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Formulary Update

At A Glance

Formulary Additions - Effective 3.15.2023

- Medroxyprogesterone Intramuscular Pre-Filled Syringes
- Sacubitril 97 mg/Valsartan 103 mg Tablets
- Sacubitril 49 mg/Valsartan 51 mg Tablets

Formulary Removal - Effective 4.19.2023

- Humira (adalimumab)

Prior Authorization (QRM) Additions

- Pyrukynd (mitapivat)
- Verquvo (vericiguat)

Prior Authorization (QRM) Updates

- Cosentyx (secukinumab)
- Glucagon-Like Peptide-1 Receptor Agonists (GLP- 1 RAs)
- Humira (adalimumab)
- Noxafil (posaconazole)
- Otezla (apremilast)
- Stelara (ustekinumab)
- Skyrizi (risankizumab)
- Taltz (ixekizumab)
- Tremfya (guselkumab)

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 March 15, 2023:

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

- **Medroxyprogesterone intramuscular (IM) pre-filled syringes (generic Depo-Provera):** Indicated for prevention of pregnancy.
- **Sacubitril 97 mg/Valsartan 103 mg and Sacubitril 49 mg/Valsartan 51 mg tablets (Entresto):** Indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure and reduced ejection fraction. Also indicated in pediatric patients age one year and older in the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction.

Commercial HMO/Closed Formulary Removals

The following medications will be REMOVED from the Commercial HMO/Closed Formularies effective April 19, 2023:

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

- **Humira (adalimumab):** Indicated to treat many inflammatory conditions in adults such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis.

QHP-ACA/Open Formulary Tier Changes

The following tier changes will be effective March 15, 2023:

- **Medroxyprogesterone intramuscular (IM) pre-filled syringes (generic Depo-Provera):** Down-tier to Preferred Generic Tier 2

QHP-ACA/Open Formulary Tier Changes

The following tier changes will be effective January 1, 2024:

- **Sacubitril 24 mg/Valsartan 26 mg:** Up-tier to Non-Preferred Brand Tier 4

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 Recommendations were recently approved:

- **Hemgenix (etranacogene dezaparvovec-drlb):** Indicated for the treatment of adults with Hemophilia B (congenital Factor IX deficiency) who currently use Factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.
- **Leqembi (lecanemab):** Indicated for the treatment of Alzheimer's disease.
- **Tzield (teplizumab):** Indicated to delay the onset of stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged eight years and older with stage 2 T1D.

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 March 31 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.

Interregional Practice Recommendations (continued)

The following IR Practice Recommendation UPDATES were recently approved:

- **Relyvrio (sodium phenylbutyrate and taurursodiol):** Updated to include the separate components of sodium phenylbutyrate (generic Buphenyl) and taurursodiol (available over the counter) as alternatives. In addition, recommendations updated from <18 months to within 18 months of symptoms onset based on clinical trial inclusion criteria.

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 March 15, 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.

- **Pyrukynd (mitapivat):** Indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.
- **Verquvo (vericiguat):** Indicated to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

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.

- **Dermatology Biologics:** Criteria updated to encourage the use of lower doses or maintenance doses (without the need for a loading dose) for the treatment of plaque psoriasis.
    - **Cosentyx (secukinumab)**
    - **Stelara (ustekinumab)**
    - **Skyrizi (risankizumab)**
    - **Taltz (ixekizumab)**
    - **Tremfya (guselkumab)**
- **GLP-1 Receptor Agonists (GLP- 1 RAs):** Criteria updated to 1) include both Victoza 1.2 mg daily and Ozempic 0.5 mg-1 mg weekly as preferred options (effective 4.5.2023) and 2) Jardiance is no longer required when patient is on insulin under the ASCVD criteria.
- **Humira (adalimumab):** Criteria updated to include Amjevita (adalimumab-atto) as the preferred product. Amjevita is KP's chosen Adalimumab product. Amjevita is available as Non-Formulary or Step Therapy, as a Brand copay, not a Specialty co-insurance.
- **Noxafil (posaconazole):** Criteria updated to 1) include itraconazole as an additional agent for invasive fungal infections and 2) include formulation specific criteria for further guidance.
- **Otezla (apremilast):** Criteria updated under psoriatic arthritis criteria to combine two seperate bullets into one bullet stating "History of inadequate response or intolerance to two or more conventional synthetic Disease Modifying Antirheumatic drugs (DMARDs) (e.g. methotrexate, leflunomide or sulfasalazine)."

