ISSUE 1 | VOLUME 19 | FEBRUARY 2025

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Formulary *Update*

Table of Contents

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

- Propranolol Extended-Release (ER) Capsules
- Auvi-Q (epinephrine) Auto-Injectors

Prior Authorization (QRM) Additions

- GLP-1 RAs for Metabolic Dysfunction-Associated Steatohepatitis (MASH)
- Kanjiniti (trastuzumab-anns)
- Loqtorzi (toripalimab)
- Pombiliti (cipaglucosidase alfa)
- Wainua (eplontersen)
- Ustekinumab Biosimilars

Prior Authorization (QRM) Updates

- Bimzelx (bimekizumab)
- Cimzia (certolizumab pegol)
- Cosentyx (secukinumab)
- Dupixent (dupilumab)
- Enbrel (etanercept)
- Entyvio (vedolizumab)
- Epidiolex (cannabidiol)
- Fasenra (benralizumab)
- Ibrance (palbociclib)
- Icatibant Products
- Ilumya (tidrakizumab)
- Leqvio (inclisiran)
- Nucala (mepolizumab)
- Ohtuvayre (ensifentrine)
- Omvoh (mirikizumab)
- Otezla (apremilast)
- PCSK9 Inhibitors
- Rezdiffra (resmetirom)
- Rinvoq (upadacitinib)
- Siliq (brodalumab)
- Simponi/ Simponi Aria (golimumab)
- Skyrizi (risankizumab)
- Sotyktu (deucravacitinib)
- Stelara (ustekinumab)
- Subcutaneous Immune Globulin Products
- Taltz (ixekizumab)
- Talzenna (talazoparib)
- Tezspire (tezepelumab-ekko)
- Trastuzumab Products
- Tremfya (guselkumab)
- Truqap (capivasertib)
- Ultomiris (ravulizumab)
- Velsipity (etrasimod arginine)
- Verzenio (abemaciclib)
- Xolair (omalizumab)
- Zavesca (miglustat)
- Zejula (niraparib)
- Zeposia (ozanimod)

Upcoming Formulary Items:

An important aspect of the formulary process is the involvement of all clinicians. Please contact your P&T Committee representative or your clinical department chief by March 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 via email at KPGA-DrugInformation@kp.org.

Medication Class Review
April 2025

- Stimulants, ADHD, Anti-Obesity, Anorexiants
- Antianxiety Agents
- Antiasthmatic and Bronchodilator Agents
- Anticonvulsants
- Antidepressants
- Antimyasthenics/ Cholinergic Agents
- Antiparkinsons
- Antipsychotic/Antimanic Agents
- Genitourinary-Misc
- Hematological Agents – Misc
- Hypnotics/Sedatives/Sleep Disorder Agents
- Migraine Products
- Neuromuscular Blockers
- Psychotherapeutics- Misc
- Urinary Anti-infectives
- Urinary Antispasmodics

Commercial HMO/Closed Formulary Additions

The following medication will be ADDED to the Commercial Formulary effective March 12, 2025:

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

Propranolol Extended-Release (ER) Capsules	Indicated for hypertension, chronic angina pectoris, migraine prophylaxis, and hypertrophic subaortic stenosis
Auvi-Q (epinephrine) Auto-Injectors	Indicated for anaphylaxis

QHP-ACA/ Open Formulary Step Therapy Removal

The following medications will have step therapy REMOVED effective March 12, 2025

Compro (prochlorperazine) 25 mg Rectal Suppositories	Indicated for control of severe nausea or vomiting in adults

Standing Orders

The following medications will have standing orders implemented effective February 2025 to authorize KP pharmacists to:

Stelara (ustekinumab)	• Replace existing prescriptions of Stelara with the equivalent dose and directions of Yesintek as approved by the Regional Pharmacy and Therapeutics Committee • If no refills remain, add ONE refill to existing prescription to allow the conversion to be completed
Herceptin (trastuzumab)	• Replace existing prescriptions of Herceptin or trastuzumab biosimilar product with the equivalent dose and directions of Hercessi or an alternative trastuzumab biosimilar injection as approved by the Regional Pharmacy and Therapeutics Committee • If no refills remain, add ONE refill to existing prescription to allow the conversion to be completed

