Formulary Updates

Published May 2024

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for April 2024. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in April by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Please reference the guide below to navigate this communication:

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As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (accessible via Availity® or our website). Click the **PHARMACY PROGRAM/FORMULARIES** link from the menu on the left.

Important Drug Safety Updates

Par Pharmaceutical, Treprostinil Injection

On March 12, 2024, Par Pharmaceutical, Inc. (Par), is voluntarily recalling one lot of Treprostinil Injection 20mg/20mL (1mg/mL) to the consumer level. The product is being recalled due to the potential for the presence of silicone particulates in the product solution.

Administration of an injectable product that contains particulate matter may result in local irritation or swelling in response to the foreign material. If the particulate matter reaches the blood vessels it can travel to various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death. To date, Par has not received any reports of adverse events related to this recall.

Amneal Pharmaceuticals, LLC. Vancomycin Hydrochloride Oral Solution USP, 250mg/5mL

On March 27,2024, Amneal Pharmaceuticals, LLC. Bridgewater, New Jersey (Amneal), is voluntarily recalling four lots (see table below) of Vancomycin Hydrochloride for Oral Solution, USP, 250 mg/5mL packaged in 80 mL, 150 mL, or 300 mL pack sizes, to the Consumer Level. Some bottles may have been overfilled which can result in an over potent dosing regimen.

Adult patients who are prescribed the maximum daily dose of up to 2 grams per day of Vancomycin Hydrochloride for oral solution, USP 250 mg/5mL, may receive up to 4 grams of oral vancomycin per day because of the overfilled bottle. Some patients with inflammatory disorders of the intestinal mucosa also may have significant systemic absorption of vancomycin. These patients may be at risk for the development of adverse reactions associated with higher doses of vancomycin oral solution. Worsening renal function could be associated with electrolyte abnormalities such as high potassium leading to cardiac arrest. To date, Amneal has not received any reports of adverse events that have been confirmed to be directly related to this recall.

Dr. Reddy’s Laboratories Ltd., Sapropterin Dihydrochloride Powder 100mg

On April 23,2024, Dr. Reddy's Laboratories Ltd., announced that it is voluntarily recalling six lots of Sapropterin Dihydrochloride Powder for Oral Solution 100 mg to the consumer level due to powder discoloration in some packets leading to decreased potency.

Reduced efficacy of the product would result in elevated Phenylalaninemia (Phe) levels in patients. Chronically elevated Phe levels in infants and children are likely to cause permanent neurocognitive deficits, including permanent and irreversible intellectual disability, developmental delay, and seizures. Furthermore, elevated Phe levels during pregnancy, especially in early gestation, are associated with microcephaly and congenital heart disease.

Highmark Formulary Update – May 2024

SECTION I. Highmark Commercial and Healthcare Reform Formularies

A. Changes to the Highmark Comprehensive Formulary and the Highmark Healthcare Reform Comprehensive Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. Please note that the Highmark Comprehensive Closed/Incentive Formulary is a complete subset of the Open Formulary; therefore, all medications added to the Comprehensive Closed/Incentive Formulary are also added to the Open Formulary. These updates are effective on the dates noted throughout this document. For your convenience, you can search the following formularies online:

- Highmark Comprehensive Formulary
- Highmark Healthcare Reform Comprehensive Formulary

Highmark is happy to inform you that Table 1 includes products that have been added to the formulary. Adding products to the formulary may mean lower copays or coinsurance rates for members. By adding products to the formulary, Highmark hopes to promote adherence to medication protocols and improve the overall health of our members.

Table 1. Products Added

All products added to the formulary effective May 2024, unless otherwise noted.

Brand Name	Generic Name	Comments
Eohilia	budesonide oral suspension	12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE).

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
**Commercial Comprehensive only

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Alvaiz	eltrombopag	Promacta
Clobetasol Propionate Ophthalmic Suspension*	Clobetasol Propionate Ophthalmic Suspension	prednisolone sodium phosphate 1%, prednisolone acetate 1%, Fluorometholone 0.1% suspension
Jubbonti*	denosumab-bbdz	alendronate sodium tablet, risedronate sodium tablet 5 mg, risedronate sodium tablet 150 mg
Legubeti*	acetylcysteine	acetylcysteine vial (ml)

Brand Name	Generic Name	Preferred Alternatives
Simlandi	adalimumab-ryvk	adalimumab-adaz(cf) pen, adalimumab-adbm(cf)pen, Cyltezo(cf) pen
Tyenne 162 mg/0.9 mL prefilled syringe/autoinjector*	tocilizumab-aazg	Actemra syringe (ml), Actemra act pen
Wyost*	denosumab-bbdz	Prescriber discretion
Zelsuvmi*	berdazimer sodium	Prescriber discretion

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
**Physicians may request coverage of these products using the Prescription Drug Medication Request Form.
***Healthcare Reform Comprehensive only

Table 3. Additions to the Specialty Tier Copay Option

Note: The specialty tier does not apply to Highmark Delaware Healthcare Reform members; see Highmark Delaware's online Provider Resource Center and access the **PHARMACY PROGRAM/FORMULARIES** link for details on the formularies and formulary options that apply to Highmark Delaware Healthcare Reform members.

Effective upon completion of internal review and implementation unless otherwise noted.

Brand Name	Generic Name
Alvaiz	eltrombopag
Eohilia	budesonide oral suspension
Jubbonti	denosumab-bbdz
Simlandi	adalimumab-ryvk
Tyenne 162 mg/0.9 mL prefilled syringe/autoinjector	tocilizumab-aazg
Wyost	denosumab-bbdz
Zelsuvmi	berdazimer sodium

Table 4. Products to Be Removed or Shifted to Higher Tier – Effective July 2024

Brand name	Generic Name	Preferred Alternatives
Only Commercial Comprehensive products		
Condylox	podofilox	podofilox 0.5% topical soln
Mydayis	dextroamphetamine/amphetamine	dextroamphetamine-amphet er
Restasis multidose	cyclosporine	cyclosporine 0.05% eye emuls
All Commercial & Healthcare Reform Comprehensive products		
Restasis	cyclosporine	cyclosporine 0.05% eye emuls
Votrient	pazopanib hcl	pazopanib hcl

B. Changes to the Highmark Healthcare Reform Essential Formulary

The Essential Formulary is a closed formulary for select Healthcare Reform (HCR) Individual plans. A list of drugs included on the Essential Formulary, listed by therapeutic class, is available here.

