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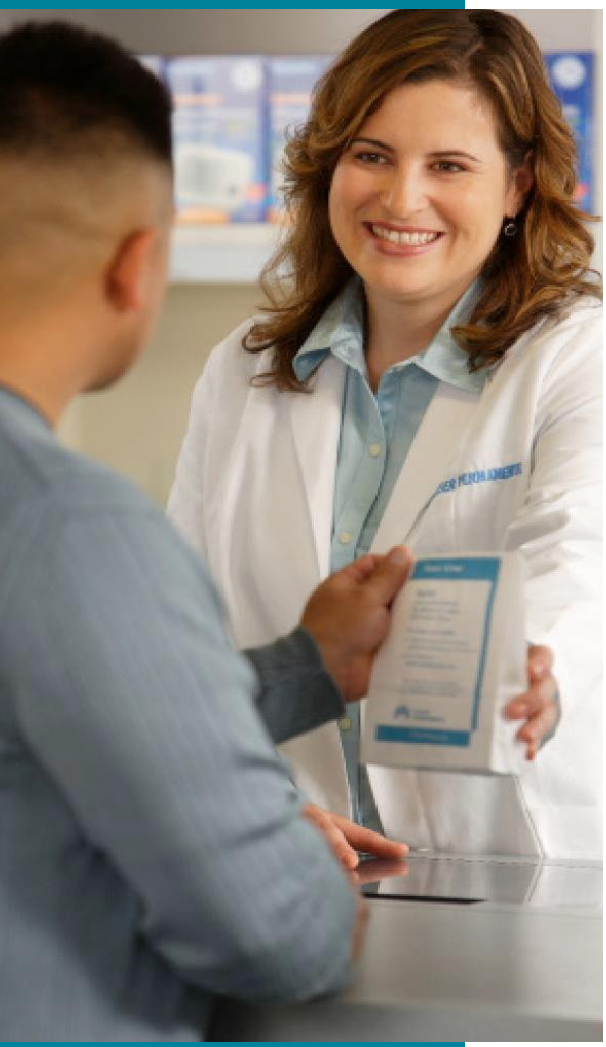
Formulary Update



At A Glance

Formulary Additions

- Flovent HFA (fluticasone) 44 mcg/actuation inhaler for children < 5 years

Prior Authorization (QRM) Additions

- Truseltiq (Infigratinib) Tablets

Prior Authorization (QRM) Updates

- Cosentyx (Secukinumab) Injection
- Enbrel (Etanercept) Injection
- Gilenya (Fingolimod) Capsule
- GLP-1 Receptor Agonists
- Humira (Adalimumab) Injection
- Interleukin Agonists
- Jemperli (Dostarlimab-gxly) Solution
- Mavyret (Glecaprevir and Pibrentasvir) Tablet
- Nucala (Mepolizumab) Injection
- Remicade (Infliximab) Solution
- SGLT-2 Inhibitors
- Tepezza (Teprotumumab-trbw) Solution
- Zynlonta (Loncastuximab Tesirine-lpyl) Solution

Formulary Additions

The following medication will be added to the Commercial Formulary effective March 9, 2022:

- **Flovent (fluticasone) HFA 44 mcg/act inhaler for us in children under 5 years of age:** Indicated for asthma maintenance therapy

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.

Tier Changes

The following tier changes will be effecitve March 9, 2022:

- **Hydrochlorothiazide 12.5 mg capsules:** down-teiring to Preferred Generic Tier 2

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:

- **Tavneos (avacopan):** Indicated for adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic auto-antibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids.
- **Voxzogo (vosoritide):** Indicated to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses.

The following IR Practice Recommendation UPDATES were recently approved:

- **Aduhelm (aducanumab):** Indicated for the treatment of Alzheimer's disease. A new section was added to the guidelines with screening recommendations prior to specialist referral for treatment.

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.

Additions to QRM (Prior Authorization)

Effective March 8, 2022:

- **Truseltiq (infigratinib)**: Indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or other rearrangment as detected by an FDA-approved test.

