th percentile on pediatric growth chart (Imcivree™)

  Wegovy®, Saxenda®, and Zepbound
  - Patient 12–18 years of age, with a BMI of ⩾ 140% of the 95th percentile by age and sex
  - Patient 12 – 18 years of age, with an initial BMI that is ⩾ 120% of the 95th percentile by age and sex with two or more of the following risk factors: coronary heart disease, dyslipidemia, hypertension, sleep apnea, type 2 diabetes
- Age Restrictions:
  - Must be ≥ 16 years old, except for
  - Saxenda and Wegovy covered for patients ≥ 12 years old
  - Imcivree covered for members ≥ 6 years old
  - Zepbound, Contrave covered for members ≥ 18 years old
- No contraindications to use including: no malabsorption syndromes, cholestasis, pregnancy and/or lactation, no history of eating disorders, previous failure of a weight loss treatment plan in the past 6 months and will continue to follow as a part of the total treatment plan (excludes Imcivree);
- Provider attest patient's obesity is disabling and life threatening (i.e., puts the patient at risk for high-morbidity conditions

Additional Criteria for Imcivree™

- Prescribed by or in consultation with an endocrinologist or geneticist; AND

- Member has proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency, as confirmed by a genetic test; AND
- Member's genetic variants are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
- Member has Bardet-Biedl syndrome (BBS)

Additional Criteria for Saxenda, Wegovy, Zepbound

- Trail and failure of a 30-day therapy of a non-GLP-1 weight loss drug in the last 6 months with listed outcomes, OR
- A documented intolerance or allergy to a non-GLP-1 weight loss drug:
- Member is not concurrently on Victoza® or Ozempic® or other GLP-1 inhibitors

Written Documentation Required for:

- Current medical status including nutritional or dietetic assessment
- Current therapy for all medical condition(s) including obesity, identifying specific treatments including medications
- Current accurate height and weight measurements
- Current weight loss plan or program including diet and exercise plan
- No medical contraindications to use a reversible lipase inhibitor (Xenical®)
- No chronic opioid use concurrently with Contrave®

Continuation of Therapy Criteria Weight Loss drugs

Note: *Applicable to all WL therapies:*

- *Members lacking a weight loss response may still be considered for renewal with two or more of the following weight related risk factors: coronary heart disease, dyslipidemia, hypertension, sleep apnea, type 2 diabetes.*
- *At this time, authorization requests over one year are subject to initial criteria including all documentation.*
- *In the event of an FDA recognized shortage, approved members will be eligible for the full allotment of approved drug once the shortage is resolved.*

Renewal requests: Varies (drug specific)

- Benzphetamine, diethylpropion, phendimetrazine, phentermine – If the member achieves at least a 10 lb. weight loss during the initial 3 months of therapy, an additional 3-month approval may be granted. Maximum length of continuous drug therapy is 6 months (waiting period of 6 months before next request).
- Qsymia® – If the member achieves a weight loss of at least 3% of baseline weight, an additional 3-month approval may be granted. For a subsequent renewal, member must meet a weight loss of at least 5% of baseline weight to qualify for an additional 6-month SA. Maximum length of continuous drug therapy is 12 months (waiting period of 6 months before next request).
- Alli®/Xenical® – If the member achieves at least a 10 lb. weight loss, an additional 6-month approval may be granted. Maximum length of continuous drug therapy is 24 months (waiting period of 6 months before next request).
- Contrave® – Approve for 6 months with each renewal if weight reduction continues.
- Saxenda® – If the member achieves a weight loss of at least 4% of baseline weight, an additional 6-month approval may be granted as long as weight reduction continues.
- Imcivree™ – If the member has experienced ≥ 5% reduction in body weight (or ≥ 5% of baseline BMI in those with continued growth potential), an additional 1 year SA may be granted.
- Wegovy™, Zepbound - If the member achieves a weight loss of at least 5% of baseline weight, an additional 6 month SA may be granted.
- Members lacking a weight loss response may still be considered for renewal with two or more of the following weight related risk factors: coronary heart disease, dyslipidemia, hypertension, sleep apnea, type 2 diabetes.
- At this time, authorization requests over one year are subject to initial criteria including all documentation.
- In the event of an FDA recognized shortage, approved members will be eligible for the full allotment of approved drug once the shortage is resolved.

Continuation of Therapy Criteria:

- BMI ≥ 24
- Continue to meet all Initial Criteria
- Documentation of continued weight loss

Antipsychotic Agents -Atypical, long acting injectable

Generic	Brand
CLOZAPINE	FAZACLO, CLOZARIL
OLANZAPINE, OLANZAPINE PAMOATE	ZYPREXA, ZYPREXA RELPREVV
HALOPERIDOL LACTATE, HALOPERIDOL , HALOPERIDOL DECANOATE	HALDOL
FLUPHENAZINE HCL, FLUPHENAZINE DECANOATE	
THIORIDAZINE HCL	
THIOTHIXENE	
CHLORPROMAZINE HCL	
TRIFLUOPERAZINE HCL	
PERPHENAZINE	
QUETIAPINE FUMARATE	SEROQUEL
ARIPIPRAZOLE	ABILIFY
PIMOZIDE	ORAP
RISPERIDONE, RISPERIDONE MICROSPHERES	RISPERDAL, PERSERIS RISPERDAL CONSTA
ZIPRASIDONE HCL, ZIPRASIDONE MESYLATE	GEODON
ARIPIPRAZOLE LAUROXIL	ARISTADA, ARISTADA INITIO
PALIPERIDONE, PALIPERIDONE PALMITATE	INVEGA
LOXAPINE, LOXAPINE SUCCINATE	ADASUVE
ILOPERIDONE	FANAPT
BREXPIPRAZOLE	REXULTI
CARIPRAZINE HCL	VRAYLAR
ASENAPINE MALEATE	SAPHRIS
LURASIDONE HCL	LATUDA
MOLINDONE HCL	
PIMAVANSERIN TARTRATE	NUPLAZID
OLANZAPINE-SAMIDORPHAN L-MALATE	LYBALV

