ISSUE 3 | VOLUME 18 | JUNE 2024

Written by: T. Mensah PharmD, BCPS, CACP

Formulary Update

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 List OR Drug Formulary for Practitioners for all KPGA Drug Formularies.

Formulary Additions

- Granix (tbo-filgrastim) prefilled syringes and vials
- Lynparza (olaparib) tablets

Formulary Removals

- Nivestym (filgrastim-aafi) prefilled syringes and vials

Prior Authorization (QRM) Additions

- Augtyro (repotrectinib)
- Brenzavvy (bexagliflozin)
- GLP-1 RAs for Cardiovascular Disease
- Lamzede (velmanase alfa-tycv)
- Lantidra (donislecel-jujn)
- Pegfilgrastim products
- Qalsody (tofersen)
- Rezlidhia (olutasidenib)
- Rivfloza (nedosiran)
- Rystiggo (rozanolixizumab-noli)
- Spevigo (spesolimab-sbzo)
- Xphozah (tenapanor)
- Zurzuvae (zuranolone)

Prior Authorization (QRM) Updates

- Abecma (idecabtagene vicleucel)
- Afrezza (inhaled insulin)
- Attention-deficit/hyperactivity disorder (ADHD) stimulants
- Breyanzi (lisocabtagene maraleucel)
- Cabenuva (cabotegravir and rilpivirine)/Vocabria (cabotegravir)
- Carvykti (ciltacabtagene autoleucel)
- Cholbam (cholic acid)
- Doptelet (avatrombopag)
- DPP-4 Inhibitors
- Evenity (romosozumab)
- Evkeeza (evinacumab)
- Fasenra (benralizumab)
- Fumeric Acid Derivatives: Bafiertam (monomethyl fumarate) and Vumerity (diroximel fumarate)
- GLP-1 RAs for Type 2 Diabetes Mellitus

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 July 17, 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.

Medication Class Review
August 2024

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

Prior Authorization (QRM) Updates (continued)

- **Iclusig (ponatinib)**
- **Interleukin Antagonists and Tumor Necrosis Factor (TNF) Blocking Agent for Plaque Psoriasis**
- **Kerendia (finerenone)**
- **Leqvio (inclisiran)**
- **Metformin Extended-Release products**
- **Mounjaro (tirzepatide)**
- **Nexletol (bempedoic acid)/ Nexlizet (bempedoic acid and ezetimibe)**
- **Orkambi (lumacaftor and ivacaftor)**
- **Otezla (apremilast)**
- **PCSK-9 Inhibitors**
- **Prolia (denosumab)**
- **Prophylaxis for Hereditary Angioedema (HAE) therapies**
- **Rhopressa/Rocklatan (netarsudil/netarsudil-latanoprost)**
- **Rukobia (fostemsavir)**
- **SGLT-2 Inhibitors**
- **Stelara (ustekinumab)**
- **Sunlenca (lenacapavir)**
- **Xolair (omalizumab)**
- **Vascepa (icosapent ethyl)**
- **Verquvo (vericiguat)**
- **Voxzogo (vosoritide)**

Prior Authorization (QRM) Removed

- **GLP-1 Receptor Agonist + SGLT2 Inhibitor Combination Therapy**
- **Lynparza (olaparib) tablets**

Commercial HMO/Closed Formulary Additions

The following medication will be ADDED to the Commercial Formulary effective July 1, 2024:

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

Granix (tbo-filgrastim) prefilled syringes and vials	Indicated for chemotherapy-induced myelosuppression in nonmyeloid malignancies.

The following medication will be ADDED to the Commercial Formulary effective July 10, 2024:

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

Lynparza (olaparib) tablets	Indicated for treating early high-risk HER2-negative, germline BRCA-mutated breast cancer, metastatic HER2-negative germline BRCA-mutated breast cancer as adjuvant therapy, advanced ovarian cancer with BRCA -mutated in first-line maintenance therapy, advanced/homologous recombination deficient-positive ovarian cancer as first-line maintenance therapy, recurrent BRCA-mutated ovarian cancer as maintenance therapy, metastatic pancreatic cancer germline BRCA-mutated as first-line maintenance therapy, metastatic/castration resistant prostate cancer BRCA -mutated, and in metastatic/castration-resistant prostate cancer, homologous recombination repair gene-mutated.