Table 1. Formulary Updates

All formulary changes effective May 2024, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Eohilia	budesonide oral suspension	4	Osteoporosis and increasing bone mass
Jubbonti*	denosumab-bbdz	4	12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE).
Items listed below were not added to the formulary			
Alvaiz	eltrombopag	NF	Promacta
Clobetasol Propionate Ophthalmic Suspension*	Clobetasol Propionate Ophthalmic Suspension	NF	prednisolone sodium phosphate 1%, prednisolone acetate 1%, Fluorometholone 0.1% suspension
Legubeti*	acetylcysteine	NF	acetylcysteine vial (ml)
Simlandi	adalimumab-ryvk	NF	adalimumab-fkjp(cf) pen, hadlima(cf) pushtouch, humira
Tyenne 162 mg/0.9 mL prefilled syringe/autoinjector*	tocilizumab-aazg	NF	Actemra syringe (ml), Actemra actpen
Wyost*	denosumab-bbdz	NF	Prescriber discretion
Zelsuvmi*	berdazimer sodium	NF	Prescriber discretion

Formulary options: **Tier 1:** Generic drugs; **Tier 2:** Generic and Brand drugs; **Tier 3:** Generic and Brand drugs; **Tier 4:** Generic and Brand drugs; **Non-formulary (NF)**.
*Effective date to be determined.

Table 2. Products to Be Removed or Shifted to Higher Tier – July 2024

Brand Name	Generic Name	Preferred Alternatives
All Healthcare Reform Essential Products		
Korlym	mifepristone	mifepristone 300 mg tablet
Livalo	pitavastatin calcium	pitavastatin calcium
Oracit	citric acid/sodium citrate	oral citrate
Rectiv	nitroglycerin	nitroglycerin 0.4% ointment
Votrient	pazopanib hcl	pazopanib hcl

C. Changes to the Highmark Core Formulary

The Core Formulary is a closed formulary for select Commercial Individual plans. A list of drugs included on the Core Formulary, listed by therapeutic class, is available here.

Table 1. Formulary Updates

All formulary changes effective May 2024, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Eohilia	budesonide oral suspension	4	Osteoporosis and increasing bone mass
Jubbonti*	denosumab-bbdz	4	12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE).
Items listed below were not added to the formulary			
Alvaiz 9 mg,18 mg, 36 mg, 54 mg tablets	eltrombopag	NF	Promacta
Clobetasol Propionate Ophthalmic Suspension*	Clobetasol Propionate Ophthalmic Suspension	NF	prednisolone sodium phosphate 1%, prednisolone acetate 1%, Fluorometholone 0.1% suspension
Legubeti*	acetylcysteine	NF	acetylcysteine vial (ml)
Simlandi	adalimumab-ryvk	NF	Adalimumab-fkjp(cf) pen, Hadlima(cf) pushtouch, Humira
Tyenne 162 mg/0.9 mL prefilled syringe/autoinjector*	tocilizumab-aazg	NF	Actemra syringe (ml), Actemra actpen
Wyost*	denosumab-bbdz	NF	Prescriber discretion
Zelsuvmi*	berdazimer sodium	NF	Prescriber discretion

Formulary options: **Tier 1:** Generic drugs; **Tier 2:** Generic and Brand drugs; **Tier 3:** Generic and Brand drugs; **Tier 4:** Generic and Brand drugs; **Non-formulary (NF)**.
*Effective date to be determined.

Table 2. Products to Be Removed or Shifted to Higher Tier – July 2024

Brand Name	Generic Name	Preferred Alternatives
All Core Products		
Korlym	mifepristone	mifepristone 300 mg tablet
Oracit	citric acid/sodium citrate	oral citrate
Votrient	pazopanib hcl	pazopanib hcl

D. Changes to the Highmark National Select Formulary

The National Select Formulary is an incentive formulary with a non-formulary drug list to manage products in therapeutic categories for which preferred alternatives are available. The National Select Formulary is available for select Commercial self-funded (ASO) plans. A list of drugs included on the National Select Formulary, listed by therapeutic class, is available here.

Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (Preferred)			
Simlandi	adalimumab-ryvk	2	
Items listed below were added to the formulary (Non-Preferred)			
Clobetasol Propionate Ophthalmic Suspension*	Clobetasol Propionate Ophthalmic Suspension	3	prednisolone sodium phosphate 1%, prednisolone acetate 1%, Fluorometholone 0.1% suspension
Jubbonti*	denosumab-bbdz	3	alendronate sodium tablet, risedronate sodium tablet 5 mg, risedronate sodium tablet 150 mg
Legubeti*	acetylcysteine	3	acetylcysteine vial (ml) (route: miscellaneous)
Tyenne 162 mg/0.9 mL prefilled syringe/autoinjector*	tocilizumab-aazg	3	Actemra syringe (ml), Actemra actpen
Wyost*	denosumab-bbdz	3	Prescriber discretion
Zelsuvmi*	berdazimer sodium	3	Prescriber discretion
Items listed below were not added to the formulary			
Alvaiz	eltrombopag	NF	Promacta, Nplate
Eohilia	budesonide oral suspension	NF	Budesonide inhalation suspension

Formulary options: **Tier 1:** Generic drugs; **Tier 2:** Preferred Brand drugs; **Tier 3:** Non-Preferred Brand drugs; **Non-formulary (NF)**.
*Effective date and final formulary position to be determined.

Table 2. Additions to the Specialty Tier Copay Option

Effective upon completion of internal review and implementation unless otherwise noted.

Brand Name	Generic Name
Alvaiz	eltrombopag

Eohilia	budesonide oral suspension
Jubbonti	denosumab-bbdz
Simlandi	adalimumab-ryvk
Tyenne 162 mg/0.9 mL prefilled syringe/autoinjector	tocilizumab-aazg
Wyost	denosumab-bbdz
Zelsuvmi	berdazimer sodium

Table 3. Products to Be Removed or Shifted to Higher Tier – July 2024

Brand Name	Generic Name	Preferred Alternatives
All National Select Products		
Advair diskus	fluticasone propion/salmeterol	Fluticasone-salmeterol, Wixela inhub
Copaxone	glatiramer acetate	glatiramer acetate, glatopa
Cuvitru	immun glob g(igg)/gly/iga ov50	Gammagard liquid, gamunex-c
Endometrin	progesterone, micronized	Crinone 8% gel
Fabrazyme	agalsidase beta	Elfabrio
Rubraca	rucaparib camsylate	Lynparza
Zejula	niraparib tosylate	Lynparza

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Adalimumab BIOSIMILARS – Commercial and Heatlhcare Reform	TBD	Policy terminated. Adalimumab biosimilars are now included in J-1049
Anti-EGFR and HER2 Kinase Inhibitors – Commercial and Healthcare Reform	04/22/2024	Policy revised for Tykerb (lapatinib) to require age of 18 years or older.
Anti-Obesity – Commercial and Healthcare Reform	TBD	Policy revised for Wegovy (semaglutide) to include FDA-approved expanded indication requiring FDA-approved age and indication; diagnosis of myocardial infarction, stroke, or peripheral arterial disease; baseline height, weight and BMI; baseline BMI ≥ 27 kg/m2; concurrent use of lifestyle modification program; and no concomitant use of another glucagon-like peptide-1 receptor agonist; for initiation,