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Required for use of antipsychotics in children ≤ 17 years old
- Prescribing provider must be either a Psychiatrist, Neurologist, or a Developmental/Behavioral Pediatrician or have consulted with one of these providers before prescribing the requested medication
- Documentation of a developmentally appropriate, comprehensive psychiatric assessment with diagnoses, impairments, treatment target, and treatment plans clearly identified
- Documentation of psychosocial treatment without adequate clinical response
- Documentation of patient's current behavior health program and pharmaceutical agents attempted with outcomes
- Treatment plan includes psychosocial treatment with parental involvement for the duration of medication therapy
- Documentation of informed consent for this medication from the parent or guardian
- Documentation of a family assessment having been performed, including parental psychopathology and treatment needs
- Documentation of evaluation of family functioning and parent-child relationship

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Cardiac Drugs, Miscellaneous

Last revised: 12/6/2022

Generic	Brand
TAFAMIDIS MEGLUMINE	VYNDAQEL
TAFAMIDIS	VYNDAMAX

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Cardiologist,
- AND patient is ≥18 years,
- AND diagnosis of cardiac amyloidosis on the problem list or per cardiologist documentation,
- AND evidence of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) demonstrated by positive biopsy demonstrating transthyretin (TTR)-amyloid deposition OR meeting all 3 of the following:
    - Diagnosis of heart failure (defined as stage C heart failure plus NYHA Class I, II, or III).
    - Pyrophosphate (PYP) scintigraphy cardiac uptake visual score of either grade 2 or 3 using Perugini Grade 1-3 scoring system, calculated heart-to-contralateral (H/CL) ration ≥1.5.
    - Absence of monoclonal gammopathy after testing for serum immunofixation (IFE) and serum free light chains
- AND medical history of heart failure with at least 1 prior hospitalization for heart failure or clinical evidence of heart failure (without hospitalization) manifested by signs or symptoms of volume overload or elevated intracardiac pressures that require treatment diuretic
- AND patient is NOT receiving inotersen or patisiran
- AND patient has NOT had prior heart or liver transplantation
- Patient does NOT have an implanted cardiac mechanical assist device

Continuation of Therapy Criteria:

- Documentation of positive clinical response AND
- Office visit or telephone visit with a specialist within the past 12 months

Cardiac Myosin Inhibitor

Last revised: 2/6/2024

Generic	Brand	HICL	GSN	Representative NDC
MAVACAMTEN	CAMZYOS CAPS 2.5 MG	47972	083317	73625011111
MAVACAMTEN	CAMZYOS CAPS 5 MG	47972	083318	73625011211
MAVACAMTEN	CAMZYOS CAPS 10 MG	47972	083319	73625011311
MAVACAMTEN	CAMZYOS CAPS 15 MG	47972	083320	73625011411

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescriber is a Cardiologist,
- AND patient is 18 years of age or older,
- AND diagnosed with oHCM consistent with current AHA/ACC guidelines and satisfies both of the following:
    - Left ventricular ejection fraction (LVEF) ≥55%
    - NYHA class II or III
- AND peak Valsalva LVOT gradient ≥50 mmHg,
- AND symptomatic oHCM despite highest tolerated dose of a non-vasodilating beta-blocker (or non-dihydropyridine calcium channel blocker if beta-blocker is not tolerated),
- AND if clinically indicated, consider other AHA/ACC Guideline Class I therapies before mavacamten:
    - Disopyramide
    - Septal reduction therapy for NYHA class III patients
- AND using effective contraception, if patient is of childbearing potential,
- AND recommend not to initiate if any of the following situations apply:
    - Known infiltrative or storage disorder causing cardiac hypertrophy that mimics oHCM (e.g. Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy)
    - History of syncope or sustained ventricular tachyarrhythmia with exercise within 6 months prior
    - History of resuscitated sudden cardiac arrest (at any time) or known history of appropriate implantable cardioverter defibrillator discharge for life-threatening ventricular arrhythmia within 6 months prior
    - Poorly controlled atrial fibrillation
    - Treatment with disopyramide or ranolazine within 14 days prior to initiation of mavacamten
    - Taking a beta blocker in combination with a calcium channel blocker
    - Successfully treated with invasive septal reduction therapy within 6 months prior
    - QTc interval >500 milliseconds
-

Continuation of Therapy Criteria:

- LVEF remains ≥50%,
- AND patient has not developed heart failure symptoms or worsening clinical status,
- AND patient is adherent to labs and monitoring as required by the REMS program (e.g. ECHO with Valsalva LVOT gradient, NYHA classification at least every 12 weeks),
- AND patient continues to be managed by Cardiologist with expertise in hypertrophic cardiomyopathy

Cystic Fibrosis (CFTR) Correctors-Trikafta

Generic	Brand
ELEXACAFTOR-TEZACAFTOR-IVACAFTOR	TRIKAFTA TBPK

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Age ≥12 years, AND • Diagnosis of CF confirmed by a clinician with expertise in proving CF care, AND • At least one F508del mutation in the CFTR gene detected using either an FDA-cleared CF mutation test or testing was completed by a CLIA certified laboratory, AND • Patient does not have either of the following: o Severe liver impairment (Child-Pugh Class C), OR o Prior solid organ or hematological transplantation, unless use of the medication is approved by the transplant center
Continuation of Therapy Criteria: • Documentation of positive clinical response AND • Specialist follow-up has occurred in the past 12 months, AND • AST, ALT, bilirubin, and ophthalmic changes (patients up to 17 years) are monitored at least annually

Cystic Fibrosis (CFTR) Correctors-Symdeko

Generic	Brand
TEZACAFTOR-IVACAFTOR	SYMDEKO

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Age ≥6 years, AND
- Diagnosis of CF confirmed by a clinician with expertise in proving CF care, AND
- At least two copies of the F508del mutation in the CFTR gene detected using either an FDA-cleared CF mutation test or testing was completed by a CLIA certified laboratory, OR
- One of the following mutations known to be responsive to tezacaftor-ivacaftor, invacaftor in the CFTR gene

