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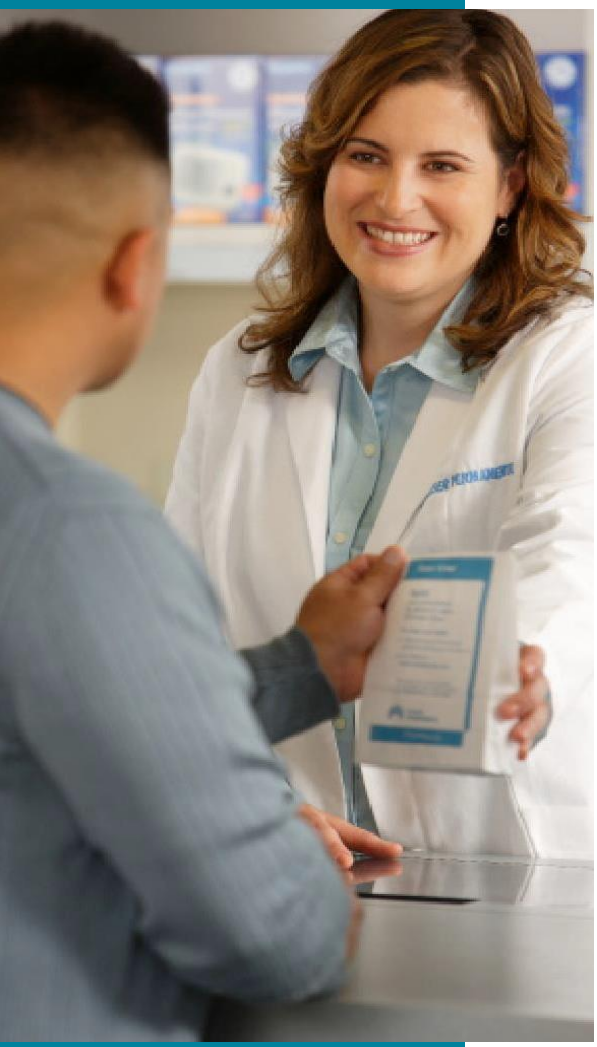
Formulary Update



At A Glance

Formulary Additions - Effective 7.13.2022

- Flovent (fluticasone) 110 mcg Actuation Inhaler for children < 5 years
- Isosorbide Dinitrate and Hydralazine 20-37.5 mg Tablets
- Nivestym (filgrastim-aafi) 300 mcg/0.5 ml and 480 mcg/0.8 ml Prefilled Syringes

Formulary Removals/Exclusions

- TobraDex Ointment 0.3-0.1 % formulary removal
- Tobramycin-Dexamethasone Ophthalmic Suspension 0.3-0.1 % formulary removal
- Zarxio (filgrastim-sndz) 300 mcg/0.5 ml and 480 mcg/0.8 ml Syringes formulary removal
- Azelastine Nasal Spray 0.1% and 0.15% formulary exclusion

Prior Authorization (QRM) Additions

- Adbry (tralokinumab-ldrm) SQ Solution
- Aveed (testosterone undecanoate) IM Solution
- Besremi (ropeginterferon alfa-2b) SQ Solution
- Emsam (selegiline) Transdermal Patch
- Jatenzo (testosterone undecanoate) Oral Capsules
- Omnipod 5 and DASH Kit and Pods
- Oxlumo (lumasiran) SQ Solution
- Ozempic (semaglutide) 2 mg SQ Solution
- Qulipta (atogepant) Oral Tablets
- Rukobia (fostemsavir) Extended-Release Tablets
- Scemblix (asciminib) Oral Tablets
- Skytrofa (lonapegsomatropin-tcgd) SQ Cartridge
- Tavneos (avacopan) Oral Capsules

Prior Authorization (QRM) Updates

- CGRP Inhibitors
- Dimethyl Fumarate Delayed Release Capsules
- GLP-1 Receptor Agonists
- Jublia (efinaconazole) External Solution
- Lynparaza (olaparib) Oral Tablets
- Novolin SQ Suspension
- Reyvow (lasmiditan) Oral Tablets
- Rinvoq (upadacitinib) Extended-Release Tablets
- Rubraca (rucaparib) Oral Tablets
- Tysabri (natalizumab) IV Solution
- Ubrevly (ubrogepant) Oral Tablets
- Zejula (niraparib) Oral 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 site: http://kpnet.kp.org:81/ga/healthcare/formularies.html or http://providers.kaiserpermanente.org/ for the full KPGA Drug Formulary.