Approved Floor Stock List Changes

Medication	Department
Approved Floor Stock List Additions	
Cathflo Activase (alteplase)	ACC-CDU
Pavblu (aflibercept-ayyh)	Ophthalmology

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:	
Kebilidi (eladocagene exuparvovec)	Indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency
The following IR Practice Recommendation UPDATES were recently approved:	
Camzyos (mavacamten)	Added maximum recommended dose, modified treatment initiation verbiage, and added information under precautions regarding contraceptive use
Duchenne Muscular Dystrophy (DMD) Drugs	Added information to alternative treatments section and modified recommendations to indicate that viltolarsen is not recommended
Elevidys (delandistrogene moxeparvovec-rokl)	Updated introduction to highlight Elevidys received full FDA approval, modified recommendations to initiate therapy in ambulatory patients ≥ 4 years old, added clarification to recommendation not to initiate therapy in non-ambulatory patients, and updated precautions section to align with the prescribing information
The following IR Practice Recommendation REMOVAL were recently approved:	
Zurzuvae (zuranolone)	Removed from U.S. market at the end of 2024

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.

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.

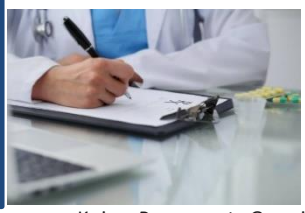
Prescriber completes the .NFRequestForm when entering drug order. Your documentation is used by OptumRx to determine whether the prescribed drug is eligible for drug benefit coverage. No documentation = No coverage.

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.



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 March 12, 2025:

GLP-1 RAs for MASH	Indicated for the treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH)
Loqtorzi (toripalimab)	Indicated for the following: • In combination with cisplatin and gemcitabine, for first-line treatment of adults with metastatic or with recurrent locally advanced nasopharyngeal carcinoma (NPC). • As a single agent for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.
Kanjiniti (trastuzumab-anns)	Indicated for the following: • Adjuvant treatment for HER2 positive breast cancer • HER2 positive metastatic breast cancer • HER2 positive metastatic gastric or gastroesophageal junction cancer
Pombiliti (cipaglucosidase alfa)	Indicated, in combination with the enzyme stabilizer miglustat (Opfolda), for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alphaglucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT).
Ustekinumab Biosimilars	Indicated for adults with: • Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy • Active psoriatic arthritis (PsA) • Moderately to severely active Crohn's disease (CD) • Moderately to severely active ulcerative colitis (UC) Indicated for pediatric patients 6 years and older with: • Moderate to severe plaque PsO who are candidates for phototherapy or systemic therapy • Active PsA
Wainua (eplontersen)	Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults.

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.

- **Bimzelx (bimekizumab):** Criteria updated to 1) add criteria for the FDA approved indications for psoriatic arthritis and spondyloarthritis, 2) add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for several indications prior to coverage, and 3) remove the trial of immunosuppressants for the treatment of plaque psoriasis.

- **Cimzia (certolizumab pegol):** Criteria updated to add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for plaque psoriasis and Crohn's disease indications prior to coverage.

- **Cosentyx (secukinumab):** Criteria updated to add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for several indications prior to coverage.

- **Dupixent (dupilumab):** Criteria updated to 1) change the age for coverage for nasal polyposis to 12 years of age or older per FDA approval and 2) add criteria for the treatment of COPD.

- **Enbrel (etanercept):** Criteria updated to 1) add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for psoriatic arthritis and plaque psoriasis prior to coverage and 2) remove the trial of immunosuppressants for the treatment of plaque psoriasis.

- **Entyvio (vedolizumab):** Criteria updated to add trial of Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics prior to coverage.

- **Epidiolex (cannabidiol):** Criteria updated to 1) allow coverage of the off-label indication of refractory seizure, 2) remove age restrictions from criteria, 3) clarify required trial agents, and 4) remove breastfeeding as a reason for non-coverage.