A1067T	D1270N	E56K	K1060T	R117C	S945L	2789+5G→A
A455E	D110E	E831X	L206W	R347H	S977F	3272-26A→G
D110H	D579G	F1052V	P67L	R352Q		3849+10kbC→T
D1152H	E193K	F1074L	R1070W	R74W		711+3A→G

Continuation of Therapy Criteria:

- Documentation of positive clinical response AND
- Specialist follow-up has occurred in the past 12 months, AND
- AST, ALT, bilirubin, and ophthalmic changes (patients up to 17 years) are monitored at least annually

Cystic Fibrosis (CFTR) Correctors-Orkambi

Generic	Brand
LUMACAFTOR-IVACAFTOR	ORKAMBI PACK

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is a specialist in the management of Cystic Fibrosis (CF), AND • Age ≥2 years, AND • Diagnosis of CF confirmed by a clinician in expertise in proving CF care, AND • At least two copies of the F508del mutation in the CFTR gene detected using either an FDA-cleared CF mutation test or testing was completed by a CLIA certified laboratory, AND • If ≥6 years, baseline percent predicted FEV1 is ≥30%
Continuation of Therapy Criteria: • Documentation of positive clinical response AND • Specialist follow-up has occurred in the past 12 months, AND • AST, ALT, bilirubin, and ophthalmic changes (patients up to 17 years) are monitored at least annually

Cystic Fibrosis (CFTR) Potentiators-Kalydeco

Generic	Brand
IVACAFTOR	KALYDECO

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Age ≥6 months, AND
- Patient is NOT homozygous for the F508del mutation in the CFTR gene, AND
- At least one of the following mutations in the CFTR gene:

P67L	R117C	R347H	E831X	K1060T	R1070W	S1251N	2789+5G→A
R74W	G178R	R352Q	S945L	A1067T	F1074L	S1255P	3272-26A→G
D110E	E193K	A455E	S977F	G1069R	D1152H	D1270N	3849+10kbC→T
D110H	L206W	S549N	F1052V	R1070Q	G1244E	G1349D	711+3A→G
						E56K	

-OR-

- Patients with a R117H mutation in the CFTR gene who have clinically significant disease (patients with RII7H and the 5T form of the poly-T tract, but not 7T or 9T)

Continuation of Therapy Criteria:

- Documentation of positive clinical response AND
- Specialist follow-up has occurred in the past 12 months, AND
- AST, ALT, bilirubin, and ophthalmic changes (patients up to 17 years) are monitored at least annually

Enzymes

Generic	Brand
PEGVALIASE-PQPZ	PALYNZIQ

Prior Authorization Criteria:
Length of Authorization: • Initial: 6 months • Reauthorization: 12 months
Initial Review Criteria: • Patient is ≥18 years, AND • Documented diagnosis of classical phenylketonuria (PKU) confirmed by metabolic specialist, AND • Pre-treatment baseline phenylalanine (Phe) level >600 micromol//L, AND • Dose does not exceed maximum FDA-approved dosing, AND • Not using concurrent Kuvan (sapropterin); sapropterin should be discontinued prior to initiation of pegvaliase-pqpz
Continuation of Therapy Criteria: • Documentation of positive clinical response AND • Office visit or telephone visit with a specialist within the past 12 months
Notes: • Do not approve continuation of therapy if Phe level >600 micromol/L after 16 weeks on the maximum 40 mg daily dose

Gastrointestinal (GI) Motility Agents

Last Revised 12.1.2023; Effective 1.1.2024

Adapted from DMAS Preferred Drug List

Generic	Brand
LUBIPROSTONE	AMITIZA
LINACLOTIDE	LINZESS
NALOXEGOL OXALATE	MOVANTIK
ALOSETRON HCL	LOTRONEX
METHYLNALTREXONE BROMIDE	RELISTOR
NALDEMEDINE TOSYLATE	SYMPROIC
PLECANATIDE	TRULANCE
ELUXADOLINE	VIBERZI
PRUCALOPRIDE	MOTEGRITY

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Documentation of adequate trial and failure of a preferred medication (Amitiza, Linzess, lubiprostone or Movantik) with clinical evidence of medical necessity is required before authorization will be given for a non-preferred medication (alosetron, Lotronex, Relistor, Trulance, Viberzi, Motegrity, Relistor, Symproic)
- Documented diagnosis of Idiopathic Chronic Constipation (ICC), Constipation Predominant Irritable Bowel Syndrome (IBS-C), Severe Diarrhea Predominant Irritable Bowel Syndrome (IBS-D), or Opioid Induced Constipation in chronic non-cancer pain (OIC)
- Criteria for Amitiza, Linzess, Trulance:
    - Documentation of treatment failure on at least two of the following classes
        - Osmotic Laxatives (i.e. lactulose, polyethylene glycol, sorbitol)
        - Bulk Forming Laxatives (i.e. psyllium, fiber)
        - Stimulant Laxatives (i.e. bisacodyl, senna)
- Criteria for Amitiza, Movantik, Relistor, Symproic (Diagnosis of OIC only):
    - Documentation of treatment failure on both polyethylene glycol and lactulose
- Criteria for Lotronex, Viberzi:
    - Documentation of treatment failure on at least three of the following classes
        - Bulk Forming Laxatives (i.e. psyllium, fiber)
        - Antispasmodic Agents (i.e. dicyclomine, hyoscyamine)
        - Antidiarrheal Agents (i.e. loperamide, diphenoxylate/atropine, codeine)
- Criteria for Motegrity:
    - Documentation and treatment failure on at least two osmotic laxatives (i.e. lactulose, polyethylene glycol, sorbitol) **AND** Amitiza, Linzess, or Trulance

