ISSUE 2 | VOLUME 17 | APRIL 2023



# Formulary Update

## At A Glance

### Formulary Additions

- Cyclosporine 0.05% (generic Restasis) Ophthalmic Emulsion

### Prior Authorization (QRM) Additions

- Amvuttra (vutrisiran) Subcutaneous Injection
- Avsola (infliximab-axxq) Intravenous Solution
- Evkeeza (evinacumab) Intravenous Solution
- Renflexis (infliximab-abda) Intravenous Solution
- Tecvayli (teclistamab-cqyv) Subcutaneous Injection

### Prior Authorization (QRM) Updates

- Cimzia (certolizumab pegol) Subcutaneous Injection
- Cosentyx (secukinumab) Subcutaneous Injection
- Enbrel (etanercept) Subcutaneous Injection
- Humira (adalimumab) Subcutaneous Injection
- Ilumya (tildrakizumab) Subcutaneous Injection
- Imcivree (setmelanotide) Subcutaneous Injection
- Omnipod 5 System and Pods
- Omnipod DASH System and Pods
- Rinvoq (upadacitinib) Tablets
- Rituxan (rituximab) Intravenous Solution
- Siliq (brodalumab) Subcutaneous Injection
- Simponi/Simponi Aria (golimumab) Subcutaneous/Intravenous Solution
- Skyrizi (risankizumab) Intravenous/Subcutaneous Solution
- Sotyktu (deucravacitinib) Tablets
- Stelara (ustekinumab) Intravenous/Subcutaneous Solution
- Taltz (ixekizumab) Subcutaneous Injection
- Tremfya (guselkumab) Subcutaneous Injection
- Zeposia (ozanimod) Capsules

**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 May 10, 2023:**

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

- **Cyclosporine 0.05% (generic Restasis) Ophthalmic Emulsion:** Indicated to increase tear production when suppressed tear production is presumed to be due to keratoconjunctivitis sicca-associated ocular inflammation (in patients not already using topical anti-inflammatory drugs or punctal plugs).

## 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 UPDATES were recently approved:**

- **Firdapse (amifampridine):** Updated to (1) incorporate the expanded indication for pediatric patients six years of age and older and (2) remove Ruzurgi from the practice recommendations as the original FDA-approval is no longer valid due to violation of Orphan Drug Exclusivity
- **Imcivree (setmelanotide):** Updated to (1) incorporate the new indication for Bardet-Biedl Syndrome (BBS) and (2) add new dosage recommendations and precautions verbiage per the updated prescribing information.

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

**The following QRM additions will be effective May 10, 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.

- **Amvuttra (vutrisiran):** Indicated for the treatment of polyneuropathy associated with hereditary transthyretin-mediated amyloidosis in adults.
- **Avsola (infliximab-axxq)/Renflexis (infliximab-abda):** Indicated for the treatment of Crohn's disease, pediatric Crohn's disease, ulcerative colitis, pediatric ulcerative colitis, rheumatoid arthritis in combination with methotrexate, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.
- **Evkeeza (evinacumab):** Indicated as adjunct to other low-density lipoprotein–lowering therapies for the treatment of homozygous familial hypercholesterolemia in adults and pediatric patients ≥5 years of age.
- **Tecvayli (teclistamab):** Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

