ISSUE 2 | VOLUME 20 | APRIL 2025

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Formulary *Update*

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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 List OR Drug Formulary for Practitioners for all KPGA Drug Formularies.

Formulary Additions

- Buspirone 30 mg tablet
- Methenamine hippurate 1g tablet

Prior Authorization (QRM) Additions

- Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)
- Cobenfy (xanomeline-trospium chloride)
- Columvi (glofitamab-gxbm)
- Epkinly (epcoritamab)
- Imdelltra (tarlatamab-dlle)
- Iqirvo (elafibranor)
- Ojemda (tovorafenib)
- Orlynvah (sulopenem etzadroxil and probenecid)
- Voranigo (vorasidenib)

Prior Authorization (QRM) Updates

- Apretude (cabotegravir)
- Bimzelx (bimekizumab-bkzx)
- Elevidys (delandistrogene moxeparvovec)
- Epclusa (sofosbuvir velpatasvir)
- GLP-1 RA and Tirzepatide Products for Weight Loss
- GLP-1 RA for Diabetes Mellitus (DM)
- Mavyret (glecaprevir and pibrentasvir)
- Mycapssa (octreotide)
- Neffy (epinephrine)
- Omvoh (mirikizumab)
- Otezla (apremilast)
- Pegfilgrastim Products
- Prolia (denosumab)
- Rebyota (fecal microbiota (live))
- Rezurock (belumosudil)
- Rituxan (rituximab)
- Scemblix (asciminib)
- Tzield (teplizumab)
- Vemlidy (tenofovir alafenamide)
- Vowst (fecal microbiota (live))
- Xolair (omalizumab)
- Zoryve (roflumilast)

Prior Authorization (QRM) Removals

- Tegsedi (inotersen)
- Liraglutide (generic Victoza)

Upcoming Formulary Items:

An important aspect of the formulary process is the involvement of all clinicians. Please contact your P&T Committee representative or your clinical department chief by May 15 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 via email at KPGA-DrugInformation@kp.org.

Medication Class Review
June 2025

- Androgen/Anabolic
- Anorectal
- Antidiabetics
- Antiemetics
- Antineoplastics
- Corticosteroids
- Dietary Products/Dietary Management Products
- Digestive Aids
- Gastrointestinal Agents– Misc
- Gout Agents
- Ophthalmic Agents
- Pharmaceutical Adjuvants
- Thyroid

Commercial HMO/Closed Formulary Additions

The following medication will be ADDED to the Commercial Formulary effective May 7, 2025:

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

Buspirone 30 mg tablets	Indicated for management of generalized anxiety disorder or the short-term relief of the symptoms of anxiety
Methenamine hippurate 1G (generic Hiprex) tablets	Indicated for prophylaxis or suppression of recurrent urinary tract infections when long-term therapy is indicated and infection has been eradicated by appropriate antimicrobial treatment

QHP-ACA/ Open Formulary Step Therapy Additions

The following medications will have step therapy ADDED effective April 9, 2025:

Liraglutide (generic Victoza)	Indicated for Type 2 Diabetes Mellitus

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 REMOVAL were recently approved:

Beqvez (fidanacogene elaparvovec)	Removed from U.S. market February 2025

ETSP recommendations as well as pipeline candidates can be found here: ETSP Home Page
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 medications will be ADDED to the QRM PA Review List effective May 7, 2025:

Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)	Indicated for the treatment of cystic fibrosis (CF) in patients ≥6 years of age who have at least one F508del mutation or another responsive mutation in the CF transmembrane conductance regulator (*CFTR*) gene.
Cobenfy (xanomeline-trospium chloride)	Indicated for the treatment of schizophrenia in adults.
Columvi (glofitamab-gxbm)	Indicated for the treatment of relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified or large B-cell lymphoma arising from follicular lymphoma in adults after 2 or more lines of systemic therapy.
Epkinly (epcoritamab)	Indicated for the following: • Treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma in adults after 2 or more lines of systemic therapy. • Treatment of relapsed or refractory follicular lymphoma in adults after 2 or more lines of systemic therapy.
Imdelltra (tarlatamab-dlle)	Indicated for the treatment of extensive stage small cell lung cancer in adults with disease progression on or after platinum-based chemotherapy.
Iqirvo (elafibranor)	Indicated for the treatment of primary biliary cholangitis, in combination with ursodeoxycholic acid (UDCA), in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.
Ojemda (tovorafenib)	Indicated for the treatment of relapsed or refractory pediatric low-grade glioma harboring a *BRAF* fusion or rearrangement, or *BRAF* V600 mutation, in patients ≥6 months of age.
Orlynvah (sulopenem etzadroxil-probenecid)	Indicated for the treatment of uncomplicated urinary tract infection caused by *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult females who have limited or no alternative oral antibacterial treatment options.
Voranigo (vorasidenib)	Indicated for the treatment of grade 2 astrocytoma or oligodendroglioma in adult and pediatric patients ≥12 years of age with a susceptible isocitrate dehydrogenase-1 (*IDH1*) or isocitrate dehydrogenase-2 (*IDH2*) mutation following surgery, including biopsy, subtotal resection, or gross total resection.

