ISSUE 4 | VOLUME 17 | August 2023



# Formulary Update

## At A Glance

**Formulary Additions - Effective 9.7.2023**

- Dimethyl fumarate (generic Tecfidera) Capsules
- Tagrisso (osimertinib) Tablets
- Teriflunomide (generic Aubagio) Tablets

**Prior Authorization (QRM) Removals**

- Dimethyl fumarate (generic Tecfidera)
- Teriflunomide (generic Aubagio)

**Prior Authorization (QRM) Additions**

- Adstiladrin (nadofaragene firadenovec)
- Filspari (sparsentan)
- Jesduvroq (daprodustat)
- Joenja (leniolisib)

**Prior Authorization (QRM) Updates**

- Aubagio (teriflunomide)
- Calcitonin gene-related peptide (CGRP) inhibitors
- Cibinqo (abrocitinib)
- Cimzia (certolizumab)
- Gilenya (fingolimod)
- Imcivree (setmelanotide)
- Interferon beta-1a
- Kesimpta (ofatumumab)
- Livmarli (maralixibat)
- Mayzent (siponimod)
- Nurtec ODT (rimegepant)
- Ocrevus (ocrelizumab)
- Ponvory (ponesimod)
- Qulipta (atogepant)
- RET Inhibitors
- Rinvoq (upadacitinib)
- Stelara (ustekinumab)
- Tascenso ODT (fingolimod lauryl sulfate)
- Tecfidera (dimethyl fumarate)
- Trikafta (elexacaftor, tezacaftor, and ivacaftor)
- Ubrelvy (ubrogepant)
- Xyrem (sodium oxybate)

**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.

## Commercial HMO/Closed Formulary Additions

**The following medications will be ADDED to the Commercial HMO/Closed Formularies effective September 7, 2023:**

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

- **Dimethyl fumarate (generic Tecfidera) capsules:** Indicated for treatment of relapsing forms of multiple sclerosis (MS).
- **Tagrisso (osimertinib) tablets:** Indicated for treatment of non-small cell lung cancer (NSCLC).
- **Teriflunomide (generic Aubagio) tablets:** Indicated for treatment of relapsing forms of MS.

## QHP-ACA/Open Formulary Tier Changes

**The following tier changes will be effective September 7, 2023:**

- **Darunavir (generic Prezista) 600 mg and 800 mg tablets:** Down-tier to Generic Tier 2

## Interregional Treatment Algorithms

**The following Interregional Treatment Algorithms were recently approved:**

- **Atopic Dermatitis (AD):** Interregional recommendations were developed for the treatment of AD in adult and pediatric patients in the outpatient setting.
- **Bipolar Disorders and Schizophrenia:** Interregional recommendations were developed to provide guidance on preferred medications in the treatment of bipolar disorder, schizoaffective disorder, and schizophrenia in patients who are newly started on treatment or in those who may be candidates for switching from a non-preferred medication to a preferred medication.

## 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 Interregional Practice Recommendations were recently approved:**

- **Adstiladrin (nadofaragene firadenovec):** Indicated for high-risk Bacillus Calmette-Guérin (BCG)-unresponsive, high-risk, nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

**The following Interregional Practice Recommendation REVISIONS were recently approved:**

- **Leqembi (lecanemab):** Lecanemab received full traditional approval from the FDA on July 6, 2023. Revisions include updates to KP's recommendation for use, recommended screening, recommendations to not initiate therapy, and recommendations for discontinuation.

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.

## 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 September 21 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) 439-4439.**

## Removal from the QRM Prior Authorization Review List of Medications for the Commercial HMO Closed Formularies & QHP-ACA/Open Formularies

**The following QRM removal will be effective September 7, 2023:**

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.

- **Dimethyl fumarate (generic Tecfidera):** Indicated for treatment of relapsing forms of MS.
- **Teriflunomide (generic Aubagio):** Indicated for treatment of relapsing forms of MS.

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

**The following QRM additions will be effective September 7, 2023:**

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.

- **Adstiladrin (nadofaragene firadenovec):** Indicated for high-risk BCG-unresponsive, high-risk, NMIBC with CIS with or without papillary tumors.
- **Filspari (sparsentan):** Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.
- **Jesduvroq (daprodustat):** Indicated for treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months.
- **Joenja (leniolisib):** Indicated for treatment of activated phosphoinositide 3-kinase delta syndrome in adult and pediatric patients 12 years of age and older who weigh 45 kg or more.

