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Written by: Charnelda Lewis, PharmD, BCPS



# Formulary Update

## At A Glance

### Formulary Additions

- Amjevita (adalimumab) High Concentration Injection
- Carteolol (generic) Ophthalmic Solution

### Prior Authorization (QRM) Additions

- Vowst (fecal microbiota spores) Capsules
- Vanflyta (quizartinib) Tablets
- Sunlenca (lenacapavir) Tablets/Subcutaneous Solution

### Prior Authorization (QRM) Updates

- Arcalyst (rilonacept)
- Balversa (erdafitinib)
- Cabenuva (cabotegravir/rilpivirine) & Vocabria (cabotegravir)
- Dupixent (dupilumab)
- Emflaza (deflazacort)
- Enzyme Replacement Therapy (Elelyso, Cerezyme, Vpriv)
- Jaypirca (pirtobrutinib)
- Keveyis (dichlorphenamide)
- Nubeqa (darolutamide)
- Prolia (denosumab) & Forteo (teriparatide)
- Xhance (fluticasone propionate)
- Xolair (omalizumab)
- Zoryve (roflumilast)

**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 Formulary effective April 10, 2024:**

**Note: Commercial Formulary additions may result in tier changes on the QHP (ACA)/Open Formulary.**

- **Amjevita (adalimumab) High Concentration Injection:** Indicated to treat rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, and uveitis.

**The following medications will be ADDED to the Commercial Formulary effective May 8, 2024:**

**Note: Commercial Formulary additions may result in tier changes on the QHP (ACA)/Open Formulary.**

- **Carteolol (generic) Ophthalmic Solution:** Indicated for treatment of elevated intraocular pressure (IOP) in patients with chronic open-angle glaucoma and intraocular hypertension.

## Commercial HMO/Closed Formulary Removal

**The following medication will be REMOVED from the Commercial Formulary effective January 1, 2025:**

- **Amjevita (adalimumab) Low Concentration Injection:** Indicated to treat rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, and uveitis.
- **Betoptic-S (bextaxolol) Ophthalmic Suspension:** Indicated for treatment of elevated intraocular pressure (IOP) in patients with chronic open-angle glaucoma and intraocular hypertension.

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

**The following medications will have quantity limit changes:**

| Medication | Quantity Limit |
|---|---|
| Jakafi 5mg & 10mg tablets | **Effective May 8, 2024: New** QL of 30 tablets per 30 days |
| Neubilizer solutions:<br>• Albuterol 0.083%<br>• Albuterol 0.5%<br>• Ipratropium-Albuterol 0.5mg-2.5mg/3mL<br>• Ipratropium Bromide 0.2%<br>• All strengths of Xopenex (levalbuterol) | **Already Implemented: Remove** QL (1 box/ month) as shortage has resolved |

## Compounding List Changes

**The compound list will change effective May 8, 2024:**

| Medication | Compounding List Change |
|---|---|
| Boric Acid suppositories | **Remove** - OTC alternative is available |

## 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 have been recently approved:**

- **Transfusion dependent beta-thalassemia (TDT) stem cell:** Exagamglogene autotemcel (Casegvy) was FDA approved January 2024 and incorporated into the practice recommendations.
- **Sickle Cell Disease:** Added alpha globin gene analysis to baseline labs due to the risk of anemia with erythroid dysplasia that may require chronic red blood cell transfusions after treatment with lovotibeglogene autotemcel in patients with α-thalassemia trait.

ETSP recommendations as well as pipeline candidates can be found here: https://sp-cloud.kp.org/sites/teams-emergingtsc/SitePages/Home.aspx. 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 May 24, if you wish to comment on any of the medications, upcoming class reviews (see list further down in newsletter), 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.**

# 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 May 8, 2024:**

- **Vowst (fecal microbiota spores) Capsules:** Indicated for prevention of recurrence of C. difficile infection in patients ≥18 years of age following antibiotic treatment of recurrent CDI.
- **Vanflyta (quizartinib) Tablets:** Indicated for treatment of adult patients with newly diagnosed acute myeloid leukemia that is FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (ITD)–positive (as detected by an approved test), in combination with standard cytarabine and anthracycline induction, cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy.
- **Sunlenca (lenacapavir) Tablets/ Subcutaneous Solution:** Indicated for Treatment of HIV-1 infection, in combination with other antiretrovirals, in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

