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Formulary Update

At A Glance

Formulary Additions

- Kisqali (ribociclib) Tablet Therapy Packs
- Lurasidone (generic Latuda) Tablets

Prior Authorization (QRM) Additions

- Brexafemme (ibrexafungerp) Tablets
- Rebyota (fecal microbiota, live-jslm) Rectal Suspension
- Tzield (teplizumab-mzwv) Intravenous Solution
- Vivjoa (oteseconazole) Capsule Therapy Pack
- Xenpozyme (olipudase alfa-rpcp) Intravenous Solution

Prior Authorization (QRM) Updates

- Adbry (tralokinumab-ldrm) Subcutaneous Injection
- Brukinsa (zanubrutinib) Capsules
- Calquence (acalabrutinib) Tablets
- Cibinqo (abrocitinib) Tablets
- Firdapse (amifampridine) Tablets
- GLP-1RAs for Weight Loss
- Growth Hormones (somatropin) Injection
- Hyaluronic Acid Derivatives Injection
- Imbruvica (ibrutinib) Capsules/Suspension/Tablets
- Jaypirca (pirtobrutinib) Tablets
- Rinvoq (upadacitinib) Tablets

Commercial HMO/Closed Formulary Additions

The following medications will be ADDED to the Commercial HMO/Closed Formularies effective July 12, 2023:

Note: Commercial HMO/Closed formulary additions may result in tier changes on the QHP-ACA/Open Formularies

- **Kisqali (ribociclib) Tablet Therapy Packs:** Indicated for the treatment of advanced or metastatic breast cancer.
- **Lurasidone (generic Latuda):** Indicated for the treatment of bipolar major depression and schizophrenia.

A PUBLICATION OF THE GEORGIA PHARMACY AND THERAPEUTICS (P&T) COMMITTEE. The Formulary Update contains information regarding formulary additions, deletions, exclusions, brief descriptions of products, and current drug related news. It also lists items to be discussed at upcoming P&T meetings. Please refer to the web pages: KP Georgia Formulary and Drug Lists OR Drug Formulary for Practitioners for the full KPGA Drug Formulary.

Interregional Practice Recommendations

The Emerging Therapeutics Strategy Program (ETSP) is a centralized effort that applies our evidence-based model to develop interregional practice recommendations with KP physician specialists, coordinates KP HealthConnect clinical content for decision support, and monitors outcomes to measure uptake of the clinical and strategy recommendations. Through the collaboration of Pharmacy, Permanente physicians, and Federation partners, the ETSP offers a unified approach in the provision and management of specialty drugs to help ensure that our members derive the greatest value from these products.

The following IR Practice Recommendation ADDITION was recently approved:

- **Skyclarys (omaveloxolone):** Indicated for the treatment of Friedreich ataxia in adults and adolescents ≥16 years of age.

The following IR Practice Recommendation UPDATE was recently approved:

- **Zulresso (brexanolone):** Updated to (1) include the expanded indication of adolescents aged 15-17 years old, (2) soften language to consider a trial of antidepressant medication or other somatic treatment prior to initiating treatment, (3) add thyroid stimulating hormone (TSH) and complete blood count (CBC) to recommended baseline labs, and (4) add pediatric specialists in consultation with a psychiatrist as recommended designated prescribers.

ETSP recommendations as well as pipeline candidates can be found here: Emerging Therapeutics Strategy Program. Please note: Newly marketed medications requiring ETSP review will also receive prior authorization (PA) review. These medications will not be eligible for consideration of drug benefit coverage until completion of drug specific ETSP and PA criteria review processes.

Additions to the QRM Prior Authorization Review List of Medications for the Commercial/HMO Closed Formularies & QHP-ACA/Open Formularies

Note: The updates below DO NOT APPLY to Medicare Part D or Dual Choice Prescription Benefit Plans. Optum and MedImpact are the external PBMs for each of these plans, respectively, externally administering all non-formulary or prior authorization criteria and coverage review.