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		continuation, and maintenance approvals. For continuation and maintenance, the requested dose must be for 1.7 mg or 2.4 mg weekly.
Anti-Obesity – Commercial and Healthcare Reform	04/22/2024	Policy revised to Zepbound (tirzepatide) to allow initial authorization duration of 7 months.
Anti-Obesity – Commercial and Healthcare Reform	04/22/2024	Policy revised for initial authorization of Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide) to require prescriber attestation that the member will use the requested therapy in combination with a lifestyle modification program that encourages reduced calorie diet and increased physical activity. For Zepbound (tirzepatide), initiation defined as less than 7 months of therapy and continuation defined as 7 to 12 months of therapy.
Anti-Obesity – Commercial and Healthcare Reform	TBD	Policy revised for Wegovy (semaglutide) for cardiovascular (CV) event risk reduction for initiation, maintenance, and continuation to require: 1) use as an adjunct to maximally-tolerated statin therapy and ezetimibe or 2) trial/failure/contraindication to ezetimibe monotherapy and statin intolerance (defined as rhabdomyolysis or skeletal-related muscle symptoms while receiving at least two (2) separate trials of different statins which resolved upon discontinuation of the statins or one (1) of the following: creatinine kinase increase to 10 times upper limit of normal, liver function tests increase to 3 times upper limit of normal, or hospitalization due to severe statin-related adverse event); concurrent use of or trial/failure/contraindication to a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor; and if the member has type 2 diabetes, trial/failure/contraindication to a preferred glucagon-like peptide-1 receptor agonist for diabetes and CV risk reduction. For Contrave (bupropion and naltrexone), Qsymia (phentermine and topiramate extended-release), Saxenda (liraglutide), Wegovy (semaglutide), Xenical (orlistat), and Zepbound (tirzepatide) to treat obesity, comorbidities for overweight patients expanded to include asthma, CV disease, osteoarthritis, type 2 diabetes, polycystic

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		ovarian syndrome, non-alcoholic steatohepatitis/non-alcoholic fatty liver disease, and chronic obstructive pulmonary disease.
Apokyn (apomorphine hydrochloride) – Commercial and Healthcare Reform	04/22/2024	Policy revised to remove Kynmobi (apomorphine) since it is off market.
BCR-ABL Kinase Inhibitors – Commercial and Healthcare Reform	04/22/2024	Policy revised for Gleevec (imatinib) to require age for dermatofibrosarcoma protruberans based on FDA-approved indication; and to require diagnosis based on FDA-approved age and indication for Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia and gastrointestinal stromal tumors. Policy revised for Tasigna (nilotinib) to allow for diagnosis of Philadelphia chromosome positive chronic myelogenous leukemia in the accelerated phase for pediatric patients.
BTK Inhibitors – Commercial and Healthcare Reform	04/22/2024	Policy revised for Brukinsa (zanubrutinib) to require age and diagnosis based on expanded FDA-approved indication for follicular lymphoma.
Camzyos (mavacamten) – Commercial and Healthcare Reform	04/22/2024	Policy revised for Camzyos (mavacamten) to include addition that drug can be prescribed by or in consultation with a cardiologist or physician who specializes in the treatment of hypertrophic cardiomyopathy. For step therapy clarified that member has trial and failure to one or contraindication to all non-vasodilating beta blocker and/or non-dihydropyridine calcium channel blocker. For reauthorization criteria, added that the member will not be taking concomitant disopyramide, ranolazine, or a combination of beta blockers and calcium channel blockers.
CDK Inhibitors – Commercial and Healthcare Reform	04/22/2024	Policy revised for Ibrance (palbociclib) to require trial/failure/contraindication to Kisqali (ribociclib) or Verzenio (abemaciclib).
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	ALREADY POSTED	Policy revised to allow continuation of therapy for members receiving Entyvio (vedolizumab) intravenous or subcutaneous > 6 months that are transitioning to pharmacy benefit subcutaneous. Adalimumab-aacf added as an additional non-preferred adalimumab biosimilar.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	ALREADY POSTED	Policy revised to add Humira [83457] labeler to non-preferred products for all Commercial and Healthcare Reform formularies.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	04/04/2024	Policy revised to add Simlandi (adalimumab-ryvk) to existing adalimumab prior authorization criteria, and add as a non-preferred adalimumab product. A request for a non-preferred adalimumab product should be directed to preferred adalimumab products. There is no clinical exception criteria for non-preferred adalimumab products. Added prescriber specialty requirement for all products and indications except Zeposia (ozanimod) in multiple sclerosis. For adalimumab in uveitis, updated from a double step to a single step through an immunosuppressant. For products indicated for ankylosing spondylitis or non-radiographic axial spondyloarthritis, removed NSAID step(s). For Janus kinase inhibitors (JAK) inhibitors, removed conventional therapy steps. For Cosentyx (secukinumab) SC and Orencia (abatacept) SC in pediatric psoriatic arthritis, added step through Enbrel (etanercept) or Stelara (ustekinumab) subcutaneous (SC). For Entyvio (vedolizumab) SC and Zymfentra (infliximab), allowing preferred step bypass if member is established on IV induction therapy already. For all SC inflammatory bowel disease (IBD) medications with IV induction therapy, removed requirement for clinical response or remission on IV before transitioning to SC.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	TBD	Policy revised for Sotyktu (deucravacitinib) to move from triple step to single step through step 1 preferred agents. Entyvio (vedolizumab) updated from step through 2 step 1 agents to 2 step 1 or 2 agents and allowing continuation if member is established on IV induction therapy already. Omvoh (mirikizumab-mrkz) subcutaneous (SC) updated from step through 2 step 1 agents to 1 step 1 agent and allowing continuation if member is established on IV induction therapy already. Velsipity (etrasimod) updated from step through 2 step 1 agents to 2 step 1 or 2 agents and 1 step 3b agent.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Demser (metyrosine) – Commercial and Healthcare Reform	04/22/2024	Policy revised for Demser (metyrosine) to require positive clinical response to therapy and one of the following: the member has experienced an incomplete response to tumor resection, resection surgery is contraindicated, or the member has malignant pheochromocytoma for reauthorization.
Denosumab Products for Bone Disease and Evenity (romosozumab-aqqg) – Commercial and Healthcare Reform	TBD	Policy revised for Jubbonti (denosumab-bbdz) to require diagnosis based on FDA-approved indication. If use is for osteoporosis or osteopenia (including glucocorticoid-induced osteoporosis) it is supported by lab values such as T-score or FRAX calculator, trial/failure to one bisphosphonate or all are contraindicated and is not using product with other injectable osteoporosis medications.
Denosumab Products for Bone Disease and Evenity (romosozumab-aqqg) – Commercial and Healthcare Reform	TBD	Policy revised for Prolia (denosumab), if requesting for all indications, member has trial/failure to Jubbonti (denosumab-bbdz).
Dupixent (dupilumab) – Commercial and Healthcare Reform	04/22/2024	Policy revised for Dupixent (dupilumab) for expanded indication of eosinophilic esophagitis (EoE) in patients 1 year and older weighing at least 15 kg. If the member is 1 to 11 years, history of EoE signs or symptoms. For reauthorization, either histological remission or reduced severity or frequency of clinical symptoms of esophageal dysfunction.
EGFR-Targeting Kinase Inhibitors – Commercial and Healthcare Reform	04/22/2024	Policy revised for Tagrisso (osimertinib) for new indication of first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test, in combination with pemetrexed and platinum-based chemotherapy.
Emflaza (deflazacort) – Commercial and Healthcare Reform	04/22/2024	Policy revised to add generic with FDA approved age and require step through generic deflazacort tablets when request is for brand Emflaza (deflazacort) tablets or suspension and the member is 5 years of age or older.
Eohilia (budesonide oral suspension) – Commercial and Healthcare Reform	TBD	New policy created for Eohilia (budesonide oral suspension) requiring age, FDA-approved indication confirmed by esophageal biopsy, clinical symptoms of esophageal dysfunction,