- **Fasenra (benralizumab):** Criteria updated to 1) only approve the autoinjector formulation for members to fill via the outpatient pharmacy benefit and 2) note that the prefilled syringes are not for outpatient use.

- **Ibrance (palbociclib):** Criteria updated to allow for coverage of Ibrance with newly approved of Itovebi (inavolisib) in combination with palbociclib and fulvestrant.

- **Icatibant Products (Firazyr and Sajazir):** Criteria updated to remove requirement of Sajazir (branded generic icatibant) prior to approval of brand Firazyr, 2) add immunologist to the list of prescribers, 3) add criteria stating icatibant products can not be used in combination with other products indicated for the acute treatment of hereditary angioedema attacks, and (4) clarify criteria for requests for brand Firazyr.

- **Ilumya (tidrakizumab):** Criteria updated to 1) add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for plaque psoriasis prior to coverage and 2) remove the trial of immunosuppressants for the treatment of plaque psoriasis.

- **Leqvio (inclisiran):** Criteria updated to revise LDL cutoffs to align 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.

- **Nucala (mepolizumab):** Criteria updated to include approval of both prefilled syringe or autoinjector for member to fill via the outpatient pharmacy benefit only.

- **Ohtuvayre (ensifentrine):** Criteria updated to 1) require a diagnosis of moderate to severe COPD with an exacerbation history of one or more severe or two or more moderate exacerbations and adherence to high-dose triple (LAMA/LABA/ICS) or double (LAMA/ICS) inhaler therapy with a documented trial of azithromycin AND roflumilast, 2) change initial approval duration to 6 months, and 3) require a decrease in exacerbation frequency, increased FEV1/FVC ratio, and continued use of dual or triple therapy for continued approval.

- **Omvoh (mirikizumab)**: Criteria updated to add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for ulcerative colitis prior to coverage.

- **Otezla (apremilast):** Criteria updated to add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for psoriatic arthritis and plaque psoriasis prior to coverage.

- **PCSK9 Inhibitors (Repatha (evolocumab) and Praluent (alirocumab)):** Criteria updated to remove adherence criteria for continued approval.

QRM Prior Authorization Review Criteria Updates (Continued)

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.

- **Rezdiffra (resmetirom):** Criteria updated to 1) clarify that if change in body weight of >5% then re-evaluation to grade and stage MASH is required, 2) add required trial of semaglutide in patients with either a BMI 27kg/m^2 or higher or diagnosis of Type 2 diabetes mellitus, 3) include concomitant use with a GLP-1RA for treatment of NASH/MASH as a reason for non-coverage, and 4) remove requirement of NAFLD activity score of >3 and liver fibrosis stage ≥ 2 for continued approval.

- **Rinvoq (upadacitinib):** Criteria updated to add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for several indications prior to coverage.

- **Siliq (brodalumab):** Criteria updated to 1) add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for plaque psoriasis prior to coverage and 2) remove the trial of immunosuppressants for the treatment of plaque psoriasis.

- **Simponi/ Simponi Aria (golimumab):** Criteria updated to add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for several indications prior to coverage.

- **Skyrizi (risankizumab):** Criteria updated to 1) add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for several indications prior to coverage and 2) remove the trial of immunosuppressants for the treatment of plaque psoriasis.

- **Sotyktu (deucravacitinib):** Criteria updated to add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for plaque psoriasis prior to coverage.

- **Stelara (ustekinumab):** Criteria updated to 1) add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for several indications prior to coverage and 2) remove the trial of immunosuppressants for the treatment of plaque psoriasis.

- **Subcutaneous Immune Globulin (SCIG):** Criteria updated to 1) highlight that Gammagard is preferred without prior authorization requirements, 2) added heading to emphasize that IVIG is preferred for all indications, 3) added a note that Hizentra is preferred and recommended prior to other non-preferred SCIG products, and 4) added indication of myasthenia gravis to allow coverage.

- **Taltz (ixekizumab):** Criteria updated to 1) add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologicsfor several indications prior to coverage and 2) remove the trial of immunosuppressants for the treatment of plaque psoriasis.