## 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.

- **Aubagio (teriflunomide):** Criteria updated to require 1) trial and failure of teriflunomide (generic Aubagio) and 2) trial of other therapeutic alternatives prior to coverage of brand Aubagio.
- **Calcitonin gene-related peptide (CGRP) inhibitors:** Criteria updated to make language uniform regarding a trial of traditional preventive medications prior to CGRP for migraine preventative therapy.
- **Cibinqo (abrocitinib):** Criteria updated to include criteria for new members to KPGA under atopic dermatitis.
- **Cimzia (certolizumab):** Criteria updated to no longer require a trial of Xeljanz (tofacitinib) for Crohn's disease.
- **Gilenya (fingolimod):** Criteria updated to separate fingolimod (generic Gilenya) criteria from brand Gilenya criteria. Brand Gilenya criteria will require trial and failure of fingolimod (generic Gilenya) and rituximab.
- **Imcivree (setmelanotide):** Criteria updated to 1) include additional requirements for coverage determination (age and weight requirements) and 2) further clarify required labs.
- **Interferon beta-1a:** Criteria updated to distinguish between the preferred and non-preferred interferon beta-1a therapies.
- **Kesimpta (ofatumumab):** Criteria updated to 1) include recently approved Briumvi (ublituximab), making it a preferred product prior to ofatumumab and ocrelizumab, 2) add screening for tuberculosis, and 3) remove concomitant use of intravenous immunoglobulin as a reason for non-coverage.
- **Livmarli (maralixibat):** Criteria updated to include the FDA label expansion to reduce the minimum age of prescribing to infants 3 months of age.
- **Mayzent (siponimod):** Criteria updated to reflect the preferred disease modifying therapies based on current cost.

## 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 within the labeled time frame (standard: 72 hours; urgent: 24 hours). If not received by the deadline, the PBM will deny the request. 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 within the labeled time frame (standard: 72 hours; urgent: 24 hours). If not received by the deadline, the PBM will deny the request. 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:**

Debbi Baker, PharmD, BCPS
Clinical Pharmacy

Karen Bolden, RN, BSN
Clinical Services

Hector Clarke, PharmD, BCOP
Ambulatory Pharmacy

Halima Daboiko, MD
Obstetrics and Gynecology

Carole Gardner, MD
P&T Chair/Geriatrics

Pierson Gladney, MD
Hematology/Oncology

Ramin Haddad, MD
Hospitalist

Larry Kang, MD
Adult Primary Care

Craig Kaplan, MD
Adult Primary Care

Christine Kofman, MD
Pediatrics

Amy Levine, MD
Pediatrics

Sophie Lukashok, MD
Infectious Disease

Chad Madill, PharmD, MBA
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Jennifer Marrast-Host, MD
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Felecia Martin, PharmD
Pharmacy/Geriatrics

Shayne Mixon, PharmD
Pharmacy Operations

Jennifer Rodriguez, MD
Behavioral Health

**P&T Committee Non-Voting Physician Members:**

Tarayn Fairlie, MD
Pediatrics

Daniel Robitshek, MD
CDU/Hospital Services

**Designated Alternates:**

Jacqueline Anglade, MD
Obstetrics and Gynecology

Lesia Jackson, RN
Clinical Services

Satya Jayanthi, MD
Hospitalist

## QRM Prior Authorization Review Criteria Updates (continued)

- **Nurtec ODT (rimegepant):** Criteria updated to make language uniform regarding a trial of traditional preventive medications prior to CGRP for migraine preventative therapy.
- **Ocrevus (ocrelizumab):** Criteria updated to 1) include recently approved Briumvi (ublituximab), making it a preferred product prior to ofatumumab and ocrelizumab, 2) add screening for tuberculosis, and 3) remove concomitant use of intravenous immunoglobulin as a reason for non-coverage.
- **Ponvory (ponesimod):** Criteria updated to reflect the preferred disease modifying therapies.
- **Qulipta (atogepant):** Criteria updated to 1) make language uniform regarding a trial of traditional preventive medications prior to CGRP for migraine preventative therapy and 2) include expanded FDA indication for the preventive treatment of chronic migraine in adults.
- **RET Inhibitors:** Criteria updated to indicate that Retevmo (selpercatinib) is the only FDA approved RET inhibitor for the treatment of medullary thyroid cancer.
- **Rinvoq (upadacitinib):** Criteria updated to include 1) criteria for new members to KPGA under atopic dermatitis and 2) new FDA approval for the treatment of adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blocker.
- **Stelara (ustekinumab):** Criteria updated under the pediatric Crohn's disease criteria to 1) remove trial and failure of Entyvio from coverage criteria and 2) include language specifying that the induction dose is only approved for back-office use and subsequent doses are only approved for a member to fill via the outpatient pharmacy benefit.
- **Tascenso ODT (fingolimod lauryl sulfate):** Criteria updated to further clarify coverage criteria concerning fingolimod capsules.
- **Tecfidera (dimethyl fumarate):** Criteria updated to require 1) trial and failure of dimethyl fumarate (generic Tecfidera) and 2) trial of other therapeutic alternatives prior to coverage of brand Tecfidera.
- **Trikafta (elexacaftor, tezacaftor, and ivacaftor):** Criteria updated to include 1) patients aged 2 years and older based on the FDA approved label expansion and 2) a table of specific CFTR gene mutations.
- **Ubrelvy (ubrogepant):** Criteria update to remove concurrent use of injectable CGRPs as a reason for non-coverage.
- **Xyrem (sodium oxybate):** Criteria updated to specify that sodium oxybate (generic sodiumoxybate) is preferred and brand Xyrem is non-preferred.