Commercial HMO/Closed Formulary Removal

The following medication will be REMOVED from the Commercial Formulary effective January 1, 2025:
Note: Commercial Formulary additions may result in tier changes on the QHP (ACA)/Open Formulary.

Nivestym (filgrastim-aafi) prefilled syringes and vials	Indicated for reducing the duration of severe neutropenia in patients with non-myeloid malignancies requiring myelosuppressive chemotherapy associated with a clinically significant incidence of febrile neutropenia, treatment of patients with acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy, cancer patients receiving bone marrow transplant (BMT), patients undergoing blood progenitor cell (PBPC) collection therapy, or in patients with severe chronic neutropenia.

QHP-ACA/Open Formulary Tier Changes

The following medication will have the tier change listed below effective July 10, 2024:

Miebo (perfluorohexyloctane)	Down-tier to Non-Preferred Tier 4	Indicated for the treatment of the signs and symptoms of dry eye disease.

QHP-ACA/Open Formulary Step Therapy Additions

The following medication will have step therapy ADDED effective July 10, 2024:

Xdemvy (lotilaner)	Indicated for treatment of Demodex blepharitis.

The following medication will have step therapy ADDED effective January 1, 2025:

Nivestym (filgrastim-aafi	Indicated for reducing the duration of severe neutropenia in patients with non-myeloid malignancies requiring myelosuppressive chemotherapy associated with a clinically significant incidence of febrile neutropenia, treatment of patients with acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy, cancer patients receiving bone marrow transplant (BMT), patients undergoing blood progenitor cell (PBPC) collection therapy, or in patients with severe chronic neutropenia.

Day Supply Additions

The following medications will have 30-day supply restrictions effective July 10, 2024:

Augtyro (repotrectinib)	**Rezlidhia (olutasidenib)**

Approved Floor Stock List Changes

Medication	Department
Approved Floor Stock List Additions	
Cathflo Activase (alteplase) 2 mg injection	Complex Nurse Clinics
Depo-SubQ Provera 104 (medroxyprogesterone acetate) prefilled syringe	Women's Health
Granix (tbo-filgrastim) syringes and vials	Hematology/Oncology
Gentamicin 40mg/mL injection	Adult Primary Care/Family Practice
Izervay (avacincaptad pegol) intravitreal solution	Ophthalmology
Narcan 0.4 mg/mL injection	MOB Primary Care areas
Approved Floor Stock List Removals	
Nivestym (filgrastim-aafi) syringes	Hematology/Oncology
Thyrogen (thyrotropin alfa) 0.9 mg intramuscular solution	Endocrinology

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:

Lenmeldy (atidarsagene autotemcel)	Indicated for the treatment of children with pre-symptomatic late-infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD).
Rezdiffra (resmetirom)	Indicated for the treatment of adults with NASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in conjunction with diet and exercise.

ETSP recommendations as well as pipeline candidates can be found here: ETSP Home Page
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.

Therapeutic Equivalent Drug Substitutions

The following standing orders were approved:

Calcitriol 3 mcg/gm ointment (Vectical) to Calcipotriene 0.005% cream
Filgrastim (Neupogen) and filgrastim biosimilar solution to tbo-filgrastim (Granix) solution
Tocilizumab (Actemra) solution to tocilizumab-aazg (Tyenne) solution

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.

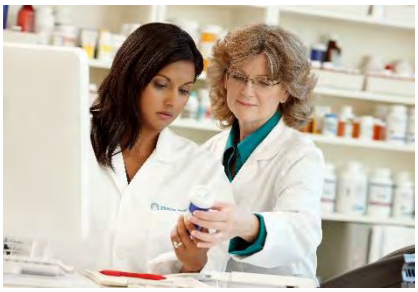
Prescriber completes the .NFRequestForm when entering drug order. Your documentation is used by OptumRx to determine whether the prescribed drug is eligible for drug benefit coverage. No documentation = No coverage.

The KP Pharmacy Consult Service will send your documentation to OptumRx for their coverage determination decision within the labeled time frame (standard: 72 hours; urgent: 24 hours). If not received by the deadline, the PBM will deny the request. 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: Medicare Part D 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 within the labeled time frame (standard: 72 hours; urgent: 24 hours). If not received by the deadline, the PBM will deny the request. If MedImpact has further questions, you will be contacted to provide responses. You may phone MedImpact at 1-888-336-2676 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.