- **Talzenna (talazoparib):** Criteria updated to 1) clarify when Talzenna can be used without a previous trial of Lynparza and 2) allow combination therapy with Xtandi for metastatic prostate cancer for patients who progress on docetaxel.

- **Tezspire (tezepelumab-ekko):** Criteria updated to 1) approve the prefilled pen for dispensing via the outpatient pharmacy only and 2) note that the prefilled syringe and vial formulations are not for outpatient use.

- **Trastuzumab products:** Criteria updated to 1) change trastuzumab-anns (Kanjinti) to non-preferred requiring QRM PA review, 2) add trastuzumab-strf (Hercessi) as the preferred trastuzumab product that does not require QRM PA review, and 3) add all other biosimilars to the criteria as non-preferred by order of preference.

- **Tremfya (guselkumab):** Criteria updated to 1) add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for plaque psoriasis and psoriatic arthritis prior to coverage and 2) remove the trial of immunosuppressants for the treatment of plaque psoriasis.

- **Truqap (capivasertib):** Criteria updated to 1) remove the requirement for an FDA approved test, 2) add examples of CDK4/6 inhibitors, 3) include both FDA approved indications, and 4) add description for Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1.

- **Ultomiris (ravulizumab):** Criteria updated to 1) add criteria for neuromyelitis optica (NMO) and 2) include confirmation that REMS requirements are met prior to coverage.

- **Velsipity (etrasimod arginine):** Criteria updated to add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for several indications prior to coverage.

QRM Prior Authorization Review Criteria Updates (continued)

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.

- **Verzenio (abemaciclib):** The criteria were updated to 1) reposition the existing criteria for early or nonmetastatic breast cancer and change the heading title for this criteria to early-stage I-III breast cancer, 2) add examples of aromatase inhibitors, and 3) add staging designations to the existing heading of 'diagnosis of advanced or metastatic breast cancer'.

- **Xolair (omalizumab):** Updated initial and continued approval criteria to note the pre-filled syringe or autoinjector must be administered by healthcare provider for three doses to assess hypersensitivity reaction.

- **Zavesca:** Criteria updated to include criteria for Niemann-Pick Disease Type C due to recent approval of Miplyffa (arimoclomol) for Niemann-Pick Disease Type C that requires use in combination with Zavesca.

- **Zejula (niraparib):** Criteria updated to 1) provide clarification to KP reviewers with regards to when the medication can be used prior to Lynparza and 2) change the approval periods from 6 months to 12 months.

- **Zeposia (ozanimod):** Criteria updated to add Yesintek as the preferred ustekinumab biosimilar to the list of preferred required trial biologics for ulcerative colitis prior to coverage.

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.

Drug Name	Commercial HMO/Closed Formulary Status	QHP-ACA/ Open Formulary Status
Adakveo (crizanlizumab)	• Not accepted – clinic administered medication • Retain approval for clinic administration under medical benefit coverage • Retain on the QRM PA Review List of Medications	
Capvaxive (pneumococcal 21-valent conjugate vaccine)	• Not accepted – clinic administered medication • Defer coverage determination by medical benefit	
Dupixent (dupilumab)	• Do not accept to formulary; Retain on the QRM PA Review List of Medications	• Retain on Specialty Tier 5; Retain on the QRM PA Review List of Medications
Loqtorzi (toripalimab)	• Not accepted – clinic administered medication • Approve for clinic administration under medical benefit coverage • Require QRM PA review	
mResvia (mRNA respiratory syncytial virus vaccine)	• Not accepted – clinic administered medication • Defer coverage determination by medical benefit	
Olinvyk (oliceridine)	• Not accepted – Formulary placement for prescription drug benefits/clinic administration does not apply as this is a hospital administered medication	
Pombiliti (cipaglucosidase alfa)	• Not accepted – clinic administered medication • Approve for clinic administration under medical benefit coverage • Require QRM PA review	
Truqap (capivasertib)	• Not accepted to formulary • Require QRM PA review • Maintain quantity limit of 64 tablets for 28 days	• Add to Specialty Tier 5 • Require QRM PA review • Maintain quantity limit of 64 tablets for 28 days

