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Formulary Update

At A Glance

Formulary Additions

- Atomoxetine (generic) Capsules
- Humulin N (insulin NPH) KwikPens (effective 1.1.2023)
- Humulin 70/30 (insulin NPH and regular) KwikPens (effective 1.1.2023)
- Pregabalin (generic) Immediate-Release Capsules

Prior Authorization (QRM) Additions

- Bylvay (odevixibat) Oral Capsule / Pellets
- Kerendia (finerenone) Oral Tablet

Prior Authorization (QRM) Updates

- Dupixent (duplimuab) SQ Solution
- Forteo (teriparatide) SQ Solution
- Interleukin Antagonists
- Radicava (edaravone) IV/Oral Suspension
- Simponi (golimumab) IV/SQ Solution

Commercial Closed HMO Formulary Additions

The following medications will be ADDED to the Commercial Closed HMO Formulary effective September 8, 2022:

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

- **Atomoxetine (generic) Capsules:** Indicated for non-stimulant treatment of attention-deficit/hyperactivity disorder (ADHD) in children >6 years, adolescents, and adults.
- **Pregabalin (generic) Immediate-Release Capsules:** Indicated for neuropathic pain associated with diabetic peripheral neuropathy and spinal cord injury, postherpetic neuralgia, fibromyalgia, and adjunctive therapy for the treatment of partial onset seizures in patients 4 years of age and older.

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 Closed HMO Formulary Additions (continued)

***Humulin N and Humulin 70/30 (insulin NPH nad 70/30) vials remain on the formulary as the most cost effective insulin options.**

The following medications will be ADDED to the Commercial Formulary effective January 1, 2023:

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

- **Humulin N (insulin NPH) KwikPens:** Indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus.
- **Humulin 70/30 (insulin NPH and regular) KwikPens:** Indicated to improve glycemic control in adult patients with diabetes mellitus.

QHP/ACA/Open Formulary Tier Changes

The following tier changes will be effective September 8, 2022:

- **Atomoxetine (generic) Capsules:** down-tier to Tier 2 Preferred Generic
- **Pregabalin (generic) Immediate-Release Capsules:** down-tier to Tier 2 Preferred Generic

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

- **Humulin N (insulin NPH) KwikPens**: down-tier to Tier 3 Preferred Brand
- **Humulin 70/30 (insulin NPH and regular) Kwikpens**: down-tier to Tier 3 Preferred Brand

Federal Employee Health Benefit Formulary Tier Changes

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

- **Qsymia (phentermine and topiramate):** down-tier to Tier 3 Preferred Brand

Interregional Treatment Algorithms

The following IR Treatment Algorithm was recently approved:

Psoriatic Arthritis: treatment algorithms and recommendations for peripheral and axial disease were developed to provide guidance on the management of psoriatic arthritis. The guidelines can be found at: Interregional Treatment Algorithm Psoriatic Arthritis

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 REVISIONS were recently approved:

- **Hereditary transthyretin-mediated amyloid (hATTR-PN) polyneuropathy drugs (inotersen-patisiran-vutrisiran):** Amvuttra (vutrisiran) was incorporated into the existing practice recommendations due to recent FDA approval.
- **Radicava (edaravone):** edaravone oral suspension was incorporated into the existing practice recommendations due to recent FDA approval of the new formulation.

ETSP recommendations as well as pipeline candidates can be found here: https://sp-cloud.kp.org/sites/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 practitioners. Please contact your P&T Committee representative or your clinical service chief by September 20, 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.

Additions to the QRM Prior Authorization List of Medications for the Commercial Closed HMO/QHP/ACA/ Open Formularies

The following QRM additions will be effective September 8,2022:

Note: QRM Prior Authorization Criteria Additions/Updates DO NOT APPLY to Medicare Part D or Dual Choice Prescription Benefit Plans. Optum and MedImpact are the external Pharmacy Benefit Managers for each of these plans, respectively, externally administering all non-formulary or prior authorization criteria and coverage review.

- **Bylvay (odevixibat):** Indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).
- **Kerendia (finerenone):** Indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2DM).

QRM Prior Authorization Criteria Updates

Note: QRM Prior Authorization Criteria Additions/Updates DO NOT APPLY to Medicare Part D or Dual Choice Prescription Benefit Plans. Optum and MedImpact are the external Pharmacy Benefit Managers for each of these plans, respectively, externally administering all non-formulary or prior authorization criteria and coverage review.