Removals from the QRM Prior Authorization Review List of Medications for the Commercial/HMO Closed Formularies & QHP-ACA/Open Formularies

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.

The following medications will have QRM PA review criteria REMOVED effective July 10, 2024:

GLP-1 Receptor Agonist + SGLT2 Inhibitor Combination Therapy
Lynparza (olaparib) tablets

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

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.

The following medications will be ADDED to the QRM PA Review List effective July 10, 2024:

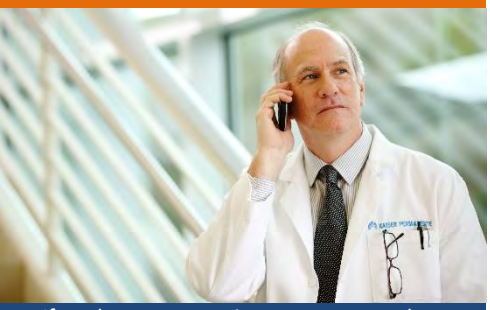
Augtyro (repotrectinib)	Indicated for 1) treatment of locally advanced or metastatic ROS1-positive non–small cell lung cancer in adults and 2) treatment of solid tumors in adult and pediatric patients ≥12 years of age that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy.
Brenzavvy (bexagliflozin)	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Lamzede (velmanase alfa-tycv)	Indicated for the treatment of noncentral nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.
Lantidra (donislecel-jujn)	Indicated for the treatment of type 1 diabetes mellitus, in conjunction with concomitant immunosuppression, in adults who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education.
Qalsody (tofersen)	Indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene.
Rezlidhia (olutasidenib)	Indicated for the treatment of relapsed or refractory acute myeloid leukemia in adults with a susceptible isocitrate dehydrogenase-1 *(IDH1)* mutation as detected by an approved test.
Rivfloza (nedosiran)	Indicated to lower urinary oxalate levels in pediatric patients ≥9 years of age and adults with primary hyperoxaluria type 1 and relatively preserved kidney function (e.g., eGFR ≥30 mL/minute/1.73 m^2).
Rystiggo (rozanolixizumab-noli)	Indicated for the treatment of generalized myasthenia gravis as chronic immunosuppressive therapy in adults who are anti-acetylcholine receptor (AChR) antibody positive or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.
Spevigo (spesolimab-sbzo)	Indicated for treatment of generalized pustular psoriasis in adults and pediatric patients ≥12 years of age and weighing ≥40 kg.
Xphozah (tenapanor)	Indicated to control of serum phosphorous in adults with chronic kidney disease on hemodialysis as an add-on therapy in patients who have an inadequate response to phosphate binders or who are unable to tolerate phosphate binder therapies.
Zurzuvae (zuranolone)	Indicated for the treatment of postpartum depression in adults.
The following medications will be added to the QRM PA Review List effective October 9, 2024:	
Pegfilgrastim products	Indicated for acute hematopoietic radiation injury syndrome and prevention of chemotherapy-induced neutropenia.

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.