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		trial/failure/contraindication to high-dose proton pump inhibitor therapy.Therapy is limited to 12 weeks with no reauthorization.
FGFR Kinase Inhibitors – Commercial and Healthcare Reform	04/22/2024	Policy revised for Balversa (erdafitinib) to require disease progression on or after at least one line of prior systemic therapy, member is FGFR3 mutation-positive, and if the member has not received prior programmed cell death protein 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor therapy, prescriber attestation that the member is not eligible for treatment with PD-1 or PD-L1 inhibitor therapy, based on updated FDA-approved indication.
Fingolimod – Commercial and Healthcare Reform	04/22/2024	Policy revised to remove requirement for new starts to brand Gilenya (fingolimod) to try generic dimethyl fumarate.
FLT3 Kinase Inhibitors – Commercial and Healthcare Reform	04/22/2024	Policy revised for Vanflyta (quizartinib) to allow for attestation that the member is tolerating therapy and disease improvement or delayed disease progression for reauthorization.
Human Growth Hormone – Commercial and Healthcare Reform	04/22/2024	Policy revised to remove Norditropin (somatropin) as a preferred product for the National Select Formulary.
Human Growth Hormone – Delaware Commercial and Healthcare Reform	04/22/2024	Policy revised to remove Norditropin (somatropin) as a preferred product for the National Select Formulary.
Interferons – Commercial and Healthcare Reform	04/22/2024	Policy revised for Besremi (ropeginterferon alfa-2b-njft) to require age based on FDA-approved indication and trial/failure/contraindication to generic hydroxyurea for high risk polycythemia vera (PV). Low-risk PV criteria updated to require the member is less than 60 years of age and does not have a prior history of thrombosis. High-risk PV criteria updated to require that the member is 60 years of age or older or has a prior history of thrombosis.
Katerzia (amlodipine benzoate) and Norliqva (amlodipine) – Commercial and Healthcare Reform	04/22/2024	Policy revised for Katerzia (amlodipine benzoate) and Norliqva (amlodipine) to require step through generic amlodipine.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Livmarli (maralixibat) – Commercial and Healthcare Reform	04/22/2024	Policy revised to allow approval for expanded indication of diagnosis of progressive familial intrahepatic cholestasis (PFIC), requiring confirmation by genetic testing, FDA-approved age and that the member does not have PFIC2 with an ABCB11 variant resulting in nonfunctional or absent bile salt export pump protein. Quantity limit updated to allow for maximum maintenance dosing per FDA labeling.
Lupkynis (voclosporin) – Commercial and Healthcare Reform	04/22/2024	Policy revised for Lupkynis (voclosporin) to allow step through any mycophenolic acid analog. Azathioprine was added as an alternative maintenance therapy option in reauthorization.
Market Watch Programs – Delaware	TBD	Policy revised to add tetracycline tablets to high cost/low value medications to require trial/failure of tetracycline capsules. Clobetasol propionate ophthalmic suspension also added to the list of high cost, low value medications with prednisolone sodium phosphate 1%, prednisolone acetate 1%, and flurometholone suspension 0.1% as therapeutic alternatives. Sovuna (hydroxychloroquine sulfate) 200 mg and 300 mg were added to the high cost/low value medication with hydoxychloroquine 100 mg, 200 mg, 300 mg, and 400 mg listed as therapeutic alternatives.
Market Watch Programs – New York, Pennsylvania, and West Virginia	TBD	Policy revised to add tetracycline tablets to high cost/low value medications to require trial/failure of tetracycline capsules. Clobetasol propionate ophthalmic suspension also added to the list of high cost, low value medications with prednisolone sodium phosphate 1%, prednisolone acetate 1%, and flurometholone suspension 0.1% as therapeutic alternatives. Sovuna (hydroxychloroquine sulfate) 200 mg and 300 mg were added to the high cost/low value medication with hydoxychloroquine 100 mg, 200 mg, 300 mg, and 400 mg listed as therapeutic alternatives.
Non-Preferred Baclofen Products – Commercial and Healthcare Reform	04/22/2024	Ozobax DS (baclofen oral solution 10 mg/5 mL) added to policy; already targeted but not listed in policy.
Oral Isotretinoin Therapy – Commercial and Healthcare Reform	04/22/2024	Policy revised for Absorica and Absorica LD (isotretinoin capsules) to update topical step therapy preferred agents. Added adapalene-

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		benzoyl peroxide (gel), non-micronized tretinoin (cream or gel), tazarotene (cream), erythromycin (gel, swab). Removed sulfacetamide lotion.
PCSK9 Inhibitors – Commercial and Healthcare Reform	04/22/2024	Policy revised for Repatha (evolocumab) and Praluent (alirocumab) for reauthorization to remove requirements of member adherence and prescriber specialty for all indications. For Praluent (alirocumab) to treat heterozygous familial hypercholesterolemia (HeFH), age requirement reduced to 8 years of age and older to reflect expanded indication. For Praluent (alirocumab) to treat HeFH in patients 10 years of age and older, require trial/failure/contraindication to plan-preferred Repatha (evolovumab).
PI3K Inhibitors – Commercial and Healthcare Reform	04/22/2024	Policy revised for Piqray (alpelisib) to remove requirement that the member is a postmenopausal female or male based on expanded FDA-approved indication. Policy revised to remove Ukoniq (umbralisib) from reauthorization and limitations of coverage, as it is no longer available. Policy revised for Copiktra (duvelisib) to require that the member has a diagnosis of relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma.
Repository Corticotropin Injection – Commercial and Healthcare Reform	TBD	Policy revised to add Acthar Gel SelfJect (repository corticotropin) with limitation that it is not to be used for the treatment of infantile spasms.
Thrombopoiesis Stimulating Agents – Commercial and Healthcare Reform	04/22/2024	Policy revised to add Alvaiz (eltrombopag) as a targeted medication. Criteria for persistent or chronic ITP requires age, diagnosis, therapeutic failure, contraindication, or intolerance to corticosteroid or immunoglobulin therapy or splenectomy, and documented platelet count of > 30 x 10^9/L to < 50 x 10^9/L with significant mucous membrane bleeding or one risk factor for bleeding or a documented platelet count of ≤ 30 x 10^9/L. Criteria for treatment of thrombocytopenia in patients with chronic Hepatitis C to require Alvaiz is being used to achieve target platelet counts to initiate or maintain interferon therapy in patients with Hepatitis C and documented platelet count of < 75 x 10^9/L. Treatment of patients with severe aplastic anemia to require diagnosis,

