Formulary Additions

The following medications will be added to the Commercial Formulary effective May 12, 2021:

- **Acitretin 10 mg and 25 mg capsules**: Indicated for the treatment of severe psoriasis in adults.
- **Bethamethasone 0.05% and Clotrimazole 1% cream**: Indicated for topical treatment of fungal infections in patients ≥17 years.
- **Clobazam suspension/tablets**: Indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients ≥2 years.
- **Nivestym (filgrastim-aafi) subcutaneous solution (vials only)**: Biosimilar to filgrastim with the same indications as the reference product filgrastim with the exception of the filgrastim indication to increase survival in patients acutely exposed to myelosuppressive doses of radiation.
- **Nystatin 100,000 units and triamcinolone acetonide 0.1% cream/ointment**: Indicated for the treatment of cutaneous candidiasis.
- **Zonisamide capsules**: Indicated for adjunctive therapy in the treatment of focal onset seizures in adolescents >16 years of age and adults.
**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:

- **Imcivree (setmelanotide):** Indicated for chronic weight management in adult and pediatric patients 26 years of age with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance.

- **Oxlumo (lumisiran):** Indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients.

ETSP Guidelines 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 05.12.21:**

- **Gavreto (pralsetinib):** Indicated for the treatment of (1) metastatic RET fusion-positive non-small cell lung cancer (NSCLC) in adults as detected by an approved test, (2) advanced or metastatic RET fusion-positive thyroid cancer in pediatric patients ≥12 years of age and adults who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate), and (3) metastatic RET-mutant medullary thyroid cancer in pediatric patients ≥12 years of age and adults who require systemic therapy.

- **Imcivree (setmelanotide):** Indicated for chronic weight management in adult and pediatric patients 26 years of age with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance.

- **Inqovi (decitabine and cedazuridine):** Indicated for the treatment of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups, in adults.


- **Onureg (azacitidine):** Indicated for the treatment (maintenance) of acute myeloid leukemia in adults who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRI) following intensive induction chemotherapy and are not able to complete intensive curative therapy.

- **Orladeyo (berotralstat):** Prevention of attacks of hereditary angioedema (HAE) in adults and pediatric patients ≥12 years of age.

**QRM Criteria Updates**

- **Benlysta (belimumab):** Criteria updated to (1) include criteria for the treatment of lupus nephritis, (2) allow prescribing by pediatric rheumatologist and use of IV formulation in pediatric patients, (3) clarification of the definition of SLE diagnosis, (4) required trial agents revised and (5) continuation criteria changes to remove SELENA-SLEDAI assessment requirement and addition of criteria for members initiated on Benlysta outside of KPGA.

- **GLP-1 Receptor Agonists:** Criteria updates include (1) revised A1C goal to within 2% of designated goal, (2) added option of trialing pioglitazone in combination with metformin, (3) criteria added to allow use without the trial of empagliflozin and (4) continuation criteria revised to require documented A1C lowering of 0.8%.

- **Humira (adalimumab) and Otezla (apremilast):** Criteria for the treatment of hidradenitis suppurativa updated to remove trial of oral corticosteroids and add option to trial infliximab.

- **Interleukin Antagonists:** Revised to align with Plaque Psoriasis Interregional Practice Guidelines to require trial of agents in order based on classification of first line, second line, third line, and last line agents.

- **PCSK9 Inhibitors (Praluent (alirocumab) and Repatha (evolocumab)):** Criteria revised to (1) add option to trial statin therapy at the maximally tolerated dose in combination with ezetimibe 10 mg and (2) provide continuation criteria for new members initiated on a PCSK9 inhibitor outside of KPGA.

- **Sunosi (solriamfetol):** Updates include requirement that the patient’s self-reported sleep log/CPAP recording demonstrates adequate sleep opportunity per a Sleep Specialist.

- **VMAT Inhibitors (Austedo (deuterabenazine) and Xenazine (tetrabenazine)):** Updated to (1) separate criteria by diagnoses for chorea associated with Huntington’s disease and tardive dyskinesia and (2) removal of trial requirements of nilutamide and amantadine.
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
Gary Beals, RPh
Executive Director, Pharmacy
Karen Bolden, RN, BSN
Clinical Services
Hector Clarke, PharmD, BCOP
Ambulatory Pharmacy
Alyssa Dayton, MD
Obstetrics and Gynecology
Pierson Gladney, MD
Hematology/Oncology
Patrick Hall, MD
Adult Primary Care
Craig Kaplan, MD
Adult Primary Care
Amy Levine, MD
Pediatrics
Sophie Lukashok, MD
Infectious Disease
Felecia Martin, PharmD
Pharmacy/Geriatrics
Shayne Mixon, PharmD
Pharmacy Operations
Jay Polokoff, MD
Pediatrics
Rachel Robins, MD
Hospitalist
Jennifer Rodriguez, MD
Behavioral Health

**Designated Alternates:**
Jacqueline Anglade, MD
Obstetrics and Gynecology
Lesia Jackson, RN
Clinical Services
Mitchell Berger, MD
Hematology/Oncology
Satya Jayanthi, MD
Hospitalist

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**QRM Criteria Updates (continued)**

- **Wakix (pitolisant) and Xyrem (Sodium Oxybate):** Updates include requirement that the patient’s self-reported sleep log demonstrates adequate sleep opportunity per a Sleep Specialist.