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
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Karen Bolden, RN, BSN
Clinical Services

Hector Clarke, PharmD, BCOP
Ambulatory Pharmacy

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Obstetrics and Gynecology

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Pierson Gladney, MD
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Shayne Mixon, PharmD
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Rachel Robins, MD
Hospitalist

Jennifer Rodriguez, MD
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P&T Committee Non-Voting Physician Members:

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Designated Alternates:

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Lesia Jackson, RN
Clinical Services

Satya Jayanthi, MD
Hospitalist

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

Medication	Quantity Limit	Effective Date
Clindesse (clindamycin) 2% vaginal cream	1 applicator per 3 months	3.15.2023
Nebulized Solutions • Albuterol 0.5% inhalation solution (generic) • Albuterol 0.083% inhalation solution (generic) • Ipratropium-albuterol 0.5 mg-2.5 mg/3 mL inhalation solution (generic & brand) • Ipratropium bromide 0.02% inhalation solution (generic) • Levalbuterol 0.31 mg/3 mL, 0.63 mg/3 mL, 1.25 mg/3 mL, 1.25 mg/0.5 mL inhalation solution (generic & brand)	1 box per 30 days **Exclusions:** • Chronic use (i.e. COPD, Cystic Fibrosis, Non-cystic fibrosis bronchiectasis, Neuromuscular disease). • Providers are allowed to override the 30-day limit if warranted for an individual patient.	Pending
Victoza (liraglutide) 1.2 mg subcutaneous injection	1.2 mg (6 mL) per 30 days	3.15.2023

QHP-ACA/Open Formulary Step Therapy Additions

Medication Name	Effective Date
Amjevita (adalimumab-atto)	2.17.2023
Abilify Mycite (aripiprazole) Maintenance Kit	3.15.2023
Entresto 24 mg – 26 mg (sacubitril/valsartan)	1.1.2024
Ermeza (levothyroxine)	3.15.2023
Kisqali (ribociclib)	3.15.2023
Ztalmy (ganaxolone)	3.15.2023

Department Floor Stock Removals

Department	Removal	Effective Date
Adult Primary Care	Kenalog-10 (10 mg/mL) Vials	3.15.2023

New Standing Orders

- Adalimumab (Humira) solution is equivalent to adalimumab-atto (Amjevita)

The directions of this product	IS EQUIVALENT TO	The directions of this product
Adalimumab (Humira) prefilled pen for subcutaneous injection **40 mg/0.4 mL (citrate-free)** **40 mg/0.8 mL** **80 mg/0.8 mL (citrate-free)** **Two x 80 mg/0.8 mL**	⟺	Adalimumab-atto (Amjevita) prefilled SureClick autoinjector for subcutaneous injection **40 mg/0.8 mL** **40 mg/0.8 mL** **Two x 40 mg/0.8 mL** **Four x 40 mg/0.8 mL**
Adalimumab (Humira) prefilled syringe for subcutaneous injection **20 mg/0.2 mL (citrate-free)** **40 mg/0.4 mL (citrate-free)** **40 mg/0.8 mL** **80 mg/0.8 mL (citrate-free)**	⟺	Adalimumab-atto (Amjevita) prefilled syringe for subcutaneous injection **20 mg/0.4 mL** **40 mg/0.8 mL** **40 mg/0.8 mL** **Two x 40 mg/0.8 mL**

New Standing Orders (continued)

- Alclometasone dipropionate 0.05% Cream/Ointment are equivalent to Desonide 0.05% Cream/Ointment.

Alclometasone dipropionate 0.05% Cream/Ointment	IS EQUIVALENT TO	Desonide 0.05% Cream/Ointment
Alclometasone dipropionate 0.05% Cream	⟺	Desonide 0.05% Cream
Alclometasone dipropionate 0.05% Ointment	⟺	Desonide 0.05% Ointment