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Growth Hormones

Last Revised 12/18/2023; Effective 02/06/2024

Generic	Brand
SOMATROPIN	GENOTROPIN, HUMATROPE, NORDITROPIN, NORDITROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, SEROSTIM, ZOMACTON ZORBTIVE
MECASERMIN	INCRELEX
LONAPEGSOMATROPIN-TCGD	SKYTROFA
SOMATROGON-GHLA	NGENLA
SOMAPACITAN-BECO	SOGROYA

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year (Exception: Serostim: 3 months)
- Reauthorization: 1 year

Initial Review Criteria:

For Pediatric Patients (≤18 years old)

- Requested medication must be prescribed by or in consultation with a specialist:
  - Endocrinology, Nephrology,
- Documentation of diagnosis of one of the following conditions:
  - Turner Syndrome, Prader-Willi Syndrome, Renal Insufficiency, Pediatric Chronic Kidney Disease, Small for Gestational Age, Idiopathic Short Stature, Growth Hormone Deficiency, or Newborn with Hypoglycemia and Diagnosis of Hypopituitarism or Panhypopituitarism, Familial Short Stature, Noonan Syndrome, SHOX Deficiency
- Requirements for Growth Hormone Deficiency:
  - Growth velocity < 25th percentile for bone age in a child with no other identifiable cause and in whom hypothyroidism, chronic illness, under nutrition and genetic syndromes have been excluded AND growth hormone response of less than 10 ng/mL to at least 2 provocative stimuli of growth hormone release: insulin, levodopa, arginine, clonidine, or glucagon; priming with sex steroids prior to stimulation test should be considered
- Requirements for Pediatric Chronic Kidney Disease/Chronic Renal Insufficiencies:
  - Creatinine clearance of 75 mL/min/1.73 m2 or less
  - Serum creatinine greater than 3.0 g/dL
  - Dialysis dependency

For Adult Patients (>18 years old)

- Requested medication must be prescribed by or in consultation with Endocrinology
- Documentation of diagnosis of growth hormone deficiency confirmed by growth hormone stimulation tests and rule-out of other hormonal deficiency, as follows: growth hormone response of fewer than five nanograms per mL to at least two provocative stimuli of growth hormone release: insulin, levodopa, L-Arginine, clonidine or glucagon when measured by polyclonal antibody (RIA) or fewer than 2.5 nanograms per mL when measured by monoclonal antibody (IRMA)
- Documentation of whether the cause of growth hormone deficiency is a result of Adult Onset Growth Hormone Deficiency (AO-GHD) alone or with multiple hormone deficiencies, such as hypopituitarism, because of hypothalamic or pituitary disease, radiation therapy, surgery, or trauma
- Documentation of rule-out of other hormonal deficiencies such as thyroid, cortisol, or sex steroids
- Documentation of diagnosis of short bowel syndrome
- Documentation of diagnosis of AIDS Wasting or cachexia

Continuation of Therapy Criteria:
Requirements for Pediatrics

- Documentation of improved/normalized growth velocity of at least 2 cm per year

Requirements for Adults

- Documentation of prescriber affirmation of positive response to therapy (improved body composition, reduced body fat, and increased lean body mass)

Hepatitis C Agents

Generic	Brand
LEDIPASVIR/SOFOSBUVIR	HARVONI
SOFOSBUVIR	SOVALDI
OMBITASVIR/PARITAPREVIR/ RITONAVIR	TECHNIVIE
OMBITASVIR/PARITAPREVIR/ RITONAVIR/DASABUVIR	VIEKIRA PAK VIEKIRA XR
ELBASVIR/GRAZOPREVIR	ZEPATIER
SOFOSBUVIR/VELPATASVIR	EPCLUSA
SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR	VOSEVI
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: based on standard length of treatment course
- Reauthorization: N/A

Initial Review Criteria:

- Non-preferred medication must be prescribed by or in consultation with a specialist
    - Gastroenterology, Hepatology, Infectious Disease, Transplant
- Patient may benefit from specialty consultation if meets any of these criteria: coinfected with hepatitis B or HIV; pregnant, breastfeeding, or planning to breastfeed; taking atazanavir or rifampin; severe kidney problems or is on dialysis; severe decompensated liver cirrhosis or a Child-Pugh score class B or C
- Documentation of diagnosis of Acute or Chronic Hepatitis C, Compensated cirrhosis, Hepatocellular Carcinoma, Decompensated Cirrhosis (Child Pugh Score Class B or C), Status Post Liver Transplant, and severe renal impairment (eGFR < 30 mL/min) or end stage renal disease requiring hemodialysis
- Documentation of HCV Genotype Test Results with corresponding treatment plan
- Selected therapy should be FDA-approved based on indication and specific genotype
- Documentation of any past treatment for Hepatitis C with dates, agents, and outcomes

Hereditary Angioedema (HAE) Agents

Last revised 08/09/2023 (effective 10/03/2023)

Generic	Brand
C1 ESTERASE INHIBITOR	BERINERT; CINRYZE
C1 ESTERASE INHIBITOR	HAEGARDA
ECALLANTIDE	KALBITOR
LANADELUMAB-FLYO	TAKHZYRO 150 MG/ML; 300MG/2ML
ICATIBANT ACETATE	FIRAZYR
BEROTRALSTAT HCL	ORLADEYO

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Review Criteria:

- Confirmed diagnosis of HAE by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:
    - C1-INh antigenic level below the lower limit of normal, OR
    - C1-INh functional level below the lower limit of normal, AND
- Prescribed by, or in consultation with, a board-certified allergist, immunologist, pulmonologist, hematologist, or medical geneticist
- For prophylactic use, therapy must be with one of the following:
    - Cinryze (C1 esterase inhibitor)
    - Haegarda (C1 estarase inhibitor)
    - Orladeyo (berotralstat)
    - Takhzyro (ianadelumab-flyo)
- For the treatment of acute HAE attacks, monotherapy with one of the following must be used:
    - Berinert (C1 esterase inhibitor)
    - Firazyr (icatibant)
    - Kalbitor (ecallantide)
    - Ruconest (C1 esterase inhibitor)
    - Sajazir (icatibant)
- Documentation prior pharmaceutical agents used as well as treatment outcomes
- Documentation of medical necessity providing clinical evidence that the preferred agent(s) will not provide adequate benefit
    -