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		therapeutic failure to one immunosuppressive therapy, and a documented platelet count of < 30 x10^9/L. For all indications, the member has experienced therapeutic failure, contraindication, or intolerance to plan-preferred Promacta. Reauthorization to require the prescriber attests that the member has experienced positive clinical response to therapy.
Tocilizumab Biosimilars – Commercial and Healthcare Reform	TBD	New policy for tocilizumab biosimilars requiring age and diagnosis based on FDA-approved indication and therapeutic failure or intolerance to Actemra (tocilizumab). For rheumatoid arthritis, the member has experienced therapeutic failure or intolerance to: 1) one (1) non-biologic disease modifying anti-rheumatic drug (DMARD) or all non-biologic DMARDs are contraindicated and 2) a plan-preferred adalimumab product. For giant cell arteritis, the member has experienced therapeutic failure or intolerance to one (1) systemic corticosteroid, or all corticosteroids are contraindicated. For polyarticular juvenile idiopathic arthritis, the member has experienced therapeutic failure or intolerance to a plan-preferred adalimumab product and meets one (1) of the following: 1) the member has experienced therapeutic failure or intolerance to one (1) non-biologic DMARD or all non-biologic DMARDs are contraindicated or 2) the member requires initial biologic therapy due to involvement of high-risk joints, high disease activity, and/or those judged to be at high-risk of disabling joint damage. For reauthorization, attestation of disease stability or beneficial response to therapy. Quantity limitation criteria added based on FDA-approved dosing.
Urea Cycle Disorder Medications – Commercial and Healthcare Reform	04/22/2024	Policy revised for Carbaglu (carglumic acid) to add step therapy if the request is for brand Carbaglu (carglumic acid) the member has tried and failed generic carglumic acid. For Buphenyl (sodium phenylbutyrate, Olpruva (sodium phenylbutyrate) and Pheburane (sodium phenylbutyrate), allow contraindication in addition to therapeutic failure or intolerance to required steps. Criteria for Ravicti (glycerol phenylbutyrate) revised to require documentation of specific protein deficiency subtype. For both initial authorization and reauthorization of Ravicti

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		(glycerol phenylbutyrate), if the member has a deficiency of carbamylphosphate synthetase, ornithine transcarbamylase, or argininosuccinic acid synthetase, trial/failure/intolerance/contraindication to plan-preferred generic sodium phenylbutyrate and Pheburane (sodium phenylbutyrate). Reauthorization added for Buphenyl (sodium phenylbutyrate), Carbaglu (carglumic acid), Olpruva (sodium phenylbutyrate), Pheburane (sodium phenylbutyrate), and Raviciti (glycerol phenylbutyrate) to ask that the member is continuing use of requested drug with standard of care (e.g., dietary protein restriction and/or amino acid supplementation).
Xolair (omalizumab) Syringe and Autoinjector – Commercial and Healthcare Reform	04/22/2024	Policy revised for Xolair (omalizumab) to add autoinjector for patients 12 years and older. New indication for food allergy added requiring age, allergist or immunologist prescriber consultation, FDA-approved diagnosis confirmed by skin prick test or food specific antibodies, current weight, pretreatment serum IgE levels, no history of anaphylaxis (except food), at least 3 doses under guidance of healthcare professional, and documented prescription for epinephrine. Reauthorization requiring appropriate age, current weight, pretreatment serum IgE levels, positive response, requires continuation, and will continue food allergen avoidance. Additional quantities allowed exceeding limitations based on weight and IgE levels.
Zelsuvmi (berdazimer) – Commercial and Healthcare Reform	TBD	New policy for Zelsuvmi (berdazimer) to require age, diagnosis and that Zelsuvmi be prescribed by or in consultation with a dermatologist or a provider who specializes in the treatment of molluscum contagiosum (MC). Reauthorization criteria to require prescriber attestation that the member has previously experienced complete or partial clearance of MC lesions with Zelsuvmi and that an additional course of therapy is required for recurrence of MC. Authorization duration of 12 weeks.

*For Commercial and Healthcare Reform policies, an exception to some or all the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.
**All effective dates are tentative and subject to delay pending internal review or approval.

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Additional Antibiotic Quantities – Commercial and Healthcare Reform	04/22/2024	Policy revised for Xenleta (lefamulin) to require that the member is 18 years of age or older.
Additional Quantities of Reliever Inhalers – Commercial and Healthcare Reform	04/22/2024	Policy revised to add Airsupra (budesonide and albuterol) as a targeted medication to require that the member is adherent to maximally tolerated controller medication, the member has been counseled on proper inhaler technique, and the member requires chronic maintenance of reliever inhaler therapy.
Atypical Antipsychotics – Commercial	04/22/2024	Policy revised to divide bipolar criteria for Vraylar (cariprazine) into bipolar acute manic or mixed episodes and bipolar with depressive episodes. The plan-preferred step therapy alternatives differ with each diagnosis. For acute manic and mixed episodes, the alternatives are quetiapine and aripiprazole; for bipolar depression, the alternatives are quetiapine product and olanzapine/fluoxetine.
Atypical Antipsychotics – Healthcare Reform	04/22/2024	Policy revised to divide bipolar criteria for Vraylar (cariprazine) into bipolar acute manic or mixed episodes and bipolar with depressive episodes. The plan-preferred step therapy alternatives differ with each diagnosis. For acute manic and mixed episodes, the alternatives are quetiapine and aripiprazole; for bipolar depression, the alternatives are quetiapine product and olanzapine/fluoxetine.
Beta Blocker Management – Commercial National Select	04/22/2024	Policy revised to remove Trandate (labetalol) and Zebeta (bisoprolol).
Direct Oral Anticoagulants (DOACs) – Commercial and Healthcare Reform	04/22/2024	Policy revised for Savaysa (edoxaban) to add limitation of coverage stating that Savaysa is contraindicated in patients with non-valvular atrial fibrillation and a creatine clearance > 95 mL/min. For Pradaxa and Pradaxa oral pellets (dabigatran etexilate), step through generic dabigatran etexilate removed for pediatric patients.
Gralise (gabapentin extended-release) – Commercial and Healthcare Reform	04/22/2024	Two strengths of generic Gralise (gabapentin extended-release) are now available; policy revised to differentiate between gabapentin extended-release (Gralise) and gabapentin immediate-release (Neurontin).