- **Dupixent (duplimumab):** Criteria updated to 1) include the addition of eosinophilic esophagitis based on the new FDA-approved indication and 2) change the age limit for coverage for the treatment of atopic dermatitis to 6 months due to new FDA approval.
- **Forteo (teriparatide):** Criteria updated to 1) require documentation of lab values within normal limits for parathyroid hormone (PTH), calcium, serum creatinine (SCr), and vitamin D and 2) add elevated PTH as a reason for non-coverage.
- **Radicava (edaravone):** Criteria updated to align with the Interregional Practice Recommendation changes.
- **Simponi/Simponi Aria (golimumab):** Criteria updated to 1) change the terminology from spondyloarthropathy to ankylosing spondylitis under the inclusion criteria and 2) distinguish which preferred therapies apply to the separate rheumatology indications.
- **Interleukin Antagonists:** Criteria updated to 1) align the criteria for the treatment of psoriatic arthritis and spondyloarthritis with the Interregional Practice Algorithm and current clinical practice and 2) add criteria for the use of Skyrizi to treat Crohn's disease based on the new FDA-approved indication.

Quantity Limit Additions for the Commercial Closed HMO/ QHP/ACA/Open Formularies

Medication Name	Quantity Limit	Effective Date
Kerendia (finerenone)	30 tablets per 30 days	09.08.2022

Quantity Limit Removals for the Commercial HMO/ QHP/ACA/ Open Formularies

Medication Name	Effective Date
Buprenorphine-Naloxone Products	09.08.2022
Pregabalin (generic) Immediate-Release Capsules	09.08.2022

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 futher 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 futher 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 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 Daboiko, 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
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Chad Madill, PharmD, MBA
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Jennifer Marrast Host, MD
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Felecia Martin, PharmD
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Pharmacy Operations

Rachel Robins, MD
Hospitalist

Jennifer Rodriguez, MD
Behavioral Health

Designated Alternates:

Jacqueline Anglade, MD
Obstetrics and Gynecology

Lesia Jackson, RN
Clinical Services

Satya Jayanthi, MD
Hospitalist

QHP/ACA/Open Formulary Step Therapy Additions

Medication Name	Effective Date
Adlarity (donepezil transdermal patch)	09.08.2022
Lyvispah (baclofen granule packets)	09.08.2022
Semglee and Unbranded (insulin glargine-yfgn)	09.08.2022

QHP/ACA/Open Formulary Step Therapy Removals

Medication Name	Effective Date
Atomoxetine (generic) Capsules	09.08.2022
Humulin N (insulin NPH) KwikPens	01.01.2023
Humulin 70/30 (insulin NPH and regular) KwikPens	01.01.2023

Department Floor Stock Additions

Department	Addition	Effective Date
ACC-CDU	Phospha 250 Neutral (potassium and sodium phosphate) 250 mg Tablets	09.08.2022
General Surgery	Sotradecol (sodium tetradecyl sulfate) 1% IV Solution	09.08.2022

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 Formulary Removals

Medication Name	Alternative	Effective Date
Esbriet 267 mg Tablets	Pirfenidone 267 mg Tablets (generic Esbriet)	08.01.2022
Esbriet 801 mg Tablets	Pirfenidone 801 mg Tablets (generic Esbriet)	08.01.2022
Nexavar 200 mg Tablets	Sorafenib Tosylate 200 mg Tablets (generic Nexavar)	09.01.2022
Targretin 1% Gel	Bexarotene 1% Gel (generic Targretin)	09.01.2022
Viibryd 10 mg Tablets	Vilazodone 10 mg Tablets (generic Viibryd)	09.01.2022
Viibryd 20 mg Tablets	Vilazodone 20 mg Tablets (generic Viibryd)	09.01.2022
Viibryd 40 mg Tablets	Vilazodone 40 mg Tablets (generic Viibryd)	09.01.2022
Vimpat 10 mg/ml Solution	Lacosamide 10 mg/ml Solution (generic Vimpat)	08.01.2022