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
bendamustin 25 mg, 100 mg injection (generic)	Specialty Tier 5	1/11/2023
pirfenidone 267 mg capsules	Specialty Tier 5	1/10/2023
pexidartinib HCL 125 mg capsules (Turalio)	Specialty Tier 5	1/4/2023
tasimelteon 20 mg capsules (generic)	Specialty Tier 5	12/30/2022
voxelotor 300 mg tablets (Oxbryta)	Specialty Tier 5	12/29/2022
ublituximab-xiiy 150 mg/6 mL injection (Briumvi)	Specialty Tier 5	12/29/2022
mosunetuzumab-axgb 1 mg/mL, 30 mg/30 mL injection (Lunsumio)	Specialty Tier 5	12/28/2022
risankizumab-rzaa subcutaneous 180 mg/1.2 mL injection (Skyrizi)	Specialty Tier 5	12/20/2022
sodium oxybate 500 mg/mL oral solution	Specialty Tier 5	12/19/2022
fingolimod lauryl sulfate 0.5 mg disintegrating tablets (Tascenso ODT)	Specialty Tier 5	12/19/2022
pegfilgrastim-fpgk 6 mg/0.6 mL prefilled injection (Stimufend)	Specialty Tier 5	12/15/2022
adagrasib 200 mg tablets (Krazati)	Specialty Tier 5	12/14/2022
bendamustine HCl 100 mg/4 mL injection (Vivimusta)	Specialty Tier 5	12/8/2022
olutasidenib 150 mg capsules (Rezlidhia)	Specialty Tier 5	12/6/2022

Class Review

April 2023:

Medication Class Reviews
ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants
Antianxiety Agents
Antiasthmatics and Bronchodilator Agents
Anticonvulsants
Antidepressants
Antimyasthenics/Cholinergic Agents
Antiparkinsons
Antipsychotics/Antimanic Agents
Genitourinary – Misc
Hematological Agents – Misc
Hypnotics/sedatives/sleep disorder agents
Migraine Products
Neuromuscular Blockers
Psychotherapeutics – Misc
Urinary Anti-infectives
Urinary Antispasmodics
Urinary Antiseptic-Antispasmodic & /or Analgesic

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
DALIRESP TABS 250 MCG	ROFLUMILAST TABS 250 MCG	3/1/2023
PENTASA CPCR 500 MG	MESALAMINE ER CPCR 500 MG	2/1/2023
GILENYA CAPS 0.5 MG	FINGOLIMOD HCL CAPS 0.5 MG	2/1/2023
TAZORAC GEL 0.05 %	TAZAROTENE GEL 0.05 %	2/1/2023
TAZORAC GEL 0.1 %	TAZAROTENE GEL 0.1 %	2/1/2023
DALIRESP TABS 500 MCG	ROFLUMILAST TABS 500 MCG	2/1/2023

In the news...

On January 26, 2023, the FDA announced that it revised the emergency use authorization (EUA) of AstraZeneca's Evusheld (tixagevimab and cilgavimab) to restrict its use based on Evusheld's activity against susceptible SARS-CoV-2 variants. The revised EUA states that Evusheld is only authorized for use when >10% of circulating variants are expected to be neutralized by the drug. Therefore, based on currently circulating variants, Evusheld is no longer authorized for emergency use in the United States.

The FDA granted EUA to Evusheld on December 8, 2021, for pre-exposure prophylaxis (PrEP) of COVID-19 in adults and children with moderate to severe immune compromise due to a medical condition or immunosuppressive medications and who may not mount an adequate immune response to COVID-19 vaccination, as well as those individuals for whom COVID-19 vaccination is not recommended.

Although several antivirals remain approved or authorized to treat COVID-19, including Pfizer's Paxlovid (nirmatrelvir and ritonavir), Gilead's Veklury (remdesivir) and Merck's Lagevrio (molnupiravir), Evusheld was the only product available for PrEP. In neutralization studies, Evusheld demonstrated a significant reduction (i.e. more than 2000-fold) in susceptibility of the Omicron BQ.1 and BQ.1.1 variants. Based on AstraZeneca's in vitro pseudovirus assay laboratory data, Evusheld was not shown to neutralize Omicron subvariants that currently represent >90% of circulating variants in the United States (i.e. BQ.1, BQ.1.1, BF.7, BF.11, BA.5.2.6, BA.4.6, BA.2.75.2, XBB, and XBB.1.5).

In its press release, the FDA indicated Evusheld is no longer authorized for use in the United States until further notice by the agency. The FDA, Centers for Disease Control and Prevention (CDC), National Institutes for Health (NIH), and other organizations conduct surveillance of currently circulating SARS-CoV-2 variants that may impact use of available therapies. The FDA further noted that Paxlovid, Veklury, and Lagevrio are expected to maintain activity against the newer variants.