Interleukin Inhibitors (Dupixent)

Last Revised 06/09/2023. Effective 07/01/2023

Generic	Brand
DUPILUMAB	DUPIXENT

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Review Criteria:

- Atopic Dermatitis
  - ≥ 6 months of age, AND
  - Diagnosis of moderate to severe atopic dermatitis, AND
  - Prior documented trial for 30 days and failure (or contraindication) of:
    - One topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone); OR
    - One topical calcineurin inhibitor (tacrolimus or pimecrolimus)

- Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)
  - ≥ 18 years of age, AND
  - Patient has inadequate response after 3 consistent months' use of intranasal steroids or oral corticosteroids, AND
  - Patient is concurrently treated with intranasal corticosteroids, AND
  - Physician has assessed baseline disease severity utilizing an objective measurement/tool

- Asthma
  - ≥ 6 years of age, AND
  - Diagnosis of moderate to severe asthma with either:
    - Eosinophil count ≥ 150 cells/mcL, OR
    - Oral corticosteroid-dependent asthma with at least one month of daily oral corticosteroid use within the last 3 months

- Diagnosis of eosinophilic esophagitis (EoE)
  - ≥ 12 years of age, AND
  - Patient weighs ≥ 40 kg, AND
  - Prescribed by or consultation with an allergist or gastroenterologist; AND
  - Patient did not respond clinically to treatment with a topical glucocorticosteroid or proton pump inhibitor

- Prurigo nodularis (PN)
  - ≥ 18 years of age, AND
  - Diagnosis of PN, AND
  - Prescribed by or in consultation with a dermatologist, allergist, or immunologist

Immunomodulators (Atopic Dermatitis)

Last revised: 12.18.2023

Generic	Brand
PIMECROLIMUS	ELIDEL
CRISABOROLE	EUCRISA
TACROLIMUS	PROTOPIC
RUXOLITINIB	OPZELURA
TRALOKINUMAB-LDRM	ADBRY

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Clinical Criteria for Elidel, Protopic, and tacrolimus
  - Patient must have an FDA age approved diagnosis of atopic dermatitis
    - Elidel mild to moderate for ages ≥ 2 years old Protopic 0.03%: moderate to severe for ages ≥ 2 years old
    - Protopic 0.1%: moderate to severe for ages ≥ 16 years
  - Failure of 8 weeks therapy to topical corticosteroids (i.e. desonide, fluticasone propionate, hydrocortisone butyrate, etc.)
- Clinical Criteria for Eucrisa and Opzelura
  - Patient must have an FDA age approved diagnosis of atopic dermatitis
    - Eucrisa: mild to moderate for ages equal or > 3 months old
    - Opzelura: mild to moderate for ages equal or ≥ 12 years of age
    - **Topical Opzelura is not covered for nonsegmental vitiligo in adult and pediatric patients ≥ 12 years old**
  - Eucrisa-prior trial & failure for 30 days (or contraindication) of:
    - Topical corticosteroids (i.e. desonide, fluticasone propionate, hydrocortisone butyrate, etc.); AND
    - Topical calcineurin inhibitors (tacrolimus or pimecrolimus)
  - Opzelura prior trial & failure for 8 weeks (or contraindication)
    - Topical corticosteroids (i.e. desonide, fluticasone propionate, hydrocortisone butyrate, etc.); AND
    - Topical calcineurin inhibitors (tacrolimus or pimecrolimus)
    - Dupixient
    - Eucrisa
- Clinical Criteria for Adbry
  - Patient must have an FDA age approved diagnosis of atopic dermatitis
    - Adbry: moderate to severe for ages ≥18 years
  - Prior documented trial and failure of 8 weeks of each:
    - One topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone), AND
    - One topical calcineurin inhibitor (tacrolimus or pimecrolimus), AND

Continuation of Therapy Criteria:

- Documentation that the initial review criteria are still met

Leptins

Generic	Brand
METRELEPTIN	MYALEPT

Prior Authorization Criteria:

Length of Authorization:

- Initial: 4 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Endocrinologist, AND
- Diagnosis of congenial or acquired generalized lipodystrophy associated with leptin deficiency (less than 12.0 ng/mL in females and less than 8.0 mg/mL in males), AND
- Is being used as an adjunct to diet modification, AND
- Documentation demonstrates that patient has at least ONE of the following:
    - Diabetes mellitus or insulin resistance with persistent hyperglycemia (HgbA1C >7) despite BOTH of the following:
        - Dietary intervention
        - Optimized insulin therapy at maximum tolerated doses
    - Persistent hypertriglyceridemia (TG >200) despite BOTH of the following:
        - Dietary intervention
        - Optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses

Continuation of Therapy Criteria:

- Documentation of positive clinical response and/or stabilization of laboratory parameters provided in initial authorization (i.e. fasting triglyceride concentrations, and/or HbA1C), AND
- Is being used as an adjunct to diet modification, AND
- Continues to be prescribed by an Endocrinologist

Movement Disorder Agents

Generic	Brand
TETRABENAZINE	XENAZINE
DEUTRABENAZINE	AUSTEDO
VALBENAZINE	INGREZZA and INGREZZA CPPK

*representative **list**

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Diagnosis of Tardive Dyskinesia or Huntington's disease
- Prescribed by or in consult with a neurologist or psychiatrist

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Multiple Sclerosis (Kesimpta) – Step Therapy (ST)

Generic	Brand
OFATUMUMAB	Kesimpta

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Authorization required for:
  - Kesimpta - Step therapy – Trial and failure of preferred Tecfidera

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Opioid Agents

Last reviewed 06/09/2023 (effective 07/01/2023)

Short-Acting Opioids
Long-Acting Opioids
Methadone

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Up to 1 month for severe post-surgical pain.
- Up to 3 months for pain associated with HIV/AIDS, chronic back pain, arthritis, fibromyalgia, diabetic neuropathy, postherpetic neuralgia.
- Up to 6 months for cancer pain, sickle cell disease, palliative care, end-of life care, hospice.