Commercial/Closed Formulary Additions

The following medications will be ADDED to the Commercial Formulary effective July 13, 2022:
Note: Commercial Formulary additions may result in tier changes on the QHP (ACA)/Open Formulary.

- **Flovent (fluticasone HFA) 110 mcg/actuation inhaler for use in children under 5 years of age:** Indicated for maintenance treatment of asthma.
- **Isosorbide Dinitrate and Hydralazine 20-37.5 mg tablets:** Indicated for the treatment of heart failure as an adjunct therapy to standard.
- **Nivestym (filgrastim-aafi) 300 mcg/0.5 ml and 480 mcg/0.8 ml prefilled syringes**: Indicated to reduce the incidence and duration of neutropenia.

Commercial/Closed Formulary Removals/Exclusions

The following medications will be REMOVED from the Commercial Formulary effective January 1, 2023:
NOTE: Commercial Formulary removals may result in tier changes on the QHP (ACA)/Open Formulary.

- **TobraDex ointment 0.3-0.1 %:** Indicated for steroid-responsive inflammatory ocular conditions.
- **Tobramycin-Dexamethasone ophthalmic suspension 0.3-0.1 %:** Indicated for steroid-responsive inflammatory ocular conditions.
- **Zarxio (filgrastim-sndz) 300 mcg/0.5 ml and 480 mcg/0.8 ml syringes**: Indicated to reduce the incidence and duration of neutropenia.

The following medication will be EXCLUDED from the Commercial Formulary effective date pending OTC availability

- **Azelastine nasal spray 0.1% and 0.15%:** indicated for relief of symptoms of perennial allergic rhinitis in adults and pediatric patients 6 months and older; for relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 2 years and older (Astepro 0.1% and 0.15%) and pediatric patients 2 years and older (generic azelastine 0.1%); and for relief of symptoms of vasomotor rhinitis in adults and adolescents 12 years and older.

QHP (ACA)/Open Formulary Tier Changes

The following tier changes will be effective July 13, 2022:

- **Flovent (fluticasone HFA) 110 mcg/actuation inhaler for use in children under 5 years of age:** down-tier to Tier 3 Preferred Brand.
- **Isosorbide Dinitrate and Hydralazine 20-37.5 mg tablets**: down-tier to Tier 2 Preferred Generic.
- **Warfarin 3 mg tablets:** down-tier to Tier 1 Preventative Generic.

The following tier changes will be effective January 1, 2023:

- **TobraDex ointment 0.3-0.1 %:** up-tier to Tier 4 Non-Preferred Brand.

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 ADDITIONS were recently approved effective July 13, 2022:

- **Camzyos (mavacamten)**: Indicated for adults with symptomatic New York Health (NYHA) Class II-III obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms.
- **Enjaymo (sutimlimab)**: Indicated to decrease the need for red blood cell transfusion due to hemolysis in adults with cold agglutinin disease.

The following IR Practice Recommendation UPDATES were recently approved effective July 13, 2022:

- **Aduhelm (aducanumab)**: Indicated for the treatment of Alzheimer's disease.

ETSP recommendations as well as pipeline candidates can be found here: https://secure.sp.kp.org/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 clinicians. Please contact your P&T Committee representative or your Department Chief by July 22 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) 439-4439.

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 Chair:

Carole Gardner, MD

P&T Committee Members:

Debbi Baker, PharmD, BCPS
Clinical Pharmacy

Karen Bolden, RN, BSN
Clinical Services

Hector Clarke, PharmD, BCOP
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Obstetrics and Gynecology

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Jennifer Rodriguez, MD
Behavioral Health

Designated Alternates:

Jacqueline Anglade, MD
Obstetrics and Gynecology

Lesia Jackson, RN
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Satya Jayanthi, MD
Hospitalist

Commercial/Closed and QHP (ACA)/Open Formulary QRM Additions (Prior Authorization)

The following QRM additions will be effective July 13, 2022:

- **Adbry (tralokinumab-ldrm)**: Indicated for treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescriptions or when therapies are not advisable.
- **Besremi (ropeginterferon alfa-2b):** Indicated for treatment of adults with polycythemia vera.
- **Omnipod 5 Kit and Pods:** Indicated for Type 2 Diabetes (T2D).
- **Oxlumo (lumasiran)**: Indicated for treatment of primary hyperoxaluria type 1 to lower urinary oxalate levels in pediatric and adult patients.
- **Ozempic (semaglutide) 2 mg weekly dose**: Indicated for T2D as an adjunct to diet and exercise to improve glycemic control and risk reduction of major cardiovascular events in adults with T2D and established cardiovascular disease.
- **Qulipta (atogepant)**: Indicated for preventive treatment of episodic migraine in adults.
- **Scemblix (asciminib)**: Indicated for treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase, previously treated with two or more tyrosine kinase inhibitors.
- **Skytrofa (lonapegsomatropin-tcgd)**: Indicated for treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone.
- **Tavneos (avacopan)**: Indicated as an adjunctive treatment for adult patients with severe active ANCA-associated vasculitis (granulomatosis with polyangiitis and microscopic polyangiitis) in combination with standard therapy.

The following QRM additions will be effective January 1, 2023:

- **Aveed (testosterone undecanoate)**: Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.
- **Emsam (selegiline)**: Indicated for the treatment of major depressive disorder.
- **Jatenzo (testosterone undecanoate):** Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.
- **Omnipod DASH Kit and Pods**: Indicated for type 1 and 2 diabetes.
- **Rukobia (fostemsavir)**: Indicated for adults with human immunodeficiency virus type 1 infection as an adjunct to treatment in patients considered heavily treatment-experienced, with resistance to multiple antiretroviral therapies.

QRM Criteria Updates

The following updates will be effective July 13, 2022:

- **CGRP Inhibitors**: Criteria updated to align with clinical practice. The update included removing Pain Management Specialist as an authorized prescriber, updating the reasons for non-coverage, and re-defining medication overuse headache.
- **Dimethyl Fumarate**: Criteria updated for the new member section to align with similar fumaric ester therapies QRM criteria.
- **GLP-1 Receptor Agonists**: Criteria updated to include continued approval for Ozempic 2 mg and coverage criteria for new members. In addition, language from previous guidelines re-added to address current KP members on insulin.
- **Jublia (efinaconazole) External Solution**: Tavaborole 5% topical solution daily for 48 weeks added to the criteria as an additional anti-fungal treatment option.
- **Lynparaza (olaparib) Oral Tablets:** Criteria updated to include Gynecologic Oncologist as an authorized prescriber and all FDA-approved indications for PARP agents.
- **Novolin Products**: Criteria language was improved to clarify and differentiate the various Novolin products.
- **Reyvow (lasmiditan)**: Criteria updated to allow concomitant use of Reyvow and CGRP agents as clinically appropriate.
- **Rinvoq (upadacitinib)**: Criteria updated to include new FDA approved indication for treatment of moderate-to-severe active ulcerative colitis.
- **Rubraca (rucaparib)**: Criteria updated to include Gynecologic Oncologist as an authorized prescriber. In addition, the statement regarding use of Rucaparib in patients with platinum-resistant disease over platinum-sensitive disease was updated to better align with the NCCN Panel recommendations.
- **Tysabri (natalizumab)**: A documentation of JC virus antibody test within 3 months has been updated to 6 months to avoid excluding patients on maintenance Tysabri. In addition, the initial approval was extended from 3 months to 1 year.
- **Ubrevly (ubrogepant)**: The statement "Approve ½ tablets for lower strength (Ubrevly 100 mg, ½ tablet ONCE PRN) unless patient is unable or unwilling to split tablets" added to criteria to support the half-tablet initiative.
- **Zejula (niraparib)**: Criteria updated to include Gynecologic Oncologist as an authorized prescriber.

Commercial/Closed and QHP (ACA)/Open Formulary Quantity Limits

Quantity Limits will be added to the following medications effective July 13, 2022:

Drug	Quantity Limit
Nextstellis (drospirenone-estetrol)	84-day supply per 72 days
Omnipod 5	Kit: 1 kit per 366 days Pods: 10 pods per 30 days
Oxlumo (lumasiran)	4 vials every month for 3 doses then every 3 months thereafter
Ozempic (semaglutide) 2 mg	3 mL per 30 days
Qulipta (atogepant)	30 tablets per 30 days
Quviviq (daridorexant)	30 tablets per 30 days
Scemblix (asciminib)	30-day supply per 30 days
Skytrofa (lonapegsomatropin-tcgd)	30-day supply per 30 days
Tavneos (avacopan)	30-day supply per 30 days

Quantity Limits will be added to the following medications effective January 1, 2023:

Drug	Quantity Limit
Jatenzo (testosterone undecanoate)	60 capsules per 30 days
Omnipod DASH	Kit: 1 kit per 366 days Pods: 10 pods per 30 days

Commercial/Closed and QHP (ACA)/Open Formulary Unit of Use Additions

Unit of Use will be added to the following medications effective July 13, 2022:

- **Cosentyx (secukinumab)**
- **Dupixent (dupilumab)**
- **Naloxone Nasal Spray 4 mg/0.1 mL**

QHP (ACA)/Open Formulary Step Therapy Additions

STEP therapy will be added to the following medications effective July 13, 2022:

- **Nexstellis (drospirenone-estetrol)** 3-15 mg oral tablet
- **Orphenadrine-Aspirin-Caffeine** 25-385-30 mg tablet
- **Quviviq (daridorexant)** 25 and 50 mg oral tablet
- **Zegalogue (dasiglucagon)** 1 mg/ml subcutaneous injection

STEP therapy will be added to the following medications effective January 1, 2023:

- **Granix (tbo-filgrastim)** 300mcg/ml and 480 mcg/1.6 ml syringes
- **Neupogen (filgastim)** 300mcg/ml and 480 mcg/1.6 ml syringes
- **TobraDex** ointment 0.3-0.1 %
- **Tobramycin-Dexamethasone** ophthalmic suspension 0.3-0.1 %
- **Zarxio (filgrastim-sndz)** 300 mcg/0.5 ml and 480 mcg/0.8 ml syringes

QHP (ACA)/Open Formulary Step Therapy Removals

STEP therapy will be removed to the following medication effective July 13, 2022:

- **Betaseron (interferon beta-1b)** 0.3 mg subcutaneous kit

Upcoming Class Review

August 2022

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

Floor Stock Changes

Department	Change
ACC-CDU Pyxis Machine	- Add Morphine Sulfate 10 mg oral syringe
Oncology Floorstock	- Add Nivestym (filgrastim-aafi) 300 mcg and 480 mcg syringe - Add Fulphila (pegfilgrastim-hmdb) 6 mg syringe - Remove Zarxio (filgrastim-sndz) 300 mcg and 480 mcg syringe - Remove Neulasta (pegfilgrastim) 6 mg syringe
Pulmonology Floorstock (Brookwood location only)	- Add Xopenex (levalbuterol) 45 mcg/actuation
Urgent Care Floorstock	- Add Nivestym (filgrastim-aafi) 300 mcg and 480 mcg syringe - Remove Zarxio (filgrastim-sndz) 300 mcg and 480 mcg syringe

New Standing Orders

- Zarxio (filgrastim-sndz) and Nivestym (filgrastim-aafi) are biosimilars approved by the FDA, based on the reference product filgrastim (Neupogen). NIvestym and Zarxio have no clinically meaningful difference in terms of safety and effectiveness from filgrastim (Neupogen).

	EQUIVALENT TO	
Filgrastim (Neupogen) 300 mcg/0.5 mL prefilled syringe OR Filgrastim-sndz (Zarxio) 300 mcg/0.5 mL prefilled syringe ***All sigs***	⟷	Filgrastim-aafi (Nivestym) 300 mcg/0.5 mL prefilled syringe ***Same sig***
Filgrastim (Neupogen) 480 mcg/0.8 mL prefilled syringe OR Filgrastim-sndz (Zarxio) 480 mcg/0.8 mL prefilled syringe ***All sigs***	⟷	Filgrastim-aafi (Nivestym) 480 mcg/0.8 mL prefilled syringes ***Same sig***
Filgrastim (Neupogen) 300 mcg/1 mL vial ***All sigs***	⟷	Filgrastim-aafi (Nivestym) 300 mcg/1 mL vial ***Same sig***
Filgrastim (Neupogen) 480 mcg/1.6 mL vial ***All sigs***	⟷	Filgrastim-aafi (Nivestym) 480 mcg/1.6 mL vial ***Same sig***

- Riabni (rituximab-arrx) FDA approved in 2020 based on comprehensive totality of evidence proving biosimilarity to Rituxan (rituximab) with no clinically meaningful differences in safety and efficacy.

	EQUIVALENT TO	
Rituximab-abbs (Truxima) solution for intravenous infusion ***All sigs and infusion rates***	⟷	Rituximab-arrx (Riabni) solution for intravenous infusion ***Same sig and infusion rates***

Medicare Part D Formulary Additions

Medication	Designated Tier and Restrictions	Effective Date
Methadone 5 mg/5 mL Oral Solution	Tier 2 with non-extended day supply (NDS) of a 30-day limit	7/27/2022

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.