## 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 May 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.

- **Biologics/JAK Inhibitors/S1P Receptor Modulators:** Several updates were made to the criteria for the drugs listed below due to the launch of Amjevita (adalimumab-atto) as the preferred adalimumab product for KPGA. In addition to highlighting Amjevita as the preferred adalimumab product , updates included: (1) criteria for intolerance changed to include a clinical evaluation/significant reaction to the trial product, (2) TB screening criteria updated and Hepatitis B/C screening requirements removed, (3) Inflectra and Amjevita added as required trial products, and (4) administrative changes to provide clarity for reviewers.
    - Cimzia (certolizumab pegol)
    - Cosentyx (secukinumab)
    - Enbrel (etanercept)
    - Humira (adalimumab)
    - Ilumya (tildrakizumab)
    - Rinvoq (upadacitinib)
    - Siliq (brodalumab)
    - Simponi/Simponi Aria (golimumab)
    - Skyrizi (risankizumab)
    - Sotyktu (deucravacitinib)
    - Stelara (ustekinumab)
    - Taltz (ixekizumab)
    - Tremfya (guselkumab)
    - Zeposia (ozanimod)
- **Glucagon-like Peptide-1 Receptor Agonists (GLP-1 RAs) for Weight Loss*:** Criteria updated with (1) the addition of Ozempic (semaglutide) as the preferred GLP-1 RA product, (2) age updated to 12 years and older per recent FDA approval, (3) trial products updated, (4) addition of alternate path for coverage for patients with BMI ≥40, and (5) reasons for non-coverage and continued approval criteria updated to provide clarity for reviewers.
- **Imcivree (setmelanotide):** Criteria updated with administrative changes and (1) addition of criteria/dosing information for Bardet-Biedl syndrome, (2) added requirement of baseline BMI and weight measurement in office within 1 month of start date and (3) reasons for non-coverage updated to include concurrent use of other medications indicated for weight loss.
- **Omnipod 5/DASH System and Pods:** Criteria updated to (1) require a total rapid acting insulin requirement of <200 units per 72 hours per manufacturer specifications for the device and (2) add the existing quantity limit of 10 pods per 30 days to initial approval criteria.
- **Rituxan (rituximab):** Updated with the addition of criteria for the treatment of bullous pemphigoid.

*Please note: KP Pharmacy and Manufacturers do **not** endorse compounded GLP-1 RAs injections from any source, due to safety and efficacy concerns.

- Manufacturers do **not** sell GLP-1 RAs ingredients for the purpose of compounding.
- KP does **not** cover compounded GLP-1 RAs injections.

## 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:**

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
Executive Director of Pharmacy Operations

Jennifer Marrast-Host, MD
Emergency Medicine/ACC

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

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

**Effective 5.10.2023**

| Medication | Quantity Limit |
|---|---|
| Azelex (azelaic acid) 20% Cream | 1 tube (30 gm or 50 gm) per 30 days |
| EluRyng/ Nuvaring (ethinyl Estradiol and etonogestrel) Vaginal Ring | 4 rings per 120 days |

## QHP-ACA/Open Formulary Step Therapy Additions

**Effective 5.10.2023**

| Medication | Notes |
|---|---|
| Ajovy (fremanezumab-vfrm) 225mg/1.5ml Subcutaneous Solution (auto-injector and syringes) | Prior authorization requirements removed effective 5.10.2023 |
| Relexxii (methylphenidate ER) 45, 63, 72mg Tablets | N/A |

## Department Floor Stock Additons

**Effective 5.10.2023**

| Medication | Department |
|---|---|
| Aquaphor (petrolatum 41%) Ointment | Otolaryngology |
| Byooviz (ranibizumab-nuna) 0.5mg/0.05ml Intravitreal Solution | Ophthalmology |
| Medroxyprogesterone Acetate 150mg/ml Suspension Prefilled Syringe | Pediatrics |

## Removal of Prescribing Restrictions

**Actemra (tocilizumab) 162mg/0.9ml auto-injector/prefilled syringes:**

- Restrictions to limit prescribing to TSPMG Rheumatology Specialists will be removed effective 5.10.2023