The following QRM additions will be effective July 12, 2023:

- **Rebyota (fecal microbiota, live-jslm):** Indicated for the prevention of recurrence of C. difficile infection (CDI) in patients ≥18 years of age following antibiotic treatment of recurrent CDI.
- **Tzield (teplizumab-mzwv):** To delay the onset of stage 3 type 1 diabetes mellitus in adults and pediatric patients ≥8 years of age with stage 2 type 1 diabetes mellitus.
- **Vivjoa (oteseconazole):** Indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential, alone or in combination with fluconazole.
- **Xenpozyme (olipudase alfa-rpcp):** Indicated for treatment of non-CNS manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.

The following QRM additions will be effective January 1, 2024:

- **Brexafemme (ibrexafungerp):** Indicated for treatment of vulvovaginal candidiasis (VVC) and reduction in the incidence of recurrent VVC in adult and postmenarchal pediatric patients.

Upcoming Formulary Items

An important aspect of the formulary process is the involvement of all practitioners. Please contact your P&T Committee representative or your clinical service chief by July 18 if you wish to comment on any of the medications, class reviews, or other agenda items under consideration. To make formulary addition requests, you must submit a Formulary Additions/Deletions Form and Conflict of Interest Form to Drug Information Services or call (404) 439-4417 OR (404) 777-3784.

QRM Prior Authorization Review Criteria Updates

Note: The updates below DO NOT APPLY to Medicare Part D or Dual Choice Prescription Benefit Plans. Optum and MedImpact are the external PBMs for each of these plans, respectively, externally administering all non-formulary or prior authorization criteria and coverage review.

- **Adbry (ralokinumab-ldrm):** Criteria updated to (1) highlight tacrolimus as the preferred topical calcineurin inhibitor and (2) remove the required trial of Dupixent.
- **Brukinsa (zanubrutinib):** Ibrutinib removed as an alternative agent to zanubrutinib for the treatment of mantle cell lymphoma.
- **Calquence (acalabrutinib):** Ibrutinib removed as an example of a B-cell receptor inhibitor for the treatment of mantle cell lymphoma.
- **Cibinqo (abrocitinib):** Criteria updated to (1) include the expanded indication for age 12 years and older, (2) highlight tacrolimus the preferred topical calcineurin inhibitor, (3) add Adbry as an optional trial agent prior to approval, and (4) remove Opzelura and Rinvoq as required trial products.
- **Firdapse (amifampridine):** Criteria updated to (1) remove Ruzurgi from the criteria, (2) remove adequate swallowing function for adults as a requirement, and (3) add history of seizures and remove adults with gastronomy tube under reasons for non-coverage.
- **Imbruvica (ibrutinib):** Removed criteria for the treatment of mantle cell lymphoma and marginal zone lymphoma.
- **Jaypirca (pirtobrutinib):** Ibrutinib removed from the criteria as an example of a prior therapy for mantle cell lymphoma required in the criteria.
- **Glucagon-like Peptide-1 Receptor Agonists (GLP-1 RAs) for Weight Loss:** Criteria updated to remove requirement that a patient is not a candidate for weight loss surgery or there is inadequate weight loss with weight loss surgery for patients with a BMI ≥40.
- **Growth Hormones (somatropin injection):** Criteria updated to (1) change the order of preference of growth hormone products to Omnitrope followed by Genotropin, then Norditropin and (2) align reasons for non-coverage regarding children with Prader-Willi syndrome with Prescribing Information.
- **Hyaluronic Acid Derivatives:** Criteria updated to (1) change Gelsyn-3 as the second line agent for approval if trial of Supartz is ineffective or if patient is intolerant to Supartz and (2) add Durolane as a non-preferred product.
- **Rinvoq (upadacitinib):** Criteria updated to (1) highlight tacrolimus as the preferred topical calcineurin inhibitor, (2) add Adbry as an optional trial agent prior to approval, and (3) remove Opzelura as a required trial product.

Commercial HMO/Closed Formulary & QHP-ACA/Open Formulary Quantity Limit Changes

Effective 7.12.2023

Medication	Current Quantity Limit	New Quantity Limit
Brexafemme (ibrexafungerp)	4 tablets per 365 days	4 tablets per 30 days with maximum of 6 fills

Information Concerning Coverage Determinations

Medicare Part D: Medicare Part D Plan Non Formulary and Prior Authorization criteria and coverage determination are made externally by the Pharmacy Benefit Manager Optum Rx.