- **Abecma (idecabtagene vicleucel):** Criteria updated to allow coverage as third line treatment of triple-class-exposed relapsed/refractory (R/R) multiple myeloma (MM) due to recent FDA expanded approval.
- **Breyanzi (lisocabtagene maraleucel):** Criteria updated for the treatment of chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) due to recent FDA expanded approval.
- **Cabenuva (cabotegravir and rilpivirine)/Vocabria (cabotegravir):** Criteria updated to reduce the number of required antiretroviral backbone classes for coverage from three to two, to align with clinical practice recommendations.
- **Carvykti (Ciltacabtagene autoleucel):** Criteria updated to allow coverage as second-line treatment of R/R multiple myeloma (MM) who have received at least one prior line of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), and are refractory to lenalidomide due to recent FDA expanded approval.
- **Doptelet (avatrombopag):** Criteria updated to include the FDA approved indication for chronic immune thrombocytopenia.
- **Evenity (romosozumab):** Criteria updated to 1) define the approved indications for Evenity and 2) reduce the number of required oral bisphosphonates to one, to align with clinical practice.
- **Fasenra (benralizumab):** Criteria updated to allow coverage for pediatric patients 6 years of age or older due to recent FDA expanded approval.
- **Fumeric Acid Derivatives - Bafiertam (monomethyl fumarate) and Vumerity (diroximel fumarate):** Criteria updated to 1) provide clarification in making a distinction between fumeric acid derivatives based on the slight differences in GI adverse effects and 2) remove requirement for history of persistent injection site reactions or inability for caregiver to administer injection/self-injection.
- **GLP-1 RA for Type 2 diabetes mellitus:** Criteria updated to allow coverage of a GLP-1 RA if member already at goal on current metformin dose per clinical practice recommendations.
- **Iclusig (ponatinib):** Criteria updated to allow coverage for treatment of adult patients with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy due to recent FDA expanded approval.
- **Interleukin Antagonists and Tumor Necrosis Factor (TNF) Blocking Agent for Plaque Psoriasis:** Criteria for each drug was updated to 1) place the required trial of IL-23 inhibitors (Tremfya and Skyrizi) and IL-12/IL-23 inhibitor (Stelara) on equal footing with no order for preference and 2) for Bimzelx only: add criteria to address requests for loading doses.
- **Nexletol (bempedoic acid)/ Nexlizet (bempedoic acid and ezetimibe):** Criteria updated to 1) align LDL cutoffs for coverage with the 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk and 2) remove required trial of ezetimibe for Nexlizet approval if patient requires >25% additional lowering of LDL-C.
- **Otezla (apremilast):** For the treatment of plaque psoriasis: criteria updated to 1) remove trial of alternative therapies if patient is on a biologic or is biologic experienced, 2) add criteria for new members initiated on Otezla outside of KPGA, and 3) lower the age threshold for coverage from 18 to 6 years per recent FDA approval.
- **PCSK-9 Inhibitors - Repatha (evolocumab)and Praluent (alirocumab):** Criteria updated to align LDL cutoffs for coverage with the 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk.
- **Prolia (denosumab):** Criteria updated to 1) reduce the number of required oral bisphosphonates to one, to align with clinical practice and 2) clarify when appropriate to bypass bisphosphonates for high-risk fracture patients per clinical practice.
- **Prophylaxis for Hereditary Angioedema (HAE) therapies - Human C1 Esterase Inhibitors (Cinryze, Haegarda) and Takhzyro (lanadelumab-flyo):** Criteria updated to 1) align with clinical practice and prescribing information and 2) clarify the diagnosis of type I or type II hereditary angioedema with lab data.
- **Rhopressa/Rocklatan (netarsudil/netarsudil-latanoprost):** Criteria updated to only require a trial of one prostaglandin analog if there is an inadequate response or contraindication.
- **Stelara (ustekinumab):** Criteria updated to remove the required trial of Entyvio (vedolizumab) in small bowel, perianal disease or fistulizing disease based on IBD Clinical Practice Recommendations.
- **Xolair (omalizumab):** Criteria for food allergies updated to 1) require trial and failure of oral immunotherapy Palforzia (peanut allergen powder), 2) remove requirement of dose limiting symptoms at ≤ 100 mg of peanut protein and ≤ 300 mg of other food allergens, 3) add requirement for positive response to oral challenge, 4) require history of an allergic reaction per specific criteria, and 5) require prescription for epinephrine per standard of care.

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
Clinical Pharmacy

Hector Clarke, PharmD, BCOP
Ambulatory Pharmacy

Halima Daboiko, MD
Obstetrics and Gynecology

Carole Gardner, MD
P&T Chair/Geriatrics

Pierson Gladney, MD
Hematology/Oncology

Ramin Haddad, MD
Adult Hospitalist

Larry Kang, MD
Adult Primary Care

Mary Kangoma, RN, MSN
Clinical Services

Craig Kaplan, MD
Adult Primary Care

Christine Kofman, MD
Pediatrics

Amy Levine, MD
Pediatrics

Sophie Lukashok, MD
Infectious Disease

Chad Madill, PharmD, MBA
Executive Director of Pharmacy Operations

Jennifer Marrast-Host, MD
Emergency Medicine/ ACC

Felecia Martin, PharmD
Pharmacy/Geriatrics

Shayne Mixon, PharmD
Pharmacy Operations

Jennifer Rodriguez, MD
Behavioral Health

P&T Committee Non-Voting Physician Members

Elizabeth Greco, MD
Physician Lead, Pharmacy Safety and Systems

Daniel Robitshek, MD
CDU/Hospital Services

Designated Alternates:

Jacqueline Anglade, MD
Obstetrics and Gynecology

Lesia Jackson, RN
Clinical Services

Satya Jayanthi, MD
Hospitalist

QRM Prior Authorization Review Adherence Criteria Changes

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.