## 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 Initial Tier Placement

**Initial Tier Placements: Recently launched and approved medications**

| Drug Name | Tier Status | Implementation Date |
|---|---|---|
| trofinetide 200 mg/mL oral solution (Daybue) | Specialty Tier 5 | 3/21/2023 |
| velmanase alfa-tycv 10 mg injection (Lamzede) | Specialty Tier 5 | 3/16/2023 |
| omaveloxone 50 mg capsules (Skyclarys) | Specialty Tier 5 | 3/13/2023 |
| teriflunomide 7 mg, 14 mg tablets (generic) | Specialty Tier 5 | 3/9/2023 |
| sotorasib 320 mg tablets (Lumakras)** | Specialty Tier 5 | 3/3/2023 |
| adalimumab-atto 40 mg/0.8 mL auto-injection; 20 mg/0.4mL, 40 mg/0.8 mL prefilled injection (Amjevita) | Brand Tier 3 | 3/1/2023 |
| adalimumab-atto 40 mg/0.8 mL auto-injection (Amjevita) | Brand Tier 3 | 3/1/2023 |
| treprostinil 126 x 0.125 mg & 42 x 0.25 mg (month 1), 126 x 0.125 mg & 210 x 0.25 mg (month 2), 126 x 0.125 mg & 42 x 0.25 mg & 84 x 1 mg (month 3) extended-release tablets titration pack (Orenitram) | Specialty Tier 5 | 2/27/2023 |
| apalutamide 240 mg tablets (Erleada)** | Specialty Tier 5 | 2/23/2023 |
| sparsentan 200 mg, 400 mg tablets (Filspari) | Specialty Tier 5 | 2/22/2023 |
| pegcetacoplan 15 mg/0.1 mL intravitreal solution (Syfovre) | Specialty Tier 5 | 2/21/2023 |
| bevacizumab-adcd 100 mg/4 mL, 400 mg/16 mL injection (Vegzelma) | Specialty Tier 5 | 2/16/2023 |
| dabigatran etexilate mesylate 20 mg, 30 mg, 40 mg, 50 mg, 110 mg, 150 mg pellet pack (Pradaxa) | Specialty Tier 5 | 2/16/2023 |
| lanadelumab-flyo 150 mg/mL injection (Takhzyro) | Specialty Tier 5 | 2/13/2023 |
| tezepelumab-ekko 210 mg/1.91 mL injection (Tezspire) | Specialty Tier 5 | 2/13/2023 |
| elacestrant hydrochloride 86 mg, 345 mg tablets (Orserdu)** | Specialty Tier 5 | 2/1/2023 |
| pirtobrutinib 50 mg, 100 mg tablets (Jaypirca)** | Specialty Tier 5 | 1/30/2023 |

**Protected Class

# 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 |
|---|---|---|---|---|
| ESBRIET CAPS 267 MG | 5 | PIRFENIDONE CAPS 267 MG | 5 | 4/1/2023 |
| HETLIOZ CAPS 20 MG | 5 | TASIMELTEON CAPS 20 MG | 5 | 5/1/2023 |
| LATUDA TABS 20 MG | 5 | LURASIDONE HCL TABS 20 MG | 4 | 5/1/2023 |
| LATUDA TABS 40 MG | 5 | LURASIDONE HCL TABS 40 MG | 4 | 5/1/2023 |
| LATUDA TABS 60 MG | 5 | LURASIDONE HCL TABS 60 MG | 4 | 5/1/2023 |
| LATUDA TABS 80 MG | 5 | LURASIDONE HCL TABS 80 MG | 4 | 5/1/2023 |
| LATUDA TABS 120 MG | 5 | LURASIDONE HCL TABS 120 MG | 4 | 5/1/2023 |

**The following table lists all drugs that received Prior Authorization (PA) addition for the Medicare Part D Formulary effective 3/1/2023.**