Medicare Part D Initial Tier Placement

Initial Tier Placements- Recently launched and approved medications

Medication	Tier	Implementation Date
vutrisiran sodium 25 mg/0.5 mL injection (Amvuttra)	5	6/27/2022
risankizumab-rzaa 600 mg/10 mL injection; 360 mg/2.4 mL cartridge injection (Skyrizi)	5	6/23/2022
pemetrexed ditromethamine 100 mg, 500 mg, 1 gm/40 mL injection	5	6/22/2022
baricitinib 4 mg tablets (Olumiant)	5	6/16/2022
ganaxolone 50 mg/mL oral suspension (Ztalmy)**	5	6/13/2022
pemetrexed disodium 100 mg/4 mL, 500 mg/20 mL injection (generic)**	5	6/10/2022
sorafenib tosylate 20 mg tablets (generic)	5	6/9/2022
treprostinil 16 mcg, 32 mcg, 48 mcg, 64 mcg cartridge; 32 mcg & 48 mcg, 16 mcg & 32 mcg, 16 mcg &32 mcg & 48 mcg powder inhalation (Tyvaso DPI)	5	6/7/2022
ranibizumab-nuna 0.5 mg/0.05mL injection (Byooviz)	5	6/3/2022
pemetrexed 100 mg/4mL, 500 mg/20 mL, 1g/40 mL injection	5	6/3/2022
mepolizumab 40 mg/0.4 mL prefilled injection (Nucala)	5	6/3/2022
sorafenib tosylate 200 mg tablets (generic Nexavar)**	5	6/1/2022
bevacizumab-maly 100 mg/4 mL, 400 mg/16 mL injection (Alymsys)**	5	5/27/2022
pemetrexed disodium 100 mg, 500 mg, 750 mg, 1000 mg injection (generic)**	5	5/26/2022
oxycodone HCL 5 mg, 15 mg, 30 mg abuse deterrent tablets (Roxybond)	5	5/25/2022
bexarotene 1% topical gel (generic)**	5	5/24/2022
baclofen 20 mg granule packets (Lyvispah)	5	5/19/2022
tirzepatide 2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, 10 mg/0.5 mL, 12.5 mg/0.5 mL, 15 mg/0.5 mL pen-injector (Mounjaro)	5	5/19/2022
metformin HCL 625 mg tablets (generic)	5	5/18/2022
diclofenac sodium/lidocaine 1-4.5% topical gel (Diclona)	5	5/16/2022
edaravone 105 mg/5 mL oral suspension (Radicava ORS, Radicava ORS Starter Kit)	5	5/13/2022
pirfenidone 267 mg, 801 mg tablets (generic Esbriet)	5	5/3/2022
mavacamten 2.5 mg, 5 mg, 10 mg, 15 mg capsules (Camzyos)	5	5/2/2022
tapinarof 1% cream (Vtama)	5	4/28/2022
valsartan 20 mg/5 mL solution (generic)	5	4/22/2022

Class Review

October 2022:

Medication Class Review
Analgesics – Anti-Inflammatory
Analgesics – Non-Narcotic
Analgesics – Opioids
Anticoagulants
Antiseptics & Disinfectants
Diagnostic Products
Endocrine and Metabolic Agents – Misc
Hematopoietic Agents
Hemostatics
Minerals & Electrolytes
Mouth/Throat/Dental
Multi-Vitamins
Local Anesthetics – IV
Musculoskeletal Therapy Agents
Otic
Vitamins

Medicare Part D Initial Tier Placement (continued)

Initial Tier Placements- Recently launched and approved medications

Medication	Tier	Implementation Date
alpelisib 50 mg, 125 mg daily dose tablet therapy pack; 250 mg (200 mg & 50 mg) daily dose tablets pack (Vijoice)	5	4/8/2022
cyclosporine 0.1% ophthalmic emulsion (Verkazia)	5	3/28/2022
semaglutide 2 mg/dose pen-injection (Ozempic)	4	3/30/2022
nivolumab-relatlimab-rmbw 240 mg-80 mg/20 mL injection (Opdualag)**	5	3/22/2022
upadacitinib 45 mg extended-release tablets (Rinvoq)	5	3/18/2022
siponimod fumarate 1 mg tablets (Mayzent)	5	3/17/2022
hydrocortisone acetate/pramoxine 25 mg/18 mg rectal suppositories	5	3/17/2022
pacritinib citrate 100 mg capsules (Vonjo)	5	3/9/2022
difelikefalin acetate 65 mcg/1.3 mL injection (Korsuva)	5	3/9/2022
tenapanor HCl 50 mg tablets (Ibsrela)	5	3/8/2022

** Protected Class

In the News....

FDA Approves First Targeted Therapy for HER2-Low Breast Cancer

On August 5, 2022, the U.S. Food and Drug Administration approved Enhertu (fam trastuzumab-deruxtecan-nxki), an IV infusion for the treatment of patients with unresectable or metastatic HER2-low breast cancer. This is the first approved therapy for patients with the HER2-low breast cancer subtype, which is a newly defined subset of HER2-negative breast cancer. With this approval, a proportion of patients who were previously classified as HER2-negative can now be considered as HER2-low subtype and have access to a targeted cancer treatment option. Patients with HER2-low breast cancer are eligible for Enhertu if they have received a prior chemotherapy in the metastatic setting, or their cancer returned during, or within 6 months of completing, adjuvant chemotherapy.[1]