Ustekinumab Products (Non-Preferred) ***(*Does not include Yesintek (ustekinumab-kfce)***	• Subcutaneous Solution/ Prefilled Syringe:
	  • Do not accept to formulary
	  • Require QRM PA review
	• Intravenous (IV) formulation
	  • Not accepted – clinic administered medication
	  • Approve for clinic administration under medical benefit coverage
	  • Require QRM PA review
		• Subcutaneous Solution/ Prefilled Syringe:
		  • Add to Specialty Tier 5
		  • Require QRM PA review
		• IV formulation
		  • Not accepted – clinic administered medication
		  • Approve for clinic administration under medical benefit coverage
		  • Require QRM PA review

Wainua (eplontersen)	Do not accept to formulary; Add to the QRM PA Review List of Medications	Add to Specialty Tier 5; Add to the QRM PA Review List of Medications

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:

Stanley Allen III, MD
Emergency Medicine/ ACC

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

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

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.	datopotamab deruxtecan-dlnk 100 mg injection (Datroway)	Specialty Tier 5	1/23/2025
2.	ustekinumab-stba 90 mg/mL injection (Steqeyma)	Specialty Tier 5	1/23/2025
3.	mesna 400 mg tablets (generic)	Specialty Tier 5	1/15/2025
4.	letermovir 120 mg pellet packs (Prevymis)	Specialty Tier 5	1/15/2025
5.	gabapentin 100 mg, 400 mg tablets (Gabarone)	Specialty Tier 5	1/9/2025
6.	nivolumab-hyaluronidase-nvhy 60010,000 mg-unit/5 mL injection (Opdivo)	Specialty Tier 5	1/3/2025
7.	nimodipine 60 mg/20 mL oral solution (generic)	Specialty Tier 5	1/2/2025
8.	vanzacaftor/tezacaftor/deutivacaftor 4 mg/20 mg/50 mg, 10 mg/50 mg/125 mg tablets (Alyftrek)	Specialty Tier 5	12/30/2024
9.	olezarsen 80 mg/0.8 mL injection (Tryngolza)	Specialty Tier 5	12/27/2024
10.	zenocutuzumab-zbco 375 mg/18.75 mL injection (Bizengri)	Specialty Tier 5	12/27/2024
11.	tiopronin 100 mg, 300 mg delayedrelease tablets (Venxxiva)	Specialty Tier 5	12/26/2024
12.	crinecerfont 50 mg, 100 mg capsules, 50 mg/mL oral solution (Crenessity)	Specialty Tier 5	12/26/2024
13.	bimekizumab-bkzx 320 mg/2 mL auto-injection; 320 mg/2 mL injection (Bimzelx)	Specialty Tier 5	12/24/2024
14.	ustekinumab-auub 45 mg/0.5 mL, 90 mg/mL prefilled injection; 45 mg/0.5 mL, 130 mg/26 mL injection (Wezlana)	Specialty Tier 5	12/23/2024
15.	imatinib mesylate 80 mg/mL oral solution (Imkeldi)	Specialty Tier 5	12/18/2024
16.	pemetrexed dipotassium 100 mg, 500 mg injection (Axtle)	Specialty Tier 5	12/5/2024
17.	adalimumab-adaz 20 mg/0.2 mL injection (generic)	Specialty Tier 5	12/4/2024
18.	trastuzumab-strf 150 mg, 420 mg injection (Hercessi)	Specialty Tier 5	12/4/2024
19.	acoramidis 356 mg tablet packs (Attruby)	Specialty Tier 5	11/27/2024
20.	pemetrexed dipotassium 100 mg, 500 mg injection (generic Pemetrexed)	Specialty Tier 5	11/26/2024
21.	zanidatamab-hrii 300 mg injection (Zihera)	Specialty Tier 5	11/26/2024
22.	filgrastim-txid 300 mcg/0.5 mL, 480 mcg/0.8 mL injection (Nypozi)	Specialty Tier 5	11/25/2024
23.	nilotinib tartrate 71 mg, 95 mg tablets (Danziten)	Specialty Tier 5	11/22/2024
24.	datopotamab deruxtecan-dlnk 100 mg injection (Datroway)	Specialty Tier 5	11/22/2024