Prescriber completes the .NFRequestForm when entering drug order. Your documentation is used by OptumRx to determine whether the prescribed drug is eligible for drug benefit coverage. No documentation = No coverage.

The KP Pharmacy Consult Service will send your documentation to OptumRx for their coverage determination decision. If OptumRx has further questions, you will be contacted for responses. You may phone OptumRx at **1-888-791-7255** to address any patient / drug coverage specific questions. To see the MPD Formulary, please visit: MPD Formulary

Dual Choice: Dual Choice Plan Non Formulary and Prior Authorization criteria and coverage determination are made externally by the Pharmacy Benefit Manager MedImpact.

Prescriber completes the .NFRequestForm when entering drug order. Your documentation is used by MedImpact to determine whether the prescribed drug is eligible for drug benefit coverage. No documentation = No coverage.

The KP Pharmacy Consult Service will send your documentation to MedImpact for their coverage determination decision. If MedImpact has further questions, you will be contacted to provide responses. You may phone MedImpact at **1-844-336-2676** to address any patient / drug coverage specific questions. The Dual Choice formulary differs from the KPHC formulary (i.e. DOACs, ADHD, asthma). Please visit: Choice Formulary

Questions and Concerns?

If you have any questions or concerns, please contact any of the following P&T Committee members and designated alternates:

P&T Committee Voting Members:

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Karen Bolden, RN, BSN
Clinical Services

Hector Clarke, PharmD, BCOP
Ambulatory Pharmacy

Halima Daboiko, MD
Obstetrics and Gynecology

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Hospitalist

Larry Kang, MD
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Craig Kaplan, MD
Adult Primary Care

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Daniel Robitshek, MD
CDU/Hospital Services

Designated Alternates:

Jacqueline Anglade, MD
Obstetrics and Gynecology

Lesia Jackson, RN
Clinical Services

Satya Jayanthi, MD
Hospitalist

Department Floor Stock/ Pyxis Preference List Additions

Effective 7.12.2023

Medication	Department
Phenylephrine 100 mcg/mL Syringes	ACC-CDU

Commercial HMO/Closed Formulary & QHP-ACA/Open Formulary Unit of Use Benefit Addition

Effective July 12, 2023: the unit of use benefit will be applied to Adbry (tralokinumab-ldrm) to apply 1 copay per standard package size.

Bethanechol Oral Suspension Compounding Recipe Update

- Effective 7.12.2023: the concentration of the compounding recipe will change from bethanechol 1 mg/ml to bethanechol 5 mg/mL.
- Important changes in the updated recipe include the following:
  - Under Ingredients: the strength of bethanechol tablets used for compounding will change from bethanechol 10 mg tablets to bethanechol 50 mg tablets.
  - Under Calculations: the final volume will change from bethanechol 120 mg/120 mL to bethanechol 600 mg/120 mL to compound the new 5 mg/mL concentration.

Medicare Part D Formulary Changes

Kaiser Permanente has a National Medicare Part D (MPD) Formulary. Each regional P&T Committee reviews drugs and decides on tier status. The National Medicare Part D Pharmacy and Therapeutics Committee is charged with reconciling regional differences in MPD Formulary recommendations through consensus building in order to maintain one National MPD Formulary for Kaiser Permanente.

Medicare Part D Formulary Removals

During the year, Kaiser Permanente may make changes to our Medicare Part D Formulary (Drug List). The information provided below is intended to inform you of these changes.

The following table lists all brand-name drugs recently removed from the Medicare Part D Formulary with the new generic formulation added to formulary

Brand Medication	Brand Drug Tier	Generic Alternative	Generic Drug Tier	Effective Date
AUBAGIO TABS 7 MG	5	TERIFLUNOMIDE TABS 7 MG	4	6/1/2023
AUBAGIO TABS 14 MG	5	TERIFLUNOMIDE TABS 14 MG	4	6/1/2023
NOXAFIL SUSP 40 MG/ML	5	POSACONAZOLE SUSP 40 MG/ML	5	7/1/2023
PYLERA CAPS 140-125-125 MG	5	BISMUTH/METRONIDAZOLE/ TETRACYCLINE CAPS 140-125-125 MG	4	7/1/2023

In the news...