QRM Criteria Updates

- **Cosentyx (secukinumab):** Criteria revised to add requirements for tuberculosis, Hepatitis B and Hepatitis C testing or treatment prior to initiation of therapy for plaque psoriasis.
- **Enbrel (etanercept):** Criteria revised to add requirements for tuberculosis, Hepatitis B and Hepatitis C testing or treatment prior to initiation of therapy for plaque psoriasis.
- **Gilenya (fingolimod):** Criteria updated to remove the requirement of rituximab trial for new patients to KP who are established and stable on Gilenya due to increased risk. The criteria of the other non-preferred S1P modulator therapies continue to require Gilenya, the KP preferred S1P modulator prior to approval of non-preferred agents.
- **GLP-1 Receptor Antagonists:** Minor criteria revisions were made to improve clarity of the guidelines.
- **Humira (adalimumab):** Criteria revised to add requirements for tuberculosis, Hepatitis B and Hepatitis C testing or treatment prior to initiation of therapy for plaque psoriasis, uveitis, and hidradenitis suppurativa and to remove the requirement for an inadequate response, intolerance or contraindication to Xeljanz prior to treatment with Humira for ulcerative colitis.
- **Interleukin Agonists:** Criteria revised to add requirements for tuberculosis, Hepatitis B and Hepatitis C testing or treatment prior to initiation of therapy for plaque psoriasis.
- **Mavyret (glecaprevir and pibrentasvir):** Criteria updated to include guidelines for the pediatric formulation.
- **Nucala (mepolizumab):** Criteria were re-reviewed due to the new FDA-approved indication for chronic rhinosinusitis with nasal polyps. No revisions were made to the guidelines based on the new indication.
- **Remicade (infliximab):** Criteria were updated due to availability of unbranded infliximab (Remicade) which is marketed and distributed by the manufacturer of Remicade. Infliximab (unbranded) is identical in composition to Remicade (branded) and is now KP preferred infliximab product.
- **SGLT-2 Inhibitors:** Minor criteria revisions were made to improve clarity of the guidelines.
- **Tepezza (teprotumumab-trbw):** Criteria updated to include sections outlining an initial approval period and continued approval period to align with the recommended duration of treatment in the prescription information.

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 21 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.

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
Ambulatory Pharmacy

Halima Daiboko, MD
Obstetrics and Gynecology

Pierson Gladney, MD
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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

Felecia Martin, PharmD
Pharmacy/Geriatrics

Shayne Mixon, PharmD
Pharmacy Operations

Rachel Robins, MD
Hospitalist

Jennifer Rodriguez, MD
Behavioral Health

Ike Uzodinma, RPh
Executive Director Pharmacy (Interim)

Designated Alternates:

Jacqueline Anglade, MD
Obstetrics and Gynecology

Lesia Jackson, RN
Clinical Services

Satya Jayanthi, MD
Hospitalist

Step Therapy Additions

STEP therapy will be added to the following medications on QHP and Open Formularies effective March 8, 2022:

- **Xarelto (rivaroxaban)** oral solution
- **Betaseron (Interferon Beta-1b)** subcutaneous kit

New Age Restrictions

An age restriction will be added to the following medication(s) effective March 9, 2022:

- **Akilef (trifarotene) 0.005% cream:** added to only allow coverage for members ≤35 years of age
- **Flovent HFA (fluticasone) 44 mcg/inh:** added to only allow coverage for members <5 years of age

Floor Stock Changes

- **Cosmetic Dermatology:** Addition of Arnica Gel 1.5 oz tube
- **Dermatology:** Addition of Arnica Gel 1.5 oz tube

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

Medication	Tier	Effective Date
topiramate 25 mg/mL oral solution (Eprontia)**	4	2/1/2022
pemetrexed 500 mg/20 mL injection (Pemfexy)	5	1/24/2022
upadacitinib 30 mg extended-release tablets (Rinvoq)	5	1/24/2022
remdesivir 100 mg injection (Veklury)	5	1/21/2022
hepatitis B vaccine 3-antigen (recombinant) 10 mcg/mL injection (Prehevbrio)	6	1/17/2022
tralokinumab-ldrm 150 mg/mL injection (Adbry)	5	1/12/2022
levoketoconazole 150 mg tablets (Recorlev)	5	1/10/2022
rivaroxaban 1 mg/mL oral suspension (Xarelto)	5	1/7/2022
tezepelumab-ekko 210 mg/1.91 mL injection (Tezspire)	5	1/5/2022
budesonide 4 mg delayed-release capsules (Tarpeyo)	5	12/28/2021
voxelotor 300 mg tablets for oral suspension (Oxybryta)**	5	12/23/2021
efgartigimod alfa-fcab 400 mg/20 mL injection (Vyvgart)	5	12/22/2021
cyclophosphamide 2 g/10 mL injection	5	12/7/2021
corticotropin 80 unit/mL injection gel (Cortrophin)	5	12/3/2021
flutamide 125 mg capsules (Eulexin)**	5	12/3/2021
carglumic acid 200 mg soluble tablets (Carbaglu)	5	12/2/2021
maribavir 200 mg tablets (Livtencity)	5	11/30/21
vosoritide 0.4 mg, 0.56 mg, 1.2 mg injection (Voxzogo)	5	11/29/21
sirolimus 100 mg injection (Fyarro)**	5	11/29/21