**Departmental Floor Stock Changes**

- **ACC/CDU Pyxis Units:** Addition of Eliquis (apixaban) 5 mg tablets, Pradaxa (dabigatran) 110 mg capsules, and rosuvastatin 20 mg tablets.
- **Ophthalmology:** Removal of Beovu (brolucizumab) ophthalmic solution.
- **Vascular Surgery:** Addition of Asclera (polidocanol) intravenous solution.

**Quantity Limit Changes**

- **Benzodiazepines and Non-benzodiazepine sedative-hypnotics:** Addition of quantity limit of 30 day supply per 30 days excluding clobazam and non-oral diazepam formulations (Effective 1/1/2022).

**Additions to Approved Clinically Administered Medications (CAMs) Compounding List**

- **Alteplase Intravitreal Injection:** Indicated for treatment of subretinal hemorrhage.
- **Ganciclovir Intravitreal Injection:** Indicated for the treatment of patients with cytomegalovirus (CMV) retinitis.

**Commercial Formulary Removals**

- **Clidinium bromide and Chlordiazepoxide hydrochloride** - removal effective 5.26.2021
  - Indicated to (1) control emotional and somatic factors in gastrointestinal disorders, (2) as adjunctive therapy for treatment of irritable bowel syndrome (e.g., irritable colon, spastic colon, mucous colitis) and acute enterocolitis and (3) as adjunctive therapy for treatment of peptic ulcer.
  - Alternatives: hyoscyamine, dicyclomine, proton pump inhibitors (PPIs), metoclopramide, amitriptyline, lubiprostone, and/or Trulance (plecanatide)

- **Ventolin HFA (albuterol sulfate)** - removal effective 5.12.2021
  - Indicated for (1) the treatment or prevention of bronchospasm in patients with reversible obstructive airway disease (e.g., asthma) or (2) prevention of exercise-induced bronchospasm.
  - Alternative: generic albuterol sulfate HFA

- **Estring (estradiol vaginal ring)** - removal effective 5.26.2021
  - Indicated for the treatment of moderate-to-severe vulvar and vaginal atrophy associated with menopause.
  - Alternatives: estradiol vaginal cream and tablets

**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.

- **Removals - effective 5.1.2021**
  - Advair Diskus (Fluticasone and Salmeterol) 100-50 mcg/dose aerosol powder
  - Advair Diskus (Fluticasone and Salmeterol) 250-50 mcg/dose aerosol powder
  - Advair Diskus (Fluticasone and Salmeterol) 500-50 mcg/dose aerosol powder
  - Generic loprednal ophthalmic gel
  - Truvada (Emtricitabine and Tenofovir Disoproxil Fumarate) 100-150 mg tablets
  - Truvada (Emtricitabine and Tenofovir Disoproxil Fumarate) 133-200 mg tablets
  - Truvada (Emtricitabine and Tenofovir Disoproxil Fumarate) 167-250 mg tablets
  - Vivodex (Meloxicam) 5mg capsules
  - Vivodex (Meloxicam) 10 mg capsules
Medicare Part D Formulary Changes (Continued)

- **Removals** - effective 6.2.2021
  - Northera (Droxidopa) 100 mg capsules
  - Northera (Droxidopa) 200 mg capsules
  - Northera (Droxidopa) 300 mg capsules

- **Tier Changes** - effective 5.1.2021
  - Lotemax (loteprednol) ophthalmic gel changed from Tier 4 Non-Preferred to Tier 2 Generic due to addition to the Brand to Generic List.