The approval is based on a randomized, multicenter, open label, Phase 3 trial titled DESTINY-Breast04. Treatment with Enhertu led to a statistically significant improvement in progression-free survival and overall survival in patients with unresectable or metastatic HER2-low breast cancer. The most common adverse reactions included nausea, fatigue, alopecia, vomiting, constipation, decreased appetite, musculoskeletal pain, and diarrhea. The label also contains a boxed warning for the risk of interstitial lung disease and embryo-fetal toxicity.[2]

Enhertu received priority review and breakthrough therapy designation. It was also granted approval 4 months prior to the actual PDUFA deadline. Under the new initiative from the FDA Oncology Center of Excellence, this approval process involved collaboration with the Australian Therapeutic Goods Administration, Health Canada, and Switzerland's Swissmedic.[1] Continued approval of Enhertu will be contingent upon the confirmation of a clinical benefit in real world settings.

1. FDA approves first targeted therapy for HER2-low breast cancer. U.S. Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-approves-first-targeted-therapy-her2-low-breast-cancer. Accessed August 15, 2022.
2. Enhertu. [package insert]. Basking Ridge, NJ. Daiichi Sankyo Inc; 2022.

New Emergency Use Authorizations for COVID-19 Vaccines

On June 17, 2022 the U.S. Food and Drug Administration (FDA) updated the Emergency Use Authorization for the Pfizer-BioNTech (BNT 162b2) COVID-19 Vaccine and Moderna (mRNA-1273) COVID-19 Vaccine to include individuals as young as 6 months of age.[1] The approval is based on the results of several clinical trials that demonstrated these vaccines, when given to children 6 months to 11 years, elicit an immune response comparable to the immune response in adults. The vaccines are indicated for the prevention of COVID-19, but vaccination also reduces the risk of COVID-19-related symptoms in this population. The most common side effects for participants 6 through 36 months was irritability, tiredness, and decreased appetite. Other common side effects in all age groups included pain, redness, and swelling at the injection site, headache, fever, chills, muscle and joint pain, and nausea/vomiting. The dosing for children may differ depending on age and immunocompetence. The CDC recommendations for immunocompetent children and adolescents are below[2]:

Manufacturer	Age	Dose	Primary Series	Booster?
Pfizer-BioNTech	6 months - 4 years	3 mcg	3 doses Give 2nd dose 3-8 weeks after the 1st dose. Give 3rd dose at least 8 weeks after the 2nd dose.	Not recommended
	5 - 11 years	10 mcg	2 doses Give 3-8 weeks apart.	1 booster at least 5 months after the final dose in the primary series.
	12 - 17 years	30 mcg	2 doses Give 3-8 weeks apart.	1 booster at least 5 months after the final dose in the primary series.
Moderna	6 months - 5 years	25 mcg	2 doses Give 4-8 weeks apart.	Not recommended
	6 - 11 years	50 mcg	2 doses Give 4-8 weeks apart.	Not recommended
	12 - 17 years	100 mcg	2 doses Give 4-8 weeks apart.	Not recommended

Specific recommendations for patients who may be immunocompromised are available on the CDC website.

On July 13, 2022, the FDA granted Emergency Use Authorization for NVX-CoV2373, a new Novavax COVID-19 vaccine, indicated for the prevention of COVID-19 in individuals 18 years and older[3]. It is an adjuvanted recombinant protein vaccine, with a mechanism similar to other non-COVID-19 vaccines that have long been available—making it an attractive option for individuals who may prefer a more established vaccine technology. It is administered as a two-dose series.

The efficacy of the Novavax vaccine was demonstrated in a phase 3 randomized, placebo-controlled trial conducted in the United States and Mexico. Though the trial was conducted before the emergence of delta and omicron variants, it proved to be 90.4% effective in preventing mild, moderate, or severe COVID-19. The most commonly reported side effects include pain, redness, and swelling at the injection site, fatigue, headache, fever, muscle and joint pain, and nausea/vomiting. The Fact Sheet for Healthcare Providers Administering Vaccine includes a warning that there is evidence for increased risk of myocarditis and pericarditis following administration. The FDA expects Novavax Inc. to continue their clinical trials to obtain additional efficacy and safety data.

1. Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age. U.S. Food and Drug Administration. June 17, 2022. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children. Accessed August 16, 2022.
2. Stay Up to Date with Your COVID-19 Vaccines. Center for Disease Control and Prevention. July 19, 2022. Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#footnote01. Accessed August 16, 2022.
3. Coronavirus (COVID-19) Update: FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted. U.S. Food and Drug Administration. July 13, 2022. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted. Accessed August 16, 2022.