Continuation Criteria: Adherence Criteria Removed	
Medication (s)	**Summary of Update**
Afrezza (inhaled insulin)	Adherence criteria required for coverage of the medication was removed from the continued approval section.
Attention-deficit/hyperactivity disorder (ADHD) Stimulants	
Cholbam (Cholic acid)	
DPP-4 Inhibitors	
GLP-1 RAs	
Kerendia (finerenone)	
Metformin Extended-Release products	
Mounjaro (tirzepatide)	
Nexletol (bempedoic acid)/ Nexlizet (bempedoic acid and ezetimibe)	
Orkambi (lumacaftor and ivacaftor)	
PCSK-9 Inhibitors	
SGLT-2 Inhibitors	
Vascepa (icosapent ethyl)	
Verquvo (vericiguat)	

Adherence Criteria Updates	
Medication (s)	**Summary of Update**
Cabenuva (cabotegravir and rilpivirine)/Vocabria (cabotegravir)	Adherence parameters added to review requests for members with a medication refill adherence ratio (MRAR)< 80% for required trial medications.
DPP-4 Inhibitors	
Evkeeza (evinacumab)	
GLP-1 RAs for T2DM indication	
Leqvio (inclisiran)	
Mounjaro (tirzepatide)	
Nexletol (bempedoic acid)/ Nexlizet (bempedoic acid and ezetimibe)	
PCSK-9 Inhibitors	
Prolia (denosumab)	
Rukobia (fostemsavir)	
SGLT-2 Inhibitors	
Sunlenca (lenacapavir)	
Vascepa (icosapent ethyl)	
Voxzogo (vosoritide)	

Medications Reviewed But Not Accepted to the Commercial HMO Formulary

Note: Medications that can be dispensed via the outpatient pharmacy benefit, but are not accepted to the closed Commercial HMO formulary, will be placed on a tier for the QHP-ACA/ Open formularies.

Medication	Commercial HMO/Closed Formulary Status	QHP-ACA/ Open Formulary Status
Augtyro (repotrectinib)	• Non-Formulary • Require QRM PA review • 30-day supply limits	• Specialty Tier 5 • Require QRM PA review • 30-day supply limits
Brenzavvy (bexagliflozin)	• Non-Formulary • Require QRM PA review	• Non-Preferred Tier 4 • Require QRM PA review
Dengvaxia (dengue tetravalent vaccine, live)	• Not accepted – clinic administered medication • Approve for clinic administration under medical benefit coverage	
Elahere (mirvetuximab soravtansine-gynx)	• Not accepted – clinic administered medication • Approve for clinic administration under medical benefit coverage	
Lamzede (velmanase alfa-tycv)	• Not accepted – clinic administered medication • Approve for clinic administration under medical benefit coverage • Require QRM PA review	
Lantidra (donislecel-jujn)	• Not accepted – clinic administered medication • Approve for clinic administration under medical benefit coverage • Require QRM PA review	
Neupogen (filgrastim)	Retain as Non-Formulary	Retain as Specialty Tier 5 with step therapy required
Penbraya (meningococcal Groups A, B, C, W, and Y vaccine)	• Not accepted – clinic administered medication • Approve for clinic administration under medical benefit coverage	
Qalsody (tofersen)	• Not accepted – clinic administered medication • Approve for clinic administration under medical benefit coverage • Require QRM PA review	
Releuko (filgrastim-ayow)	Retain as Non-Formulary	Retain as Specialty Tier 5 with step therapy required
Rezlidhia (olutasidenib)	• Non-Formulary • Require QRM PA review • 30-day supply limits	• Specialty Tier 5 • Require QRM PA review • 30-day supply limits
Rivfloza (nedosiran)	• Non-Formulary • Require QRM PA review	• Specialty Tier 5 • Require QRM PA review
Rystiggo (rozanolixizumab-noli)	• Not accepted – clinic administered medication • Approve for clinic administration under medical benefit coverage • Require QRM PA review	
Spevigo (spesolimab-sbzo)	• Not accepted – clinic administered medication • Approve for clinic administration under medical benefit coverage • Require QRM PA review	
Xdemvy (lotilaner)	Non-Formulary	• Specialty Tier 5 • Step therapy required
Xolair (omalizumab) for food allergy indication	• Non-Formulary • Require QRM PA review	• Specialty Tier 5 • Require QRM PA review
Xphozah (tenapanor)	• Non-Formulary • Require QRM PA review	• Specialty Tier 5 • Require QRM PA review
Zarxio (filgrastim-sndz)	Retain as Non-Formulary	Retain as Specialty Tier 5 with step therapy required
Zurzuvae (zuranolone)	• Non-Formulary • Require QRM PA review	• Specialty Tier 5 • Require QRM PA review