| Medication | Drug Tier |
|---|---|
| MOUNJARO SOPN 2.5 MG/0.5ML | Tier 5 |
| MOUNJARO SOPN 5 MG/0.5ML | Tier 5 |
| MOUNJARO SOPN 7.5 MG/0.5ML | Tier 5 |
| MOUNJARO SOPN 10 MG/0.5ML | Tier 5 |
| MOUNJARO SOPN 12.5 MG/0.5ML | Tier 5 |
| MOUNJARO SOPN 15 MG/0.5ML | Tier 5 |
| OLUMIANT TABS 1 MG | Tier 5 |
| OLUMIANT TABS 2 MG | Tier 5 |
| OZEMPIC (0.25 OR 0.5 MG/DOSE) SOPN 2 MG/1.5ML | Tier 3 |
| OZEMPIC (0.25 OR 0.5 MG/DOSE) SOPN 2 MG/3ML | Tier 3 |
| OZEMPIC (1 MG/DOSE) SOPN 2 MG/1.5ML | Tier 3 |
| OZEMPIC (1 MG/DOSE) SOPN 4 MG/3ML | Tier 3 |
| OZEMPIC (2 MG/DOSE) SOPN 8 MG/3ML | Tier 3 |
| VICTOZA SOPN 18 MG/3ML | Tier 3 |

# Class Review

**June 2023:**

| Medication Class Reviews |
|---|
| Androgen/Anabolic |
| Anorectal |
| Antidiabetics |
| Antiemetics |
| Antineoplastics |
| Corticosteroids |
| Dietary Products/Dietary Management Products |
| Digestive aids |
| Gastrointestinal Agents – Misc |
| Gout Agents |
| Ophthalmic Agents |
| Pharmaceutical Adjuvants |
| Thyroid |

## In the news...

# Lack of Safety/Efficacy for Compounded GLP-1 Receptor Agonists (GLP-1 RAs) Products

Due to drug shortages for GLP-1RAs products like semaglutide, there has been interest from patients to explore obtaining these products from compounding pharmacies. The FDA added these products to the FDA drug shortage list which temporarily opened a door to permit 503A compounders to compound these drugs for patient specific prescriptions. Although permitted to compound, the safety / efficacy of the compounded product is uncertain. Drug manufacturers state they do not sell their proprietary active ingredient to compounding pharmacies. Novo Nordisk has a patent on the semaglutide molecule and does not sell semaglutide for compounding. As Novo Nordisk is the sole source for compounding pharmacies obtaining semaglutide, it is unclear where compounding pharmacies are obtaining semaglutide. In addition, there is no data on the safety or efficacy of the compounded products. Per a Novo Nordisk representative: "We do not sell semaglutide for the purposes of compounding with other products, and we have not conducted studies to evaluate the safety and effectiveness of semaglutide when compounded with other ingredients." Eli Lilly, which manufactures Mounjaro (tirzepatide), provided a similar statement that branded tirzepatide “is only available in a pre-filled single-dose pen manufactured by Lilly. Mounjaro is not commercially available in any other form (e.g., powder).”

There is some speculation that pharmacies compounding these products are either (1) purchasing the brand-name versions of these products and repackaging them into smaller doses with unknown additives or (2) using semaglutide sodium used for research that should not be used in human drug compounding. As these products are not FDA tested and approved, they do not have the same safety, quality, and effectiveness assurances as FDA-approved drugs, and may expose patients to potentially serious health risks.

**Key Takeaway Points concerning compounding of semaglutide and other GLP-1RAs products:**

- KP Pharmacy and GLP- RAs product manufacturers do not endorse compounded GLP-1 RAs injections from any source.
- Manufacturers do not sell GLP-1 RAs ingredients for the purpose of compounding.
- KP does not cover compounded GLP-1 RAs injections (the list of approved KPGA Outpatient Compounds can be found at: Compounds (kp.org)).

**References:**


Chen, E. Mix-it-yourself Wegovy? Some are trying risky sources for weight-loss drugs. STATNews. Published January 18, 2023.

FDA. Pharmacy Compounding Of Human Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance. Available at Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance (fda.gov). Accessed on April 24, 20223

Landsverk, G. Shortages of a 'game changer' weight-loss drug are driving people to buy potentially risky knockoff versions. Available at https://www.insider.com/buy-compounded-semaglutide-online-risks-wegovy-ozempic-2023-1. Accessed on April 21, 2023.