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.

- **Apretude (cabotegravir):** Criteria updated to 1) increase objectivity and standardize review process, 2) align with Cabenuva and Descovy criteria, and 3) provide provisions for social determinants of health (SDOH).
- **Bimzelx (bimekizumab-bkzx):** Criteria updated to reflect the expanded indication for hidradenitis suppurativa (HS).
- **Elevidys (delandistrogene moxeparvovec):** Criteria updated to reflect ETSP IR recommendations which 1) include all ambulatory patients 4 years and older when initiating therapy, 2) further defined ambulatory patients as able to independently complete the 10-meter walk test, 3) added clarification to the recommendations not to initiate treatment in non-ambulatory patients because clinical trials have no shown benefit, and 4) updated precautions section to include additional verbiage from the prescribing information.
- **Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) and Tirzepatide Products for Weight Loss:** Criteria updated to 1) be more specific on the weight-related comorbid conditions for BMI 35 or greater and 2) reflect administrative edits.
- **Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) for Diabetes Mellitus (DM):** Criteria updated to 1) remove QRM PA review criteria designated for generic liraglutide to promote its use as first-line GLP-1 RA for DM and increase access for patients who need GLP-1 RA for DM, 2) add failure of liraglutide for QRM PA non-preferred approval, 3) streamline metformin from optimal dose to maximally tolerated dose, 4) remove Jardiance requirement as it is not required for liraglutide, 5) add indefinite initial approval for diabetes mellitus (DM) with chronic kidney disease (CKD), 6) reflect edits in continued approval section to prevent reviewers from reviewing each initial criterion, and 7) made formatting changes for better clarity and readability.
- **Hereditary Transthyretin-Mediated Amyloidosis-Polyneuropathy (hATTR-PN) Therapies:** Criteria for Tegsedi (inotersen) removed to reflect discontinuation by the manufacturer.
- **Mycapssa (octreotide):** Criteria updated to clearly outline preferred options prior to use of oral octreotide (Mycapssa).
- **Neffy (epinephrine):** Criteria updated to 1) align with the new FDA approved indication for patients 4 years and older weighing at least 15 kg and 2) increase objectivity and standardize review process.
- **Omvoh (mirikizumab):** Criteria updated to include expanded indication for Crohn's Disease (CD).
- **Otezla (apremilast):** Criteria updated to include expanded indication for Behçet's Disease (BD).
- **Pegfilgrastim Products:** Criteria updated to separate non-response to granulocyte colony stimulating factor (G-CSF) therapy and allergy/intolerance.
- **Prolia (denosumab):** Criteria updated to add Adult Primary Care and Family Practice Specialists to the list of covered prescribers to allow use by No Sleepless Night Nurse Practitioners to address all DEXA results and follow-up care for the region.
- **Rebyota (fecal microbiota, live-jslm)** Criteria updated to 1) align with Vowst criteria and ensure that patients have completed course of 1st and 2nd line agents before Rebyota and Vowst and 2) remove Zinplava as it has been discontinued.
- **Rezurock (belumosudil):** Criteria updated to include the failure and trial of Jakafi (category 1 recommendation for chronic graft-versus-host disease (GVHD)) as part of the two failed prior treatments.
- **Scemblix (asciminib):** Criteria updated to 1) reflect recently approved indication for newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) and 2) remove any statement that would indicate use as third line treatment in Ph+ CML in chronic phase.
- **Tzield (teplizumab):** Criteria updated to remove degree relative with type 1 diabetes mellitus (T1DM) criterion for initiation of therapy.
- **Transplant Products (Epclusa (sofosbuvir/velpatasvir), Mavyret (glecaprevir/pibrentasvir), Rituxan (rituximab):** Criteria updated to allow prescribing by Transplant Specialists for post solid organ transplants.