## QHP-ACA/Open Formulary Step Therapy Removals

**The following Step Therapy Removals will be effective September 7, 2023:**

- **Tagrisso (osimertinib) tablets**

## QHP-ACA/Open Formulary Step Therapy Additions

**The following Step Therapy Additions will be effective September 7, 2023:**

- **Miebo (perfluorohexyloctane) 100% ophthalmic solution**

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

| Medication | Quantity Limit | Effective Date |
|---|---|---|
| Ozempic (semaglutide) – ALL STRENGTHS | 3 mL per 28 days | 8.10.2023 |
| Joenja (leniolisib) | 30-day supply | 9.7.2023 |

## Department Floor Stock/Pyxis Preference List Removals

**Effective September 7, 2023:**

| Medication | Department |
|---|---|
| Lantus 100 units/mL Vials | ACC/CDU Pyxis |
| Form Prescription Tamper Proof Paper 8.5 X 11 | Country Employee Clinic |

## Department Floor Stock/Pyxis Preference List Additions

**Effective September 7, 2023:**

| Medication | Department |
|---|---|
| Insulin Glargine-yfgn | ACC/CDU Pyxis |
| Altafluor Benox 0.25-0.4 % (Benoxinate Hydrochloride 0.4% and Fluorescein Sodium 0.25%) Solution | ACC/CDU |
| BIOGLO (Fluorescein) 1 Mg Ophthalmic Strips | Ophthalmology |
| Easy Touch Lancets | Internal Medicine |
| Cerave AM SPF 30 Lotion | Cosmetic Dermatology |
| Cetaphil Daily Facial SPF 15 Lotion | Cosmetic Dermatology |
| Sodium Bicarbonate Solution 8.4 % | Cosmetic Dermatology |

## Medicare Part D Formulary Removals

During the year, Kaiser Permanente may make changes to our Medicare Part D Formulary (Drug List). The list below is intended to inform you of these changes. The following table lists all products recently removed from the Medicare Part D Formulary to be replaced with the generic.

| Brand Medication | Brand Drug Tier | Generic Alternative | Generic Drug Tier | Effective Date |
|---|---|---|---|---|
| IRESSA TABS 250 MG | 5 | GEFITINIB TABS 250 MG | 5 | 8.1.2023 |
| PREZISTA TABS 600 MG | 3 | DARUNAVIR TABS 600 MG | 2 | 9.1.2023 |
| PREZISTA TABS 800 MG | 3 | DARUNAVIR TABS 800 MG | 2 | 9.1.2023 |

## In the news...

On June 28, 2023, the FDA approved Lantidra (donislecel-jujn), an allogeneic pancreatic islet cellular therapy for the treatment of adults with type 1 diabetes (T1D) unable to achieve target blood glucose levels due to frequent episodes of severe hypoglycemia despite intervention. This represents a rare subtype of T1D that is estimated to affect fewer than 80,000 patients in the United States. Lantidra is the first allogeneic cellular therapy approved for the treatment of T1D. It is derived from deceased donor pancreatic cells and administered as a single infusion into the hepatic portal vein. Up to two additional infusions may be administered depending on the patient's response. Initial infusions will occur at the University of Illinois Hospital/CellTrans facilities.

It is believed that the infused allogeneic beta cells' primary mechanism of action is the secretion of insulin. In some patients, the levels produced are sufficient to allow independence from exogenous insulin. Maintenance immunosuppression must be continued permanently to prevent islet graft rejection; this is a significant drawback of Lantidra therapy.

Lantidra was studied in two clinical studies (UIH-001 and UIH-002) that included a total of 30 patients with T1D and hypoglycemia unawareness. Patients received one to three infusions. Overall, 25 patients achieved insulin independence: 4 (13.3%) were insulin-independent for less than 1 year, 12 (36.7%) for 1 to 5 years, and 9 (33.3%) for greater than 5 years. However, 5 patients did not achieve any days of insulin independence.

A majority of patients experienced at least one serious adverse reaction related to the insulin procedure or the use of immunosuppressives needed to maintain islet cell viability.

Due to use in a specific patient population and anticipated high cost, Lantidra will require prior authorization review.

## Class Review

**October 2023:**

| Medication Class Reviews |
|---|
| Analgesics – Anti-inflammatory |
| Analgesics -- Non-Narcotic |
| Analgesics -- Opioids |
| Anticoagulants |
| Antiseptics & Disinfectants |
| Diagnostic Products |
| Endocrine and Metabolic Agents – Misc |
| Hematopoietic Agents |
| Hemostatics |
| Minerals & Electrolytes |
| Mouth/Throat/Dental |
| Multi-Vitamins |
| Musculoskeletal Therapy Agents |
| Otic |
| Vitamins |