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 for recently launched and approved medications

#	Drug Name	Tier Status	Implementation Date
1	tarlatamab-dlle 1 mg, 10 mg injection (Imdelltra)	Specialty Tier 5	5/21/2024
2	mirikizumab-mrkz 100 mg/mL injection (Omvoh)	Specialty Tier 5	5/14/2024
3	mavorixafor 100 mg capsules (Xolremdi)	Specialty Tier 5	5/7/2024
4	adalimumab-adbm 40 mg/0.4 mL auto- injector kits	Specialty Tier 5	5/7/2024
5	adalimumab-adbm 40 mg/0.4 mL auto- injector kits; 40 mg/0.4 mL injection (Cyltezo); Cyltezo Psor kit; Cyltezo Crohn	Specialty Tier 5	5/7/2024
6	valbenazine tosylate 40 mg, 60 mg, 80 mg capsules (Ingrezza)	Specialty Tier 5	5/3/2024
7	Eribulin mesylate 1 mg/2 mL injection (Eribulin)	Specialty Tier 5	5/3/2024
8	tocilizumab-bavi 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL injection (Tofidence)	Specialty Tier 5	5/2/2024
9	nogapendekin alfa inbak-pmln 400 mcg/0.4 mL intravesical solution (Anktiva)**	Specialty Tier 5	4/29/2024
10	tovorafenib 100 mg tablets; 25 mg/mL oral suspension (Ojemda)**	Specialty Tier 5	4/26/2024
11	indomethacin 50 mg suppositories (generic)	Specialty Tier 5	4/25/2024
12	docetaxel 20 mg/2 mL, 80 mg/8 mL, 160 mg/16 mL injection (Docivyx)**	Specialty Tier 5	4/25/2024
13	adalimumab-ryvk 40 mg/0.4 mL injection (Simlandi)	Specialty Tier 5	4/24/2024
14	cenobamate 25 mg tablets (Xcopri)**	Specialty Tier 5	4/23/2024
15	nirogacestat hydrobromide 100 mg, 150 mg tablets (Ogsiveo)**	Specialty Tier 5	4/18/2024
16	tocilizumab-aazg 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL injection (Tyenne)	Specialty Tier 5	4/17/2024
17	adalimumab-aaty 20 mg/0.2 mL injection (Cyltezo)	Specialty Tier 5	4/17/2024
18	adalimumab-aaty 40 mg/0.4 mL, 80 mg/0.8 mL injection (Cyltezo)	Specialty Tier 5	4/16/2024
19	cyclophosphamide 500 mg/5 mL, 1000 mg/10 mL, 2000 MG/20 mL injection (generic)**	Specialty Tier 5	4/15/2024
20	dichlorphenamide 50 mg tablets (Ormalvi)	Specialty Tier 5	4/10/2024
21	spesolimab-sbzo 150 mg/mL injection (Spevigo)	Specialty Tier 5	4/4/2024
22	danicopan 100 mg tablets; 50 mg & 100 mg tablet therapy packs (Voydeya)	Specialty Tier 5	4/4/2024
23	sotatercept-csrk 45 mg, 60 mg injection (Winrevair)	Specialty Tier 5	4/3/2024
24	macitentan/tadalafil 10 mg/20 mg, 10 mg/40 mg tablets (Opsynvi)	Specialty Tier 5	4/1/2024
25	cyclosporine 0.1% ophthalmic emulsion (Klarity-C)	Specialty Tier 5	3/29/2024
26	adalimumab-ryvk 40 mg/0.4 mL injection (Simlandi)	Specialty Tier 5	3/28/2024
27	treprostinil 16 mcg/cartridge, 32 mcg/cartridge, 48 mcg/cartridge, 64 mcg/cartridge inhalation powder (Tyvaso DPI)	Specialty Tier 5	3/25/2024
28	immune globulin (human)-stwk 5 g/50 mL, 10 g/100 mL, 20 g/200 mL injection (Alyglo)	Specialty Tier 5	3/21/2024
29	resmetirom 60 mg, 80 mg, 100 mg tablets (Rezdiffra)	Specialty Tier 5	3/18/2024
30	adalimumab-aaty 20 mg/0.2 mL injection (Yuflyma)	Specialty Tier 5	3/6/2024
31	pemetrexed disodium 100 mg/10 mL, 500 mg/50 mL injection (Pemrydi RTU)**	Specialty Tier 5	3/5/2024
32	tiopronin 100 mg, 300 mg delayed- release tablets	Specialty Tier 5	2/28/2024
33	infliximab-dyyb 120 mg/mL injection (Zymfentra)	Specialty Tier 5	2/23/2024
34	birch triterpenes 10% gel (Filsuvez)	Specialty Tier 5	2/21/2024
35	eltrombopag choline 9 mg, 18 mg, 36 mg, 54 mg tablets (Alvaiz)	Specialty Tier 5	2/15/2024
36	omalizumab 75 mg/0.5 mL, 150 mg/mL, 300 mg/2 mL injection; 300 mg/2 mL injection (Xolair)	Specialty Tier 5	2/14/2024
37	budesonide 2 mg/10 mL oral suspension (Eohilia)	Specialty Tier 5	2/14/2024
38	deflazacort 6 mg, 18 mg, 30 mg, 36 mg tablets (generic)	Specialty Tier 5	2/9/2024