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Latuda (lurasidone) – Commercial	04/22/2024	Policy revised for the bipolar depression indication from requiring all members to experience therapeutic failure or intolerance to either a quetiapine product or olanzapine/fluoxetine, to only members 18 years of age and older.
Latuda (lurasidone) – Healthcare Reform	04/22/2024	Policy revised for the bipolar depression indication from requiring all members to experience therapeutic failure or intolerance to either a quetiapine product or olanzapine/fluoxetine, to only members 18 years of age and older.
Mesalamine Ulcerative Colitis Treatments – Commercial and Healthcare Reform	04/22/2024	Policy revised to remove AB-rated generic step for Asacol HD (mesalamine) (brand not on market), and Pentasa (mesalamine) 500 mg (generic not on market). Brand Asacol HD (mesalamine) was removed from policy.
Minocycline & Tetracycline Tablets – Commercial and Healthcare Reform	TBD	Policy revised to add tetracycline tablets requiring FDA-approved diagnosis and therapeutic failure or intolerance to plan-preferred, generic tetracycline capsules.
Naprosyn (naproxen) Oral Suspension, meloxicam suspension, and ketoprofen 25 mg – Commercial National Select Formulary	04/22/2024	Policy revised to add Kiprofen (ketoprofen) to require an FDA-approved diagnosis and therapeutic failure or intolerance to three (3) generic alternatives (diclofenac, ibuprofen, indomethacin, meloxicam, nabumetone, or naproxen), or contraindication to all 6 of the products.
Non-Preferred Basal Insulins – Commercial	04/22/2024	Policy revised to add insulin glargine solostar and insulin glargine solostar max 300 units/mL to require diagnosis of diabetes, trial and failure of metformin or using with metformin if member has type 2 diabetes, and documentation of trial and failure through all of the following: insulin glargine/insulin glargine solostar 100 units/mL, Lantus (insulin glargine), Toujeo/Toujeo Max (insulin glargine), and Tresiba (insulin degludec).
Non-Preferred Basal Insulins – Healthcare Reform	04/22/2024	Policy revised to add insulin glargine solostar and insulin glargine solostar max 300 units/mL to require diagnosis of diabetes, trial and failure of metformin or using with metformin if member has type 2 diabetes, and documentation of trial and failure through all of the following: Basaglar (insulin glargine), Lantus (insulin glargine), Toujeo/Toujeo Max (insulin glargine), and Tresiba (insulin degludec).
Non-Preferred Blood Glucose Testing Products	TBD	Policy revised to add Freestyle Precision Neo as a plan-preferred product.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
– Commercial and Select Healthcare Reform		
Non-Preferred NSAIDs – Commercial and Healthcare Reform	04/22/2024	Policy revised to add Kiprofen (ketoprofen) to require an FDA-approved diagnosis and therapeutic failure or intolerance to three (3) generic alternatives (diclofenac, ibuprofen, indomethacin, meloxicam, nabumetone, or naproxen), or contraindication to all 6 of the products.
Non-Preferred Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Commercial and Healthcare Reform	04/22/2024	Policy revised for dapagliflozin to require diagnosis of type 2 diabetes and trial/failure/contraindication to a brand dapagliflozin- and empagliflozin-containing product.
Non-Preferred Tramadol Products – Commercial and Healthcare Reform	04/22/2024	Policy revised to add Tramadol HCl 25 mg tablets to non-preferred drug products. Members must have a diagnosis of pain (ICD-10: R52) and have experienced therapeutic failure or intolerance to generic plan-preferred tramadol HCl 50 mg tablet.
Non-Preferred Methylphenidate ER Products for ADHD – Commercial and Healthcare Reform	TBD	Policy revised to include criteria for Metadate CD (methylphenidate HCl extended release). The member must have an FDA-approved diagnosis, be between 6 and 15 years of age, and either experienced therapeutic failure, contraindication, or intolerance to at least two of the following generic, plan-preferred products: amphetamine/dextroamphetamine extended-release, methylphenidate HCl extended-release, dexmethylphenidate HCl extended-release, or dextroamphetamine extended-release and have an inability to swallow tablets or capsules. Reauthorization criteria requiring prescriber attestation that the member has experienced positive clinical response to therapy and the member still cannot swallow tablets or capsules. Authorization duration of 12 months.
Tazarotene Products – Commercial and Healthcare Reform	TBD	Policy revised for Arazlo (tazarotene), Fabior (tazarotene), and Tazorac (tazarotene) to update topical step therapy preferred agents to include topical retinoids (adapalene cream or gel; adaplene-benzoyl peroxide gel; non-micronized tretinoin cream or gel) and topical antibiotics (clindamycin phosphate gel, lotion, or solution; clindamycin phosphate-benzoyl peroxide 1.2-2.5% or 1-5% gel; erythromycin gel, solution, or swab;

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		and erythromycin-benzoyl peroxide gel. Removed automatic authorization.

*For Commercial and Healthcare Reform policies, an exception to some or all the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.
**All effective dates are tentative and subject to delay pending internal review or approval.
Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria.

3. Formulary Program

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Self-Administered Injectables – Commercial and Healthcare Reform – New York	04/22/2024	Policy revised for Gammagard Liquid (immune globulin infusion (human), 10% solution) requiring adult and FDA approved diagnosis, self-administration, progressive symptoms, and progressive/relapsing motor sensory for at least 2 months, hypo- or areflexia, nerve conduction studies, nerve biopsy, demyelination, and cerebrospinal fluid studies. Policy revised for Hyqvia (immune globulin infusion 10% (human) with recombinant human hyaluronidase) to add initial authorization criteria for CIDP requiring age, diagnosis, self-administration and improvement in symptoms and reauthorization criteria for self-administration and improvement/stability in symptoms due to expanded indication.

4. Quantity Level Limit (QLL) Programs*

Effective immediately upon completion of internal review and implementation, unless otherwise noted.

Table 1. Quantity Level Limits – Quantity per Duration for Commercial and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Eohilia (budesonide oral suspension)	168 single-dose stick packs per 365 days	168 single-dose stick packs per 365 days

Drug Name	Retail Edit Limit	Mail Edit Limit
Hemlibra (emicizumab-kxwh) 12 mg/0.4 mL	8 vials (20 mL) every 21 days	24 vials (60 mL) every 63 days
Hemlibra (emicizumab-kxwh) 300 mg/2 mL	4 vials (8 mL) every 21 days	12 vials (24 mL) every 63 days
Simlandi (adalimumab-ryvk)	2 autoinjectors per 28 days	6 autoinjectors per 84 days
Tyenne (tocilizumab-aazg) 162 mg/0.9 mL prefilled syringe/autoinjector*	4 syringes/autoinjectors per 28 days	12 syringes/autoinjectors per 84 days
Xolair (omalizumab) autoinjector	2 mL per 21 days [cumulative total across all strengths and dosage forms]	6 mL per 63 days [cumulative total across all strengths and dosage forms]

*Effective date to be determined.

Table 2. Quantity Level Limits – Quantity per Dispensing Event – Commercial and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Clobetasol Propionate Ophthalmic Suspension*	One (5 mL) bottle per fill	One (5 mL) bottle per fill
Lidocaine-HC Rectal Kits, Tubes*	1 kit or tube per dispensing event	1 kit or tube per dispensing event
Zelsuvmi (berdazimer sodium)*	1 carton (containing Tube A and Tube B) per dispensing event	1 carton (containing Tube A and Tube B) per dispensing event

*Effective date to be determined.

Quantity per dispensing event limits the quantity of medication that can be dispensed per each fill. If the submitted day supply on a claim is 34 days or less, the retail limit will apply. If the submitted day supply on a claim is greater than 34 days, the mail limit will apply.