Review Criteria:

- Authorization required for:
  - All Long-Acting Opioids
  - Any Short-Acting Opioid prescribed for > 7 days or two (2) 7-day supplies per 60 days
  - Any cumulative opioid prescription > 90 morphine milligram equivalents (MME)
- Authorization Exclusion Criteria:
  - Intractable pain from active cancer, end-of-life, palliative care, hospice care
  - Remission from cancer and prescriber is safely weaning patient off opioids
  - Patient is living in a long-term care facility
- Documentation of Cumulative Total Daily MME dose calculated from PMP
  - If patient's Active Daily MME ≥ 90, the prescriber must attest that he/she will be managing the patient's opioid therapy long term, has reviewed the Virginia BOM Regulations for Opioid Prescribing, has prescribed naloxone, and acknowledges the warnings associated with high dose opioid therapy including fatal overdose, and that therapy is medically necessary for this patient
- Criteria for methadone pain management:
  - Documentation of treatment failure with at least 2 or more preferred long-acting opioids
  - Documentation of signed chronic pain agreement with patient
- Documentation of type of pain being treated as well as a list of opioid and non-opioid treatments trialed with outcomes
- If the patient is female between 18 and 45 years old, documentation of discussion of risk of neonatal abstinence syndrome and counseling on contraceptive options
- Documentation that prescriber has checked the PMP and provide the last fill date of the patient's most recent opioid and benzodiazepine prescription
  - If benzodiazepine filled in past 30 days, the prescriber must attest that he/she has counseled the patient on the FDA black box warning on the dangers of prescribing Opioids and Benzodiazepines including fatal overdose, has documented that the therapy is medically necessary, and has recorded a tapering plan to achieve the lowest possible effective doses of both opioids and benzodiazepines

- Documentation that naloxone has been prescribed for patients with risk factors of substance use disorder, doses in excess of 50 MME/day, antihistamines, antipsychotics, benzodiazepines, gabapentin, pregabalin, tricyclic antidepressants, or the “Z” drugs (zopiclone, zolpidem, or zaleplon).
- Documentation of a treatment plan with goals that addresses benefits and harm established with patient.

Opioid-Benzodiazepine Concurrent Use

Opioids
Benzodiazepines

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Authorization required when a benzodiazepine is prescribed while a patient is taking an opioid medication to ensure patient safety according to CDC Guidelines and FDA Black Box Warning when these agents are concurrently used
- Documentation of the patient's diagnosis for taking a benzodiazepine:
    - Acute alcohol withdrawal
    - Adjunct for relief of skeletal muscle spasms
    - Anxiety
    - Convulsive disorders
- Documentation of the patient's diagnosis for taking an opioid:
    - Active Cancer Pain
    - Hospice care/Palliative care
    - Chronic, non-cancer pain
    - Acute Pain
- Documentation that prescriber has checked the PMP and provide the last fill date of the patient's most recent opioid and benzodiazepine prescription
- Prescriber attestation that he/she will be managing the patient's therapy long term and that they have read the FDA Black Box Warning on prescribing opioids and benzodiazepines and the dangers involved and that therapy is medically necessary for this patient

Continuation of Therapy Criteria:

- Documentation that initial review criteria are still met

Opioid Dependency Oral Agents

Buprenorphine-Naloxone SL film
Zubsolv SL tablet

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Review Criteria:

The following criteria applies to non-preferred products only.

- Patient must be ≥ 16 years old
- Patient must meet criteria for a diagnosis of Opioid Use Disorder (defined by DSM 5)
- If the patient is pregnant, include expected date of delivery as well as positive pregnancy test
- Buprenorphine monotherapy will only be covered during the following:
    - Pregnant women for a maximum of 10 months
    - Patients when being converted to buprenorphine/naloxone combination therapy for 7 days
- If the requested product is non-preferred, provide documentation indicating medical necessity and reasoning for why a non-preferred product is required
- Daily doses of buprenorphine greater than 24 mg will deny.

Other Miscellaneous Therapeutic Agents

Generic	Brand
BUROSUMAB-TWZA	CRYSVITA

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

X-Linked Hypophosphatemia

- Prescribed by, or in consultation with, a specialist experienced in the treatment of metabolic bone disorders, AND
- Patient is ≥1 year, AND
- Patient has a diagnosis of X-linked hypophosphatemia (XLH) supported by at least one of the following: genetic testing (PHEX mutation) OR family member with X-linked inheritance OR serum fibroblast growth factor 23 (FGF23) level >30 pg/mL, AND
- Fasting serum phosphorus below the reference range for age, AND
- Patient meets either of the following based on age group: pediatric patients (epiphyseal growth plates are open), at least one of the following:
    - o radiographic evidence of active bone disease (rickets in wrists and/or knees and/or femoral/tibial bowing), OR
    - o documented abnormal growth velocity, OR
    - o 1 to 2 years of age without radiographic evidence or abnormal growth velocity; but with confirmed genetic testing or family history, and low fasting serum phosphorus; consider treatment per clinical judgement

  -OR-
- Adults and adolescents at final adult height (epiphyseal growth plates are closed) have presence of non-healing fractures (e.g., visible fracture lines), AND
- Patient does NOT have any of the following: chronic kidney disease (CKD) stage 2 or greater, evidence of tertiary hyperparathyroidism

Tumor-Induced Osteomalacia (TIO)

- Prescribed by, or in consultation with, a specialist experienced in the treatment of metabolic bone disorders and/or oncologist, AND
- Patient is ≥2 years, AND
- Patient has a diagnosis of TIO not amenable to surgical excision of the offending tumor/lesion, AND
- Serum phosphorus is within or above the normal range for age prior to treatment initiative, AND,
- Patient has no evidence of tertiary hyperparathyroidism