## 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.**

- **Arcalyst (rilonacept)** Criteria updated to include the indication for treatment or reduction in risk of recurrent pericarditis.
- **Balversa (erdafitinib):** Criteria updated to include 1) FGFR3 as detected by an FDA approved companion diagnostic and 2)reason that patient may or may not qualify for erdafitinib based on prior therapy.
- **Cabenuva (cabotegravir/ rilpivirine) & Vocabria (cabotegravir):** Criteria updated to include 1) reason the member may be unable to take oral medications including severe complicated mental health or socioeconomic factors making adherence to standard oral drug improbable and 2) noted that Cabenuva should be approved for administration at a KPGA facility only.
- **Dupixent (dupilumab):** Criteria updated to include 1) how to confirm diagnosis of eosinophilic esophagitis and 2) added weight based dosing. Removed specific dosing since ages now range from 1 year to adults.
- **Emflaza (deflazacort):** Criteria updated to remove 1) the specific age for diagnosis and 2) remove increased stanine as a reason for discontinuation.
- **Enzyme Replacement Therapies- Cerezyme, Elelyso, and Vpriv:** Criteria updated to change the preferred therapy to Elelyso.
- **Jaypirca (pirtobrutinib):** Criteria updated to include 1) diagnosis of chronic lymphocytic leukemia and small lyphocytic leukemia (SLL) and 2) prior therapies required based on indication. Removed select reasons for non-coverage.
- **Keveyis (dichlorphenamide):** Criteria updated to change the preferred therapy to dichlorphenamide (generic Keveyis).
- **Nubeqa (darolutamide):** Criteria updated to delineate prior therapies required based on indication. Removed documented treatment failure to Xtandi (enzalutamide).
- **Prolia (denosumab) & Forteo (teriparatide):** Criteria updated to 1) define osteopenia/osteoporosis requiring treatment and 2) define very high risk for osteoporotic fractures.
- **Xhance (fluticasone):** Criteria updated to include indications of documented chronic rhinosinusitis with nasal polyps or chronic rhinosinusitis.
- **Xolair (omalizumab):** Criteria updated to include 1) the autoinjector dosage form, 2) administration guidelines by healthcare professional then via outpatient pharmacy benefit and 3) new indication for IgE mediated food allergy.
- **Zorvye (roflumilast):** Criteria updated to include 1) indication for diagnosis of seborrheic dermatitis and 2) time frames for prior use of topical medications.

## 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: Medicare Part D Formulary

Dual Choice: Dual Choice Plan Non Formulary and Prior Authorization criteria and coverage documentation are made externally by the Pharmacy Benefit Manager MedImpact. Presciber completes .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 **1-888-336-2676** 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, PhamD, BCOP
Ambulatory Pharmacy

Halima Daboiko, MD
Obstetrics and Gynecology

Carole Gardner, MD
P&T Chair/Geriatrics

Pierson Gladney, MD
Hematology/Oncology

Ramin Haddad, MD
Adult 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**

Daniel Robitshek, MD
CDU/Hospital Services

**Designated Alternates:**

Jacqueline Anglade, MD
Obstetrics and Gynecology

Lesia Jackson, RN
Clinical Services

Satya Jayanthi, MD
Hospitalist

# Medications Reviewed But Not Accepted to the Commercial HMO Formulary

**Note: Medications that can be dispensed via the outpatient pharmacy benefit, but are not accepted to the closed commercial HMO formulary, will be placed on a tier for the open QHP-ACA formulary.**

| Medication | Commercial HMO/Closed Formulary Status | QHP-ACA/Open Formulary Status |
|---|---|---|
| Accrufer (ferric maltol) | • Non-Formulary<br>• Exclude from prescription benefit coverage (OTC options available) | • Not accepted - exclude from prescription benefit coverage (OTC options available) |
| Briuvmi (ublituximab-xiiy) | • Not accepted – clinic administered medication<br>• Approved for clinic administration under medical benefit coverage<br>• Require QRM PA Review | • Not accepted – clinic administered medication<br>• Approved for clinic administration under medical benefit coverage<br>• Require QRM PA Review |
| Elrexfio (elranatamab-bcmm) | • Not accepted – clinic administered medication<br>• Approved for clinic administration under medical benefit coverage<br>• Require QRM PA Review | • Not accepted – clinic administered medication<br>• Approved for clinic administration under medical benefit coverage<br>• Require QRM PA Review |
| Iglami (dexmedetomidine) | • Not accepted – clinic administered medication<br>• Approved for clinic administration under medical benefit coverage | • Not accepted – clinic administered medication<br>• Approved for clinic administration under medical benefit coverage |
| Vanflyta (quizartinib) | • Non-Formulary<br>• Require QRM PA Review | • Specialty Tier 5<br>• Require QRM PA Review |
| Vowst (fecal microbiota spores) | • Non-Formulary<br>• Require QRM PA Review | • Specialty Tier 5<br>• Require QRM PA Review |
| Xacduro (sulbactam/ durlobactam) | • Not accepted – clinic administered medication<br>• Approved for clinic administration under medical benefit coverage | • Not accepted – clinic administered medication<br>• Approved for clinic administration under medical benefit coverage |
| Ycanth (cantharidin) | • Not accepted – clinic administered medication<br>• Approved for clinic administration under medical benefit coverage | • Not accepted – clinic administered medication<br>• Approved for clinic administration under medical benefit coverage |
| Zituvio (sitagliptin) | • Non-Formulary<br>• Require QRM PA Review | • Non-Preferred Brand Tier 4<br>• Require QRM PA Review |