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**Medicare Part D Initial Tier Placement**

Initial Tier Placements—Recently launched and approved medications

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>NDC#</th>
<th>Tier Status</th>
<th>Implementation Date</th>
</tr>
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<tbody>
<tr>
<td>mannotol 40 mg capsules; tolerance test (Drochlor)</td>
<td>10122-0212-04, 10122-0212-56</td>
<td>Specialty Tier 5</td>
<td>2/3/2021</td>
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<td>peginterferon beta-1A 125 mcg/0.5 mL injection (Plergy)</td>
<td>644686-017-01</td>
<td>Specialty Tier 5</td>
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<td>cabotegravir sodium 30 mg tablets (Vocabria)**</td>
<td>497020-2481-3</td>
<td>Non-Preferred Brand 4</td>
<td>2/1/2021</td>
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<tr>
<td>vodeco de 7/9 mg capsules (Lupkynis)</td>
<td>75626-0001-01</td>
<td>Specialty Tier 5</td>
<td>1/26/2021</td>
</tr>
<tr>
<td>ponatinib HCl 10 mg, 30 mg tablets (Iclusig)**</td>
<td>63020-0536-30, 63020-0533-30</td>
<td>Specialty Tier 5</td>
<td>1/18/2021</td>
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<tr>
<td>trubantin 1% ointment (Kisely)</td>
<td>16110-0391-05</td>
<td>Specialty Tier 5</td>
<td>1/18/2021</td>
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<tr>
<td>adalimumab-pznr peroxide 0.1-2.5% pad (generic)</td>
<td>69150-0001-14</td>
<td>Specialty Tier 5</td>
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<tr>
<td>lonafarnib 50 mg, 75 mg capsules (Zokinvy)</td>
<td>73079-0050-30, 73079-0075-30</td>
<td>Specialty Tier 5</td>
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<tr>
<td>ursodiol 200 mg, 400 mg capsules (Relton)</td>
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<td>oxycodone-acetaminophen 10-300 mg/5 mL oral solution (generic)</td>
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<td>Specialty Tier 5</td>
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<td>oxycodone-acetaminophen 10-300 mg/5 mL oral solution (Prolong)</td>
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<tr>
<td>rituximab-arrx 100 mg/10 mL, 500 mg/50 mL injection (Riabni)</td>
<td>55513-0224-01, 55513-0326-01</td>
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<td>relacorilix 120 mg tablets (Orgovyx)**</td>
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<td>emapalumab-iazg 100 mg/20 mL injection (Gamifant)</td>
<td>66568-0510-01</td>
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<td>abiraterone acetate 500 mg tablets (generic Zytiga)**</td>
<td>00378-6921-91</td>
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<td>calcipotriene-betamethasone dipropionate 0.005-0.064% cream (Wyzogra)</td>
<td>73499-0001-01</td>
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<td>12/15/2020</td>
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<td>bicalutamide HCl 110 mg, 160 mg capsules (Orladeyo)</td>
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<td>fidaxomicin 40 mg/mL suspension (Dificid)</td>
<td>52015-0700-22</td>
<td>Specialty Tier 5</td>
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<tr>
<td>pegfilgrastim-afgp 6 mg/0.6 mL injection (Nvargy)**</td>
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<td>Specialty Tier 5</td>
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<td>epoetin alfa-epbx 20,000 unit/mL injection (Relsent)</td>
<td>00069-1311-10</td>
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</table>
In the News....

FDA approves alirocumab as adjunctive therapy for patients with homozygous familial hypercholesterolemia

On April 1, 2021, the U.S. Food and Drug Administration (FDA) announced approval of Praluent (alirocumab) as add-on therapy for adult patients with homozygous familial hypercholesterolemia (HoFH). HoFH is a rare life-threatening genetic condition characterized by markedly elevated untreated circulating levels of low-density lipoprotein cholesterol (LDL-C) >500 mg/dL and accelerated, premature atherosclerotic cardiovascular disease (ACVD). The goal of therapy is intensive lowering of LDL-C levels to decrease progression of angiographically demonstrated coronary artery disease and reduce cardiovascular disease events, coronary heart disease mortality, and all-cause mortality.

Praluent is a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor that binds to PCSK9, preventing the ability of PCSK9 to bind to LDL receptors (LDLR) on hepatocyte surfaces. This results in an increase in the number of LDLRs available to clear LDL, thereby lowering LDL-C levels.

The safety and efficacy of Praluent as adjunctive therapy in patients with HoFH was evaluated in the phase 3 ODYSSEY HoFH trial, a 12-week, double-blind, randomized, parallel group trial that enrolled adult patients with HoFH. Patients received alirocumab 150 mg every 2 weeks. The primary endpoint of the trial was the percent reduction from baseline in LDL-C versus placebo after 12 weeks of treatment. At the end of the 12-week treatment period, patients randomized to alirocumab had an average LDL-C decrease of 27% compared to an LDL-C increase of 9% in the placebo group (P < .0001). There were no serious adverse events, permanent treatment discontinuations, or deaths due to treatment-emergent adverse events reported during the double-blind treatment period. The common adverse effects of Praluent included nasopharyngitis, injection site reactions, and influenza.

In conclusion, the approval of Praluent as adjunctive therapy for patients with homozygous familial hypercholesterolemia provides an additional therapeutic agent to provide intensive LDL lowering in combination with other cholesterol lowering agents in patients with HoFH.