Continuation of Therapy Criteria:

- Documentation of positive clinical response (defined below), AND
- Office visit or telephone visit with a specialist within the past 12 months

Notes:

- Discontinuation only recommended if: intolerance to medication OR non-adherence to medication, lab-monitoring or follow-up assessments with a specialist OR lack of normalization of serum phosphorus OR lack of positive clinical response (a positive response is defined as an improvement in growth velocity, deformities, fractures, or bone pain) OR if initiating chemotherapy or planned surgical excision of tumor/lesion

Pancreatic Enzymes

Generic	Brand
PANCRELIPASE	CREON, ZENPEP, PANCREAZE, VIOKACE , PERTZYE

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Documentation of diagnosis of pancreatic insufficiency due to one of the following conditions:
    - Cystic fibrosis
    - Chronic pancreatitis
    - Pancreatectomy

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Potassium Sparing Diuretics

Generic	Brand	HICL	GSN	Representative NDC
FINERENONE	KERENDIA TABS 10 MG	47487	082499	50419054001
FINERENONE	KERENDIA TABS 20 MG	47487	082500	50419054101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Nephrologist or Endocrinologist,
- AND documented diagnosis of type 2 diabetes mellitus in patients at least 18 years of age,
- AND documented diagnosis of CKD (defined as eGFR 25-74 mL/min/1.73 m^2 and/or urinary albumin-to-creatinine ratio of >300),
- AND patient is on ACEI or ARB therapy, or if not prescribed, provider has documented rationale,
- AND documented baseline eGFR and serum potassium ≤4.8 mEq/L within past 3 months,
- AND documented adequate therapeutic trial (≥3 months) and failure, contraindication, or intolerance to Jardiance AND at least 1 anti-mineralocorticoid (i.e. spironolactone/eplerenone)

Continuation of Therapy Criteria:

- Documented beneficial response to therapy (i.e. no documentation of initiation of dialysis, kidney transplant, or decrease in eGFR of 40% or greater)
- AND patient continues to be under the care of a specialist

Proprotein Convertase Subtilisin Kexin Type-9 (PCSK-9) Inhibitors and Antihyperlipidemic – Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors

Last revised 12.1.2023; Effective 1.1.2024

Adapted from DMAS Preferred Drug List

Generic	Brand
ALIROCUMAB	PRALUENT
EVOLOCUMAB	REPATHA
BEMPEDOIC ACID	NEXLETOL
BEMPEDOIC ACID-EZETIMIBE	NEXLIZET

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Must be prescribed by or in consultation with either a Cardiologist or Endocrinologist
- Documentation of age group for appropriate indication:
    - 13-75 years old being considered for treatment of homozygous familial hypercholesterolemia (HoFH)
    - 18-75 years old being considered for treatment of heterozygous familial hypercholesterolemia (HeFH)
    - 18-75 years old being considered for treatment of suspected familial hypercholesterolemia (LDL ≥220 mg/dL)
    - 40-75 years old being considered for treatment of very high-risk ASCVD
        - Very high-risk ASCVD is defined as history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions.
            - Major ASCVD events include:
                - ❑ Recent ACS (within 12 months)
                - ❑ History of MI
                - ❑ History of ischemic stroke
                - ❑ Symptomatic PAD (history of claudication with ABI <0.85, or previous revascularization or amputation
            - High-risk conditions include:
                - ❑ Age ≥65 years
                - ❑ Heterozygous familial hypercholesterolemia
                - ❑ History of prior CABG or PCI outside of the major ASCVD events
                - ❑ Diabetes mellitus
                - ❑ Hypertension
                - ❑ CKD (eGFR 15-59 ml/min/1.73 m^2
                - ❑ Current smoking
                - ❑ Persistently elevated LDL-C (LDL-C ≥100 mg/dL despite maximally tolerated statin therapy and ezetimibe
                - ❑ History of congestive HF

- For HeFH/HoFH: Documentation of LDL-C > 100 mg/dL in the last 90 days
- For patients with suspected familial hypercholesterolemia: Documentation of LDL-C > 130 mg/dL in the last 90 days
- For patient with very high-risk ASCVD: Documentation of LDL-C ≥ 70 mg/dL in the last 90 days
- Patient had an adequate trial (8+ weeks) of high-dose, high-potency statin (atorvastatin 40-80 mg daily or rosuvastatin 20-40 mg daily) plus ezetimibe

- If statin intolerant:
    - Inability to tolerate at least 2 statins, with at least one started at the lowest starting daily dose AND
        - Statin dose reduction attempted for resolution of muscle symptoms, abnormal biomarkers OR
        - Muscle symptoms, abnormal biomarkers recur with low intensity/lowest possible statin dose re-challenge OR
        - Muscle symptoms, abnormal biomarkers recur with an adequate trial of hydrophilic statins – Pravastatin, Rosuvastatin
- Repatha 140 mg will only be approved for very high-risk ASCVD, suspected familial hypercholesterolemia, heterozygous familial hypercholesterolemia (HeFH).
- Repatha 420 mg will only be approved for diagnosis of homozygous familial hypercholesterolemia (HoFH).
- Praluent should only be prescribed if the patient has a documented failure to or adverse drug reaction to Repatha.
    - Praluent 150 mg will only be approved if there has been a trial of Praluent 75 mg for a minimum of 8 weeks with an LDL-C change of less than 30%: including lab results demonstrating LDL-C reduction pre and post therapy

Continuation of Therapy Criteria:

- Repatha should only be continued beyond 8 weeks in presence of LDL-C decrease of greater than 30%
- Praluent should only be continued beyond 8 weeks in presence of LDL-C decrease of greater than 30%
- Leqvio should only be continued beyond 8 weeks in presence of LDL-C decrease of greater than 30%