Medication	Alternative	Effective Date
Vimpat 50 mg, 100 mg, 150 mg, 200 mg Tablets	Lacosamide 50 mg, 100 mg, 150 mg, 200 mg Tablets	6/1/2022
Restasis 0.05 % Emulsion	Cyclosporine 0.05 % Emulsion	7/1/2022
Ferriprox 1000 mg Tablets	Deferiprone 1000 mg Tablets	7/1/2022
Chantix Starting Month Pak 0.5 mg x 11 & 1 mg x 42 Tablets	Varenicline Tartrate 0.5 mg x 11 & 1 mg x 42 Tablets	7/1/2022

In the news...

Lexicon Resubmits New Drug Application (NDA) for Sotagliflozin for Treatment of Heart Failure

May 31, 2022, Lexicon Pharmaceuticals announced that it has resubmitted a NDA to the U.S. Food and Drug Administration (FDA) for sotagliflozin after the results from the SOLOIST-WFH and SCORED clinical trials. The FDA has a 60-day filing review period to determine whether the NDA is acceptable.

Sotagliflozin is the first oral agent with dual inhibition of sodium-glucose co-transporter types 1 and 2 (SGLT1 and SGLT2). SGLT1 is responsible for glucose absorption in the gastrointestinal tract and SGLT2 is responsible for glucose reabsorption by the kidney. The agent has been studied in multiple patient populations, including heart failure, type 1 and type 2 diabetes, and chronic kidney disease.

SOLOIST-WFH a multi-center, randomized, double-blinded, placebo-controlled Phase 3 study evaluated the cardiovascular efficacy of sotagliflozin versus placebo when added to standard of care in 1,222 patients with type 2 diabetes, recently hospitalized for worsening heart failure. SCORED a multi-center, randomized, double-blinded, placebo-controlled phase 3 study evaluated the cardiovascular efficacy of sotagliflozin versus placebo when added to standard of care in 10,584 patients with type 2 diabetes, chronic kidney disease (eGFR 25-60 mL/min/1.73 m2) and cardiovascular disease risk.

Both studies met the primary endpoint, which assessed the total number of events comprised of deaths from cardiovascular causes, hospitalizations for heart failure, and urgent visits for heart failure in patients with sotagliflozin compared with placebo. The results were published in The New England Journal of Medicine in two separate articles titled: “Sotagliflozin in Patients with Diabetes and Recent Worsening Heart Failure” and “Sotaglifozin in Patients with Diabetes and Chronic Kidney Disease”.

1. Lexicon Pharmaceuticals, Inc. Lexicon resubmits new drug application for sotagliflozin for treatment of heart failure. Accessed June 16, 2022. https://www.lexpharma.com/media-center/news/809-lexicon-resubmits-new-drug-application-for-sotagliflozin-for-the-treatment-of-heart-failure.

Kaiser Permanente Drug Take Back Program

Kaiser Permanente pharmacies offer safe, convenient, and earth-friendly ways for your patient to dispose unwanted drugs. The Drug Take Back Program for KPGA consist of 12 Drug Take Back kiosks located at 12 of our outpatient retail pharmacies that are registered with the State Board of Pharmacy and the DEA as Authorized Collectors:

Athens	Crescent
Cumberland	Douglasville
Forsyth	Glenlake
Gwinnett	Panola
Sandy Springs	Stonecrest
Sugar-Hill	Townpark

Outpatient retail pharmacies without a kiosk offer Send Away Envelopes/Mailers that are pre-addressed and postage paid as an alternative service option. The Send Away Envelopes/Mailers are available upon request in the pharmacy at no cost.

National Drug Take Back Program Overview

Drug Take Back Kiosks

- Select outpatient pharmacies host kiosks
- Program funded through region budgets, stewardship, or state program sources
- Kiosks in our pharmacy lobbies are made accessible to the public at no cost
- Host pharmacies are DEA registered as an Authorized Collector
- Collected waste is shipped to a pharmaceutical waste handler

Send Away Envelopes/Mailers

- Select KP outpatient pharmacies offer at no cost to members or public upon request
- Offers a private and safe method for immobile or home-bound patients
- Envelopes are pre-addressed and USPS First Class postage-paid
- Complies with DEA requirements
- An alternative service option from kiosks
- All regions currently participate