## Approved Floor Stock List Changes

*(Effective 5.8.2024)*

| Medication | Department |
|---|---|
| **Approved Floor Stock List Additions** | |
| Magnesium sulfate 2g/ 50mL premix<br>Potassium Chloride 10mEq/ 50mL premix | Oncology |
| Ketorolac 30mg/ 1mL | Neurology<br>Radiology<br>Rheumatology |
| **Approved Floor Stock List Removals** | |
| Ketorolac 60mg/ 2mL | Neurology<br>Internal Medicine<br>Ob/ Gyn<br>Pediatrics<br>Radiology<br>Rheumatology<br>Urology<br>Urogynecology |

## 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 | | Implementation Date |
|---|---|---|
| riluzole 50 mg/10 mL injection (Teglutik) | Specialty Tier 5 | 2/1/2024 |
| pegfilgrastim-cbqv 6 mg/0.6 mL injection (Udenyca Onbo) | Specialty Tier 5 | 1/24/2024 |
| nedosiran sodium 80 mg/0.5 mL, 128 mg/0.8 mL, 160 mg /mL injection (Rivfloza) | Specialty Tier 5 | 1/23/2024 |
| mifepristone 300 tablets (generic) | Specialty Tier 5 | 1/22/2024 |

## Class Review

**June 2024:**

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

## Update: Insulin glargine-ygfn, Preferred Basal Insulin

Effective 4/1/2024, insulin glargine-yfgn is the preferred basal insulin at KP. For new insulin starts, providers should prescribe insulin glargine-yfgn. If patient was previously prescribed NPH once daily (up to 50 units), convert unit per unit to glargine-yfgn once daily. If prescribed NPH twice daily, reduce total daily dose by 20% and dose glargine-yfgn once daily. Beginning 5/1/2024, existing Humulin NPH prescriptions will be converted to glargine-yfgn. Insulin glargine-yfgn is a long acting basal insulin analog. It does not have a peak and can last up to 24 hours. Its efficacy for blood glucose control is equivalent to NPH. In addition, insulin glargine-yfgn is associated with a lower risk of level 2 hypoglycemia and nocturnal hypoglycemia when compared to NPH. Humulin NPH and glargine-ygn will have the same cost share for the remainder of 2024.

# KP Quality Joint Message - Weight Loss Drug Coverage

**A Message From:**
**Nancy Gin, MD, FACP**
Executive Vice President and Chief Quality Officer, The Permanente Federation

**Andrew Bindman, MD**
Executive Vice President, Chief Medical Officer, Kaiser Foundation Health Plan and Hospitals

Dear physicians and clinicians,

The Centers for Medicare & Medicaid Services (CMS) announced on March 21, 2024, that semaglutide (Wegovy) and other weight-loss medications with a Food and Drug Administration approval for an additional medically accepted indication are eligible for Medicare Part D coverage.

Semaglutide (Wegovy) received an FDA indication "to reduce the risk of major cardiovascular events (such as cardiovascular death, non-fatal myocardial infarction, or non-fatal strokes) in adults with established cardiovascular disease who are either obese or overweight."

Members with established cardiovascular disease who are overweight or obese are eligible for semaglutide (Wegovy). Part D coverage is still not available for weight-loss only for individuals who do not have cardiovascular disease.

Kaiser Permanente is developing a comprehensive evidence-based plan to ensure our members receive high quality and safe care. This includes a clinical review with input from our chiefs of Cardiology, Obesity Medicine, Vascular Surgery, and Neurology to align definitions for indicated use and to create decision-support tools and educational materials. This process is being expedited so that we can have the clinical guidance completed within the next month.