Table 3. Maximum Daily Quantity Limits – Commercial and Healthcare Reform Plans

Drug Name	Daily Limit
Alvaiz (eltrombopag) 36 mg, 54 mg tablets	2 tablets per day
Alvaiz (eltrombopag) 9 mg, 18 mg tablets	1 tablet per day

*Quantity per Duration (QD) rule also applies to this medication (refer to Table 1).
Members can receive up to the maximum day supply according to their benefits, but the daily limit must not be exceeded for each individual day.

Requests for coverage of select medications exceeding the defined quantity level limits may be submitted for clinical review. Maximum-day supply on certain medications may vary depending on member's benefit design.

SECTION II. Highmark Medicare Part D Formularies

A. Changes to the Highmark Medicare Part D 5-Tier Open Formularies

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. For your convenience, you can search the Highmark Medicare Part D Formularies online at:

Incentive Formulary
Compass Formulary

Table 1. Preferred Products
Effective immediately pending Centers for Medicare and Medicaid Services (CMS) approval and upon completion of internal review and implementation.

No changes at this time.

Table 2. Non-Preferred Products
Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Preferred Alternatives
Jubbonti	denosumab-bbdz	alendronate oral tablet, ibandronate oral tablet, risedronate oral tablet
Legubeti	acetylcysteine	acetylcysteine inhalation solution
Clobetasol Propionate Ophthalmic Suspension	Clobetasol Propionate Ophthalmic Suspension	Prednisolone sodium phosphate 1%, prednisolone acetate 1%, fluorometholone 0.1% suspension

B. Changes to the Highmark Medicare Part D 5-Tier Closed Formularies

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. For your convenience, you can search the Highmark Medicare Part D Formularies online at:

- **Performance Formulary**
- **Venture Formulary**
- **Fundamental Formulary**

Table 1. Preferred Products
Effective immediately pending CMS approval and upon completion of internal review and implementation.

No changes at this time.

Table 2. Non-Preferred Products
Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Preferred Alternatives
Jubbonti	denosumab-bbdz	alendronate oral tablet ibandronate oral tablet risedronate oral tablet*

Table 3. Products Not Added*
Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Preferred Alternatives
Clobetasol Propionate Ophthalmic Suspension	Clobetasol Propionate Ophthalmic Suspension	Prednisolone sodium phosphate 1%, prednisolone acetate 1%, fluorometholone 0.1% suspension
Legubeti	acetylcysteine	acetylcysteine inhalation solution
Simlandi	adalimumab-ryvk	adalimumab-adaz, adalimumab-adbm, Cyltezo
Tyenne 162 mg/0.9 mL prefilled syringe/autoinjector	tocilizumab-aazg	Actemra ACTPen, Actemra
Tyenne vial	tocilizumab-aazg	Actemra ACTPen, Actemra
Wegovy Injection	semaglutide	atorvastatin; rosuvastatin

*Physicians may request coverage of these products using the Prescription Drug Medication Request Form.

C. Additions to the Specialty Tier
Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name
Aurlymyn	iloprost
Eohilia	budesonide oral suspension
Exblifep	cefepime/enmetazobactam
Wyost	denosumab-bbdz
Zelsuvmi	berdazimer sodium

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
EGFR-Targeting Kinase Inhibitors – Medicare	04/22/2024	Policy revised for Tagrisso (osimertinib) for new indication of first-line treatment of adult patients

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test, in combination with pemetrexed and platinum-based chemotherapy, and removal of age criteria for members 18 years of age or older.
Xolair (omalizumab) – Medicare	04/22/2024	Policy revised to remove age for all indications. New indication for food allergy requiring FDA-approved diagnosis confirmed by skin prick test or food specific antibodies and documented prescription for epinephrine. Reauthorization attesting continuation is needed and the member will continue food allergen avoidance.
Administrative Prior Authorizations for Medicare Part D Plans – Medicare	04/22/2024	Policy revised to add Aggrastat (tirofiban), Aurlumyn (iloprost) and Pemrydi RTU (pemtrexed disodium) and remove buprenorphine, deferoxamine, doxorubicin, fentanyl citrate, gallium and methadone as targets for BvD infusion pump review. Policy revised to add Qutenza (capsacin) as a target for incident to provider service review. Policy revised to define patient residence codes for Part BvD external infusion pump coverage.
Apokyn (apomorphine hydrochloride) – Medicare	04/22/2024	Policy revised to remove Kynmobi (apomorphine) since it is off market.
Atypical Antipsychotics – Medicare	04/22/2024	Policy revised to consolidate Latuda (lurasidone) from a separate policy into the Atypical Antipsychotic policy. No change in any of the approval criteria. Removed all age criteria from the policy.
BCR-ABL Kinase Inhibitors – Medicare	04/22/2024	Policy revised for Sprycel (dasatinib) to allow for use in pediatric patients with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in the chronic phase. Policy revised for Tasigna (nilotinib) to allow for diagnosis of Ph+ CML in the accelerated phase for pediatric patients.
BTK Inhibitors – Medicare	04/22/2024	Policy revised for Brukinsa (zanubrutinib) to require diagnosis based on expanded FDA-approved indication for follicular lymphoma.
Combogesic IV (acetaminophen and ibuprofen) – Medicare	04/22/2024	New policy created for Combogesic (acetaminophen/ibuprofen) IV (intravenous) to require that the member is using Combogesic (acetaminophen/ibuprofen) IV for either relief of

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		mild to moderate pain or the management of moderate to severe pain as an adjunct to opioid analgesics and the prescriber attests that the IV route of administration is considered clinically necessary, and the use of the medication is restricted to 5 days or less of therapy.
Dupixent (dupilumab) – Medicare	04/22/2024	Policy revised for Dupixent (dupilumab) to remove weight requirement eosinophilic esophagitis (EoE).
Eohilia (budesonide oral suspension) – Medicare	04/22/2024	New policy created for Eohilia (budesonide oral suspension) requiring FDA-approved indication confirmed by esophageal biopsy, and clinical symptoms of esophageal dysfunction. Therapy is limited to 12 weeks with no reauthorization.
FGFR Kinase Inhibitors – Medicare	04/22/2024	Policy revised for Balversa (erdafitinib) to require disease progression on or after at least one line of prior systemic therapy and member is FGFR3 mutation-positive based on updated FDA-approved indication.
Gralise (gabapentin extended-release) – Medicare	04/22/2024	Two strengths of generic Gralise (gabapentin extended-release) are now available; policy revised to differentiate between gabapentin extended-release (Gralise) and gabapentin immediate-release (Neurontin).
Isturisa (osilodrostat) – Medicare	04/21/2024	Policy terminated and combined with J-0175.
Katerzia (amlodipine benzoate) and Norliqva (amlodipine) – Medicare	04/22/2024	Policy revised for Katerzia (amlodipine benzoate) and Norliqva (amlodipine) to remove age criteria.
Latuda (lurasidone) – Medicare	04/21/2024	Policy will now be consolidated with J-0307 Atypical Antipsychotics - Medicare, this policy will be terminated.
Lidocaine Patches – Medicare	04/22/2024	Policy revised to add Dermacinrx Lidocan (lidocaine 5% patch) and Lidocan III (lidocaine 5% patch) to approval criteria for post-herpetic neuralgia and diabetic peripheral neuropathy to require diagnosis and one of the following: a) therapeutic failure, contraindication or intolerance to one other agent used to treat diagnosis, b) unable to swallow oral medications, or c) unable to take an oral medication due to potential adverse events.
Livmarli (maralixibat) – Medicare	04/22/2024	Policy revised to allow approval for expanded indication of diagnosis of progressive familial intrahepatic cholestasis (PFIC), confirmed by