QRM Prior Authorization Review Criteria Updates (Continued)

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.

- **Vemlidy (tenofovir alafenamide):** Criteria updated to 1) allow prescribing by Transplant Specialists for post solid organ transplants, 2) reflect updated renal and bone health parameters, 3) clarify the two different tenofovir formulations: tenofovir disoproxil fumarate (TDF) vs alafenamide (TAF), 4) align DEXA scan T-score parameters with Descovy criteria, 5) define creatinine clearance (CrCl)parameters for renal impairment, 6) include a provision for new members who were initiated on Vemlidy outside of KPGA, and 7) provide administrative edits.

- **Vowst (fecal microbiospore, live-brpk):** Criteria updated to 1) reflect use for treatment as well as prevention of recurrent *Clostridioides difficile* infection (rCDI) and 2) remove Zinplava as it has been discontinued.

- **Xolair (omalizumab):** Criteria updated to reflect use of Xolair in patients with chronic idiopathic urticaria to align with the international guidelines for management of urticaria.

- **Zoryve (roflumilast):** Criteria updated to address new members who were initiated on Zoryve 0.3% prior to joining KPGA.

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 QHP-ACA/ Open formularies.

Drug Name	Commercial HMO/Closed Formulary Status	QHP-ACA/ Open Formulary Status
Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)	• Not accepted to formulary • Require QRM PA review	• Add to Specialty Tier 5 • Require QRM PA review
Cobenfy (xanomeline-trospium chloride)	• Not accepted to formulary • Require QRM PA review	• Add to Specialty Tier 5 • Require QRM PA review
Columvi (glofitamab-gxbm)	• Not accepted – clinic administered medication • Approve for clinic administration under medical benefit coverage • Require QRM PA review	
Epkinly (epcoritamab)	• Not accepted – clinic administered medication • Approve for clinic administration under medical benefit coverage • Require QRM PA review	
Imdelltra (tarlatamab-dlle)	• Not accepted – clinic administered medication • Approve for clinic administration under medical benefit coverage • Require QRM PA review	
Iqirvo (elafibranor)	• Do not accept to formulary • Require QRM PA review	• Add to Specialty Tier 5 • Require QRM PA review
Ojemda (tovorafenib)	• Do not accept to formulary • Require QRM PA review	• Add to Specialty Tier 5 • Require QRM PA review
Orlynvah (sulopenem etzadroxil-probenecid)	• Do not accept to formulary • Require QRM PA review	• Add to Specialty Tier 5 • Require QRM PA review
Voranigo (vorasidenib)	• Do not accept to formulary • Require QRM PA review	• Add to Specialty Tier 5 • Require QRM PA review

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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Debbi Baker, PharmD, BCPS
Clinical Pharmacy

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Designated Alternates:

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Lesia Jackson, RN
Clinical Services

Satya Jayanthi, MD
Hospitalist

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 for recently launched and approved medications

#	DRUG NAME	TIER STATUS	IMPLEMENTATION DATE
1.	guselkumab 200 mg/2 mL auto-injection (Tremfya)	Specialty Tier 5	3/26/2025
2.	octreotide acetate 10 mg injection kit (generic)	Specialty Tier 5	3/21/2025
3.	ferric citrate 1 g (210 mg ferric iron) tablets (generic)	Specialty Tier 5	3/20/2025
4.	revumenib citrate 25 mg tablets (Revuforj)	Specialty Tier 5	3/18/2025
5.	selinexor 10 mg (40 mg once weekly) tablet therapy packs (Xpovio)	Specialty Tier 5	3/13//2025
6.	corticotropin gel 40 unit/0.5 mL injection (Cortrophin)	Specialty Tier 5	3/10/2025
7.	trazodone HCl 50 mg/5 mL oral solution (Raldesy)	Specialty Tier 5	3/6/2025
8.	vimseltinib 14 mg, 20 mg, 30 mg capsules (Romvimza)	Specialty Tier 5	3/3/2025
9.	mercaptopurine 2000 mg/100 mL oral suspension (generic)	Specialty Tier 5	3/3/2025
10.	hydroxyurea 100 mg/mL oral solution (Xromi)	Specialty Tier 5	2/26/2025
11.	metaxalone 640 mg tablets (generic)	Specialty Tier 5	2/26/2025
12.	mirikizumab-mrkz 100 mg/mL, 200mg/2 mL auto-injection, prefilled injection (Omvoh)	Specialty Tier 5	2/21/2025
13.	mirdametinib 1 mg, 2 mg capsules; 1 mg tablets (Gomekli)	Specialty Tier 5	2/17/2025
14.	risdeplam 5 mg tablets (Evrysdi)	Specialty Tier 5	2/14/2025
15.	cyclophosphamide 500 mg/mL, 1 g/2 mL, 2 g/4 mL injection (Frindovyx)	Specialty Tier 5	2/5/2025
16.	axatilimab-csfr 9 mg/0.18 mL, 22 mg/0.44 mL injection (Niktimvo)	Specialty Tier 5	1/31/2025
17.	griseofulvin ultramicrosize 165 mg tablets (generic)	Specialty Tier 5	1/31/2025