Medications Not Added to the Formulary

- **Nucala (mepolizumab)** is a humanized interleukin-5 (Il-5) monoclonal antibody that was recently approved for a new indication for the treatment of adults with chronic rhinosinusitis with nasal polyps (CRSwNP). It is an alternative biologic agent for use as an add-on treatment to nasal corticosteroids for adults with recurrent, refractory severe bilateral CRSwNP despite standard of care and prior history of nasal surgery. While Nucala met study endpoints for the reduction of nasal polyp size and nasal obstruction and the percentage of patients, long-term safety data in the management of CRSwNP is limited at this time. Additionally, there are no head-to-head trials comparing Nucala with other biologics FDA approved for the treatment of CRSwNP. Dupixent remains KP's preferred biologic for the treatment of CRSwNP at this time. Nucala will continue to remain non-formulary and require prior authorization.
- **Truseltiq (infigratinib)** is a small molecule kinase inhibitor of fibroblast growth factor receptor (FGFR). It is indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with FGFR2 fusion or other rearrangement as detected by an FDA-approved test. Truseltiq is the second FGFR2 inhibitor granted accelerated approval by the FDA for this indication. While long-term and head-to-head data are not available at this time, overall response rate and median duration of response observed with Truseltiq appears numerically less favorable compared to Pemazyre (pemigatinib), though notable difference in baseline characteristics were observed. Toxicity concerns such as ocular toxicity and hyperphosphatemia remain. However, this was also observed with Pemazyre and overall appears to be a class effect. Given the limited safety and efficacy data and high cost of this medication, Truseltiq is better managed as a non-formulary medication with prior authorization.

Additional Announcements for 2022

New Intranet Location for KPGA Formulary and Pharmaceutical Pages

Content from the KPGA Pharmaceutical and Formulary Pages have been moved to the SharePoint sites listed below pending retirement of the KPGA Legacy Site. Please save the web addresses listed to your bookmarks. Currently, the KPGA Pharmaceutical and Formulary Pages on the KPGA Legacy site remain active, but once it is retired later this year, pharmacy content will only be accessible from the new SharePoint sites listed below.

KP Georgia Formulary - Home: https://sp-cloud.kp.org/sites/KPGeorgiaFormulary/SitePages/Home.aspx

KP Georgia Pharmaceutical Services - Home: https://sp-cloud.kp.org/sites/KPGeorgiaPharmaceuticalServices

In the news...

Pfizer Postpones FDA Request for COVID-19 Vaccine for Children <5 Years

On February 11, 2022, the FDA announced that it is postponing the scheduled advisory committee meeting to discuss a request for authorization of the Pfizer-BioNTech COVID-19 vaccine for children 6 months through 4 years of age.

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) had previously planned to meet on February 15, 2022, to discuss Pfizer and BioNTech's application for emergency use authorization (EUA) of 2 doses of the companies' COVID-19 vaccine in the youngest age group. However, the FDA cited the emergence of additional findings provided by Pfizer regarding 3-dose data, which prompted the FDA to postpone the meeting.

In a separate announcement, Pfizer and BioNTech said they will extend the rolling submission and expect to have updated data on the 2- and 3-dose regimens in early April 2022.

In Pfizer's ongoing clinical trials, a 2-dose series failed to produce the expected level of protection among study participants between 2 and 5 years of age. However, protection among participants 6 to 24 months matched that seen in adolescents and young adults. In December 2021, the companies said that a third dose may provide a higher level of "real-world protection." The Pfizer-BioNTech vaccine has been available under an EUA for children 5 to 11 years of age since October 2021 and for adolescents 12 to 15 years of age since May 2021. It is fully approved for anyone 16 years of age or older.

The FDA will provide an update on timing for the advisory committee meeting once it completes an updated evaluation.

1. IPD Analytics. IPD Analytics Payer and Provider Update: Pfizer Postponse FDA Request for COVID-19 Vaccine for Toddlers. February 14, 2021.

Upcoming Class Review

April 2022

Medication Class Reviews
Antianginal
Antiarrhythmics
Antihistamines
Antihyperlipidemics
Antihypertensives
Beta Blockers
Calcium Channel Blockers
Cardiovascular Agents -- Misc
Cough/Cold/Allergy
Diuretics
Nasal Agents -- Systemic & Topical
Passive Immunizing and Treatment Agents
Respiratory Agents -- Misc
Vaccines
Vasopressors