FDA Approves Jardiance and Synjardy to Treat Pediatric Type 2 Diabetes

On June 20, 2023, the FDA approved the expanded indication for Jardiance (empagliflozin) and Synjardy (empagliflozin and metformin hydrochloride) as an adjunct to diet and exercise to improve blood sugar control in children 10 years of age and older with type 2 diabetes (T2D).[1] Previously, these agents were approved for the same indication in adults, as well as for indications related to the prevention of cardiovascular death and hospitalization in certain adult patients.[1] Metformin, the only other oral therapy available for the treatment of children with type 2 diabetes, was first approved for pediatric use in 2000.[2] The expanded approval of Jardiance and Synjardy provides a new class of medicines, the SGLT2 inhibitors, to treat pediatric type 2 diabetes.[1] Empagliflozin, the active ingredient found in both Jardiance and Synjardy, is a sodium-glucose cotransporter 2 (SGLT2) inhibitor and works by increasing the excretion of glucose in the urine.[1]

The expanded approval of Jardiance and Synjardy was based on safety and efficacy data from the double-blind, randomized, placebo-controlled Phase 3 DINAMO trial, which evaluated the use of empagliflozin as adjunct to diet and exercise in 157 patients 10 to 17 years of age, with inadequately controlled T2D.[1,2] Participants were randomly assigned to one of three treatment arms for 26 weeks: empagliflozin, a DPP-4 inhibitor (linagliptin), or placebo.[2] At the beginning of the trial, 51% of patients were taking metformin alone, 40% of patients were taking a combination of metformin and insulin, 3% of patients were taking insulin alone, and 6% of patients were not taking other medicines for diabetes.[2] Patients receiving baseline treatments (e.g. metformin alone, metformin and insulin, insulin alone), continued these treatments during the trial.[1] The trial found that empagliflozin was superior to placebo for the primary endpoint of reducing glycated hemoglobin (HbA1c) levels.[1] After the 26-week treatment period, the 52 patients treated with empagliflozin had an average 0.2% decrease in hemoglobin A1c compared with an average 0.7% increase in hemoglobin A1c in the 53 patients taking placebo.[2] Patients treated with empagliflozin also had reductions in fasting plasma glucose as compared to patients taking placebo, a secondary endpoint.[1,2]

Side effects of empagliflozin observed among study participants were generally similar to those reported in adults, although there was an increased risk of hypoglycemia compared to placebo, regardless of whether they were taking other therapies for diabetes.[2] The most common side effects in adults treated with empagliflozin include urinary tract infections and female fungal infections.[3] The most common side effects in patients treated with metformin include diarrhea, nausea and upset stomach.[4]

Additional information on both Jardiance and Synjardy can be found in the prescribing information available here: Jardiance Prescribing Information and Synjardy Prescribing Information.

References:

1. IPD Analytics. Boehringer Ingelheim/Lilly's Jardiance and Synjardy Receive Label Expansion to Treat Type 2 Diabetes in Children. PHARMACY & THERAPEUTICS WATCH LIST | 06.26.2023.
2. FDA News Release. FDA Approves New Class of Medicines to Treat Pediatric Type 2 Diabetes. Available at https://www.fda.gov/news-events/press-announcements/fda-approves-new-class-medicines-treat-pediatric-type-2-diabetes. Accessed on June 29, 2023.
3. Jardiance. Prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. Accessed June 29, 2023. jardiance-us-pi.pdf (boehringer-ingelheim.com)
4. Gluophage. Prescribing information. Bristol-Myers Squibb Company. Accessed June 30, 2023. https://packageinserts.bms.com/pi/pi_glucophage.pdf

Class Review

August 2023:

Medication Class Reviews
Amebicides
Aminoglycosides
Anthelmintics
Antifungals
Anti-infectives – Misc
Antimalarials
Antimycobacterial
Antivirals
Biological Misc
Cephalosporins
Dermatological
Fluoroquinolones
Local Anesthetics – IV
Macrolides
Penicillins
Psychotherapeutics and Neurological Agents Misc.
Sulfonamides
Tetracyclines
Toxoids