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
Sprycel tabs 20 mg	5	Dasatinib tabs 20 mg	5	2/1/2025
Sprycel tabs 50 mg	5	Dasatinib tabs 50 mg	5	2/1/2025
Sprycel tabs 70 mg	5	Dasatinib tabs 70 mg	5	2/1/2025
Sprycel tabs 80 mg	5	Dasatinib tabs 80 mg	5	2/1/2025
Sprycel tabs 100 mg	5	Dasatinib tabs 100 mg	5	2/1/2025
Sprycel tabs 140 mg	5	Dasatinib tabs 140 mg	5	2/1/2025
Lucemyra tabs 0.18 mg	5	Lofexidine HCl tabs 0.18 mg	5	2/1/2025
Humira (2 syringe) pskt 20 mg/0.2 mL	5	Adalimumab-adaz sosy 20 mg/0.2 mL	5	3/1/2025
Humira (2 syringe) pskt 40 mg/0.4 mL	5	Simlandi (2 syring) pskt 40 mg/0.4 mL	5	2/1/2025

New Vaccine Penmenvy Approved to Prevent Meningococcal Disease

February 2025 — The U.S. Food and Drug Administration (FDA) has approved Penmenvy (Meningococcal Groups A, B, C, W, and Y Vaccine) for use in individuals aged 10 to 25 years, marking a significant advancement in meningococcal disease prevention. Developed by GlaxoSmithKline (GSK), Penmenvy is designed to protect against the five most common disease-causing serogroups of *Neisseria meningitidis*—A, B, C, W, and Y—that can cause invasive meningococcal disease (IMD). By targeting these five serogroups in a single vaccine, Penmenvy aims to reduce the number of injections required, thereby simplifying the vaccination process and potentially increasing vaccination rates among adolescents and young adults, who are at an increased risk of contracting IMD due to behaviors like close living quarters and social interactions.

Penmenvy combines the antigenic components of GSK's two established meningococcal vaccines—Bexsero (for serogroup B) and Menveo (for serogroups A, C, W, and Y)—into one formulation. The regulatory approval was based on positive results from two Phase III clinical trials [NCT04502693; NCT04707391] involving over 4,800 participants aged 10 to 25 years. The trials evaluated the vaccine's safety, tolerability, and immune response, demonstrating a safety profile consistent with GSK's licensed meningococcal vaccines. Reported side effects were generally mild to moderate, including pain at the injection site, fatigue, and headache. The Centers for Disease Control and Prevention (CDC) is expected to provide vaccination recommendations for Penmenvy at the upcoming Advisory Committee on Immunization Practices (ACIP) meeting, further supporting its integration into routine vaccination schedules in the U.S.

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First Rapid-Acting Insulin Biosimilar FDA Approved

On February 14, 2025, the first rapid-acting insulin biosimilar, Sanofi's Merilog (insulin-aspart-szjj) was approved by the U.S. Food and Drug Administration (FDA). Sandofi's Merilog is a biosimilar to Novo Nordisk's NovoLog (insulin aspart).[1,2] This is the first rapid-acting insulin biosimilar and the third insulin biosimilar approved, as the other biosimilars approved in 2021 were long-acting insulins.[2] The FDA approval is for both the 3 mL single-patient-use prefilled pen (Merilog SoloStar) and as a 10 mL multiple-dose vial.[1,2]

Merilog was approved based on the Phase 3 GEMELLI 1 study, which compared Merilog to the reference product, NovoLog, in terms of efficacy, safety, and immunogenicity.[1] Throughout the trial both patient populations were receiving insulin glargine. Of the 597 individuals studied for 6 months, 497 patients had type 1 diabetes, and 100 patients had type 2 diabetes.[1,3] Merilog was shown to have similar efficacy and safety to Novolog.

Insulin biosimilars have emerged into the market in recent years and have helped to increase patient access to treatments.[2] At KPGA, Novolog is currently a non-formulary medication.

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