****protected class**

Medicare Part D Formulary Removal of Brand Drugs

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.

Brand Medication	Brand Drug Current Tier	Generic Alternative	Generic Drug Tier	Effective Date
RECTIV OINT 0.4 %	4	NITROGLYCERIN OINT 0.4 %	4	6/1/2024

In the News....

ACIP Revises Adult RSV Vaccine Recommendations

On June 26, 2024, the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) by majority vote (11-0) approved the recommendation that all adults 75 years of age and older should be vaccinated against respiratory syncytial virus (RSV) for the 2024–2025 RSV season. The committee also voted unanimously to recommend vaccination for adults 60–74 years of age who are at high risk of RSV-related lower respiratory tract disease (LRTD).[1,2]

The updated recommendations replace previous guidance from the CDC in 2023 that adults 60 years of age and older may receive RSV vaccination, using shared clinical decision-making between the patient and their healthcare provider.[1,2]

The CDC reports that in the United States, RSV infection leads to approximately 60,000 to 160,000 hospitalizations and 6,000 to 10,000 deaths among older adults annually. There are currently three RSV vaccines available for use in older patients:

- **Arexvy (Respiratory Syncytial Virus Vaccine, Adjuvanted):** indicated for active immunization for the prevention of LRTD caused by RSV in: 1) individuals 60 years of age and older and 2) individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.[3]
- **Abrysvo (Respiratory Syncytial Virus Vaccine):** indicated for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age and 2) active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older.[4]
- **mResvia (Respiratory Syncytial Virus Vaccine):** indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.[5]

References:

1. IPD Analytics. IPD Analytics Payer and Provider Update: ACIP Revises Adult RSV Vaccine Recommendations. IPD Analytics, LLC. Accessed July 2, 2024. http://www.ipdanalytics.com [Subscription database].
2. Centers for Disease Control and Prevention. ACIP Recommendations. CDC. Accessed July 1, 2024. ACIP Recommendations - Recent Meeting Recommendations.
3. Arexvy. Prescribing Information. GlaxoSmithKline Biologicals. Accessed July 2, 2024. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Arexvy/pdf/AREXVY.PDF.
4. Abrysvo. Prescribing Information. Pfizer Laboratories Div Pfizer Inc. Accessed July 2, 2024. https://labeling.pfizer.com/ShowLabeling.aspx?id=19589.
5. mResvia. Prescribing Information. ModernaTX, Inc. Accessed July 2, 2024. mResvia Prescribing Information.