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		genetic testing, and that the member does not have PFIC2 with an ABCB11 variant resulting in nonfunctional or absent bile salt export pump protein.
Lupkynis (voclosporin) – Medicare	04/22/2024	Policy revised for Lupkynis (voclosporin) to allow step through any mycophenolic acid analog. Azathioprine was added as an alternative maintenance therapy option in reauthorization.
MET Kinase Inhibitors – Medicare	04/22/2024	Policy revised to remove age requirement for Tepmetko (tepotinib) and Tabrecta (capmatinib).
Non-Preferred Baclofen Products – Medicare	04/22/2024	Removed strength from Baclofen Oral Solution; brand product, both strengths are included in policy.
PCSK9 Inhibitors – Medicare	04/22/2024	Policy revised for Praluent (alirocumab) for heterozygous familial hypercholesterolemia to require trial/failure/contraindication to plan-preferred Repatha (evolocumab) for members 10 years of age and older. For members 17 years of age and younger, require concurrent lipid-lowering therapy.
PI3K Inhibitors – Medicare	04/22/2024	Policy revised for Piqray (alpelisib) to remove requirement that the member is a postmenopausal female or male based on expanded FDA-approved indication. Policy revised to remove criteria for Ukoniq (umbralisib) as it is no longer available.
Programmed Death Receptor Therapies – Medicare	04/22/2024	Policy revised for Opdivo (nivolumab) to require diagnosis based on expanded FDA-approved indication for unresectable or metastatic urothelial carcinoma.
Qutenza (capsaicin) – Medicare	04/22/2024	New policy created for Qutenza (capsaicin) topical system requiring FDA-approved indication, the member has experienced either a therapeutic failure, contraindication or intolerance to one (1) systemic agent or member is unable to swallow oral medications or member is unable to take oral medication due to

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		potential adverse events, and if member has postherpetic neuralgia, they have also experienced therapeutic failure, contraindication or intolerance to either the Lidoderm patch 5% or lidocaine patch 5%.
Recorlev (levoketoconazole) – Medicare	04/21/2024	Policy terminated and combined with J-0175.
Rituximab Products – Medicare	04/22/2024	Policy revised to add Rituxan Hycela (rituximab/hyaluronidase) to require FDA-approved diagnosis and therapeutic failure or intolerance to either Truxima (rituximab-abbs) or Ruxience (rituximab-pvvr).
Rybrevant (amivantamab-vmjw) – Medicare	04/22/2024	Policy revised for Rybrevant (amivantamab-vmjw) to remove age limitation and to require diagnosis based on FDA-approved expanded indication. Quantity limit criteria revised to allow for max induction and maintenance dosing based on FDA label.
Signifor (pasireotide) Steroidogenesis Inhibitors – Medicare	04/22/2024	Policy revised for Signifor (pasireotide) to remove age requirement. Isturisa (osilodrostat) and Recorlev (levoketoconazole) added requiring FDA-approved diagnosis. For Isturisa (osilodrostat), age requirement removed for initial approval and authorization duration increased to 12 months.
Tzield (teplizumab-mzwv) – Medicare	04/22/2024	Policy revised for limitations of coverage to state that Tzield (teplizumab-mzwv) is for one course of treatment only and additional approvals should not be granted.
Wegovy (semaglutide) – Medicare	TBD	Policy created for Wegovy (semaglutide) requiring use for cardiovascular (CV) event risk reduction; pre-existing diagnosis of CV disease; baseline body mass index of ≥ 27 kg/m2; trial, failure or contraindication to moderate or high intensity statin therapy if > 75 years old, or use as an adjunct to moderate or high intensity statin therapy if ≤ 75 years old unless statin intolerant (defined as rhabdomyolysis or skeletal-related muscle symptoms while receiving at least two (2) separate trials of different statins which resolved upon discontinuation of the statins or one (1) of the following: creatinine kinase increase to 10 times upper limit of normal, liver function tests increase to 3 times upper limit of

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		normal, or hospitalization due to severe statin-related adverse event); attestation of concurrent use of a lifestyle modification program; and the medication will not be used in combination with another glucagon-like peptide-1 receptor agonist containing product. Reauthorization requiring attestation of continued need for therapy; concurrent use or trial/failure/contraindication to statin therapy; requested dose is 1.7 mg or 2.4 mg weekly; and concurrent use of lifestyle modification program. Limitation that request to reduce excess body weight and maintain weight reduction without preexisting cardiovascular disease will not be approved.

*All effective dates are tentative and subject to delay pending internal review or approval.

2. Updates to Step Therapy

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Non-Preferred ADHD Step Therapy - Medicare	04/22/2024	Policy revised to add Metadate CD (methylphenidate ER) for treatment of ADHD with therapeutic failure, contraindication, or intolerance to two generic medications: methylphenidate, dextroamphetamine/amphetamine, atomoxetine, or dexmethylphenidate.

3. Quantity Level Limit (QLL) Program

Effective date pending CMS approval, completion of internal review and implementation, unless otherwise noted.

Drug Name	Retail Edit Limit	Mail Edit Limit
Alvaiz (eltrombopag) 36 mg, 54 mg tablets	2 tablets per day	2 tablets per day
Alvaiz (eltrombopag) 9 mg, 18 mg tablets	1 tablet per day	1 tablet per day

Drug Name	Retail Edit Limit	Mail Edit Limit
Clobetasol Propionate Ophthalmic Suspension (Clobetasol Propionate Ophthalmic Suspension)	One (5 mL) bottle per fill	One (5 mL) bottle per fill
Eohilia (budesonide oral suspension)	168 single-dose stick packs per 365 days	168 single-dose stick packs per 365 days
Simlandi (adalimumab-ryvk)	2 autoinjectors per 28 days	6 autoinjectors per 84 days
Tyenne (tocilizumab-aazg) 162 mg/0.9 mL prefilled syringe/autoinjector	4 syringes/autoinjectors per 28 days	12 syringes/autoinjectors per 84 days
Xolair (omalizumab) autoinjector	2 mL per 21 days [cumulative total across all strengths and dosage forms]	6 mL per 63 days [cumulative total across all strengths and dosage forms]
Zelsuvmi (berdazimer sodium)	1 carton (containing Tube A and Tube B) per dispensing event	1 carton (containing Tube A and Tube B) per dispensing event

All effective dates are tentative and subject to delay, pending CMS approval, internal review, and implementation.