ACL Inhibitors

Initial Approval Criteria

- Patient is ≥ 18 years of age; AND
- Patient has diagnosis of heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD); AND
- Patient has failed to achieve a target LDL-C despite physician attestation that the patient is adherent to maximally tolerated doses of statins prior to the lipid panel demonstrating suboptimal reduction; AND
- Patient can be classified into ONE of the following risk factor groups:
- Extremely high risk ASCVD: (defined as extensive or active burden of ASCVD, or ASCVD with extremely high burden of adverse or poorly controlled risk cardio-metabolic risk factors including HeFH or severe hypercholesterolemia [SH] LDL-C > 220 mg/dl) with an LDL-C ≥ 70 mg/dL; OR
- Very high risk ASCVD: (defined as less extensive ASCVD and poorly controlled cardiometabolic risk factors) with an LDL-C ≥ 100 mg/dL; OR
- High risk ASCVD: (defined as either less extensive ASCVD and well-controlled risk factors or primary prevention HeFH or SH >220 mg/dl with poorly controlled risk factors) with LDL-C ≥ 130 mg/dL; AND

- Therapy will be used in conjunction with the maximum tolerated doses of a statin; AND
- Therapy will not be used with concurrent doses of simvastatin > 20 mg or pravastatin > 40 mg.

Renewal Criteria

- Laboratory analyses demonstrate a reduction in LDL-C when compared to the baseline values (prior to initiating bempedoic acid or bempedoic acid/ezetimibe); AND
- Patient has shown continued adherence to maximally tolerated statin dosage

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Pulmonary Arterial Hypertension (PAH) Agents

Generic	Brand
SILDENAFIL CITRATE (PULMONARY HYPERTENSION)	REVATIO
TADALAFIL (PULMONARY HYPERTENSION)	ADCIRCA ALYQ

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Patient must have diagnosis of pulmonary hypertension if ≥ 18 years old
- Prescriber must be a pulmonologist or cardiologist or in consultation with a specialty provider
- Documentation of clinical rationale for not taking sildenafil tablet to receive authorization for injectable Revatio

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Sotyktu (deucravacitinib)

Adapted from DMAS Preferred Drug List

Last reviewed 06/09/2023 (Effective 07/01/2023)

Prior Authorization Criteria:

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Patient must be 18 years of age or older
- Diagnosis of moderate to severe plaque psoriasis
- Prescribed by, or in consultation with, a dermatologist, rheumatologist, or other specialist in the treatment of psoriasis
- Symptoms persistent for ≥ 6 months with at least one of the following:
  - Involvement of at least 3% of body surface area (BSA), OR
  - Psoriasis Area and Severity Index (PASI) score of 10 or greater, OR
  - Incapacitation due to plaque location (i.e., head and neck, palms, soles, or genitalia), AND
- Trial and failure (≥3 months) of at least one of the following conventional therapy:
  - DMARD (e.g., methotrexate), OR
  - Immunosuppressant (e.g., cyclosporine), OR
  - Oral retinoid (e.g., acitretin), AND
- Patient is not using Sotyktu (deucravacitinib) in combination with any other biologic agent
- Trial and failure (≥3 months) unless contraindication or intolerance to, at least one preferred cytokine or CAM antagonist indicated for the treatment of this condition

Continuation of Therapy Criteria:

- Patient has a documented response to therapy compared to baseline (e.g., redness, thickness, scaliness, amount of surface area involvement, and/or PASI score)

Stimulants (ADHD)

Last revised 07/01/2023

Generic	Brand
DEXMETHYLPHENIDATE HCL	FOCALIN, FOCALIN XR
METHYLPHENIDATE HCL	QUILLICHEW ER, QUILLIVANT XR, CONCERTA, APTENSIO XR, METADATE ER, METHYLIN, RELEXXII, RITALIN, RITALIN LA, METADATE CD
METHYLPHENIDATE	DAYTRANA, COTEMPLA XR
DEXTROAMPHETAMINE/AMPHETAMINE	ADDERALL, ADDERALL XR, MYDAVIS
DEXTROAMPHETAMINE SULFATE	DEXEDRINE, DEXEDRINE SPANSULE, ZENZEDI, PROCENTRA
LISDEXAMFETAMINE DIMESYLATE	VYVANSE
METHAMPHETAMINE HCL	DESOXYN
AMPHETAMINE SULFATE	EVEKEO
AMPHETAMINE	ADZENYS ER, ADZENYS XR-ODT, DYANAVEL XR
SERDEXMETHYLPHENIDATE CHLORIDE-DEXMETHYLPHENIDATE HCL45	AZSTARYS

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Required for patients ≤ 4 years old OR ≥ 18 years old
- For patients ≤ 4 years old, prescriber must be a pediatric psychiatrist, pediatric neurologist, developmental/behavioral pediatrician, or in consultation with one of these specialists.
- For patients ≥ 18 years old:
    - Documentation of diagnosis of ADHD by Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (including documentation of impairment in more than one major setting), determined by the primary care clinician
- If the requested product is non-preferred, provide documentation of the following:
    - Pharmaceutical agents attempted with outcome
    - Indicating medical necessity and reasoning for why a non-preferred product is required

Continuation of Therapy Criteria:

- Documentation that the prescriber has regularly evaluated the patient for stimulant and/or other substance use disorder, and, if present, initiated specific treatment, consulted with an appropriate healthcare provider, or referred the patient for evaluation for treatment if indicated

Topical Retinoids

Generic	Brand
TRETINOIN	RETIN-A GEL, TRETIN-X, ATRALIN, ALTRENO, AVITA
ADAPALENE	DIFFERIN, PLIXDA
AZELAIC ACID	AZELEX
ADAPALENE-BENZOYL PEROXIDE	EPIDUO
TRETINOIN MICROSPHERE	RETIN-A MICRO

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- All patients must have a diagnosis of acne
- Patients ≥ 18 years old will require evaluation of treatment diagnosis

Continuation of Therapy Criteria:

- Documentation of continued medical necessity