Medicare Part D Formulary Removal of Brand Drugs

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 Current Tier	Generic Alternative	Generic Drug Tier	Effective Date
Mesnex Tabs 400 mg	5	Mesna Tabs 400 mg	5	4/1/2025

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 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 1-888-336-2676 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.

In the News....

GLP-1 RAs in Development for Alzheimer's Disease: An Overview

April 2025 — Glucagon-like peptide-1 (GLP-1) receptor agonists (RAs) are FDA-approved for the treatment of type 2 diabetes (T2D), chronic weight management, and other indications. While GLP-1 RAs have been used to treat T2D for more than a decade, their continued success and high demand extend beyond A1c and weight reduction.

Numerous studies have identified diabetes, insulin resistance, and aging as major risk factors for Alzheimer's disease (AD). GLP-1 RAs are thought to have several mechanisms in AD, including reducing inflammation, improving insulin sensitivity, and potentially impacting amyloid and tau pathology.

There are currently three active Phase 3 trials evaluating Novo Nordisk's semaglutide in patients with AD. Two trials (EVOKE and EVOKE Plus) are looking at the efficacy and safety of oral semaglutide, with estimated study completion dates in October 2026 and topline data expected in 2H 2025. A third Phase 3 trial is evaluating subcutaneous (SC) semaglutide and its effect on the immune system and other biological processes in patients with AD, with an estimated completion date of September 2025.

Additional data are needed to determine the optimal place in therapy for these agents within the AD treatment paradigm, should they be approved; further research is needed to determine if there is a subset of patients within the AD population that may benefit the most from GLP-1 RA therapy and whether these agents have a role in the prevention of AD.

Reference:

IPD Analytics. IPD Analytics Pharmacy & Therapeutics Watchlist | 04.02.2025. IPD Analytics, LLC. Accessed April 16.2025. http://www.ipdanalytics.com [Subscription database].

Qfitlia for Hemophilia A or B With or Without Inhibitors

March 2025 — On March 28, 2025, the FDA approved Sanofi's Qfitlia (fitusiran) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A or hemophilia B, with or without factor VIII or IX inhibitors.
Hemophilia is an X-linked genetic disease that interferes with the normal coagulation process, which causes bleeding into soft tissue, joints, and internal organs. Hemophilia can also cause severe bleeding and death in traumatic incidents. The management of severe hemophilia can be complex and costly.

Qfitlia is the first antithrombin (AT)-directed small interfering ribonucleic acid (siRNA) approved for hemophilia. Unlike other hemophilia treatments, Qfitlia can be administered subcutaneously (SC) as infrequently as once every 2 months (Q2M). Dose/frequency is adjusted by AT activity, measured using Siemens' FDA-cleared Innovance AT companion diagnostic test.

Qfitlia carries a Boxed Warning for thrombotic events and gallbladder disease, and an additional warning for hepatotoxicity.

References:

IPD Analytics. IPD Analytics Pharmacy & Therapeutics Watchlist | 04.11.2025. IPD Analytics, LLC. Accessed April 16.2025. http://www.ipdanalytics.com [Subscription database].

FDA approves novel treatment for Hemophilia A or B, with or without factor inhibitors. News release. FDA. March 28, 2025. Accessed April 7, 2025. https://www.fda.gov/newsevents/press-announcements/fda-approves-novel-treatment-hemophilia-or-b-or-withoutfactor-inhibitors