

Formulary Updates



August 2025

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for June 2025. The formularies and pharmaceutical management procedures are updated after each Pharmacy and Therapeutics Committee meeting, and the following changes reflect the decisions made in June 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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All references to "Highmark" in this document are references to the Highmark company that is providing the member's health benefits or health benefit administration and/or to one or more of its affiliated Blue companies.

Availity is an independent company that contracts with Highmark to offer provider portal services.

As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (PRC) (accessible via Availity Essentials® or our website). Once on the PRC, go to **Policies & Programs > Highmark Formulary** and then scroll down to find the formulary you're looking for.

Important Drug Safety Updates

[Amneal Pharmaceutical LLC Issues a Nationwide Recall of Sulfamethoxazole / Trimethoprim Tablets, USP, 400 mg/80 mg Only, Due to Microbial Contamination](#)

On June 02, 2025, Amneal Pharmaceutical LLC, is recalling three lots of Sulfamethoxazole/Trimethoprim Tablets, USP, 400 mg/80 mg to the consumer level as the tablets may exhibit black spots on the tablet surface due to microbial contamination. The observance of black spots was reported in a product quality complaint.

Oral products contaminated with *Aspergillus* may result in serious and life-threatening infections. The use of the defective product in patients with underlying immunosuppressive conditions increases the concern for serious infections. To date, Amneal Pharmaceuticals has received no reports of adverse events, illnesses, or injuries related to this recall.

[FDA requires warning about rare but severe itching after stopping long-term use of oral allergy medicines cetirizine or levocetirizine \(Zyrtec, Xyzal, and other trade names\)](#)

On May 16, 2025, the FDA released a Drug Safety Communication warning patients that stop the oral allergy medicines cetirizine (Zyrtec) or levocetirizine (Xyzal) after long-term use may experience rare but severe itching, also called pruritus. These medications are available in prescription and over-the-counter (OTC) forms. Itching has been reported in patients who used these medicines daily, typically for at least a few months and often for years. Itching typically occurred within a few days of stopping these medicines. Patients did not experience itching before starting these medicines. The FDA is adding a warning about the risk of itching after stopping long-term use of prescription cetirizine or levocetirizine to the prescribing information. Healthcare professionals should discuss the risk of pruritus after stopping long-term use of cetirizine or levocetirizine and encourage patients to contact their healthcare professional if they experience itching after stopping these medicines. Symptoms resolved in most patients who restarted the medicine and in some who tapered off the medicine after restarting it. To help FDA track safety issues with medicines, report side effects involving cetirizine and levocetirizine to the FDA MedWatch program.

[FDA adds warning about serious risk of heat-related complications with antinausea patch Transderm Scōp \(scopolamine transdermal system\)](#)

On June 18, 2025, the FDA released a Drug Safety Communication warning the antinausea patch Transderm Scōp (scopolamine transdermal system) can increase body temperature and cause heat-related complications, resulting in hospitalization or even death in some cases. Most cases occurred in children 17 years and younger and in adults 60 years and older. Increase in body temperature, also known as hyperthermia, occurred most often within 72 hours after the Transderm Scōp patch was applied to patients' bodies for the first time. The FDA is requiring the addition of a new warning about the risk of hypothermia to the Transderm Scōp prescribing information and patient information leaflet. Healthcare professionals should discuss the risk of hyperthermia and associated serious harms with patients when prescribing the Transderm Scōp patch. Patients should remove the patch and contact their healthcare professional if they experience hyperthermia symptoms. Symptoms of hyperthermia may persist after removal of the patch because the medicine will remain in the body for a period of hours to days. To help FDA track safety issues with medicines, report side effects involving Transderm Scōp patch to the FDA MedWatch program.

FDA requires expanded labeling about weight loss risk in patients younger than 6 years taking extended-release stimulants for ADHD

On June 30, 2025, the FDA released a Drug Safety Communication announcing labels will be updated for all extended-release stimulants indicated to treat attention-deficit/hyperactivity disorder (ADHD), including certain formulations of amphetamine and methylphenidate, to warn about the risk of weight loss and other adverse reactions in patients younger than 6 years taking these medications. This will harmonize labeling across the extended-release stimulant drug class. Extended-release stimulants are not approved for children younger than 6 years, but health care professionals can prescribe them "off label" to treat ADHD. The FDA has found that patients younger than 6 years taking extended-release stimulants have higher plasma exposures, and greater risk of weight loss and other side effects than older children taking the same medication at the same dosage. The FDA is requiring a Limitation of Use section in the prescribing information of all extended-release stimulants that includes a statement about higher plasma exposures and higher rates of adverse reactions in children younger than 6 years. Healthcare professionals should be aware that extended-release stimulants are not indicated to treat ADHD in children younger than 6 years because of greater risk of adverse. If a child younger than 6 years is taking an extended-release stimulant and experiencing weight loss or other adverse events, consider stopping the medication and/or switching to an alternative treatment (e.g., immediate-release stimulant, behavioral ADHD therapies). Healthcare professionals should monitor the child's growth and development and provide necessary interventions to mitigate weight loss. To help FDA track safety issues with medicines, report side effects involving extended-release stimulants to the FDA MedWatch program.

Highmark Formulary Update – June 2025

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 all medications added to the Comprehensive Closed/Incentive Formulary are also added to the Comprehensive Open Formulary. 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.

Brand Name	Generic Name	Comments
mNexspike	COVID-19 Vaccine, mRNA	Individuals who have been previously vaccinated with any COVID-19 vaccine and are 65 years of age and older, or 12 through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
Nuvaxovid	COVID-19 Vaccine, Adjuvanted	Active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults 65 years and older.; Active immunization for individuals 12 through 64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Arbli	losartan potassium	losartan potassium tablet, valsartan tablet, irbesartan
Atzumi	dihydroergotamine	sumatriptan succinate tablet, sumatriptan nasal spray

Brand Name	Generic Name	Preferred Alternatives
Avmapki Fakzynja	avutometinib capsules;defactinib tablets	Prescriber discretion
Blujepa	gepotidacin	Prescriber Discretion
Bomynta	denosumab-bnht	Prescriber Discretion
Brekiya	dihydroergotamine mesylate	sumatriptan succinate tablet, sumatriptan nasal spray
Bucapsol	bupirone hydrochloride	bupirone tablets
Conexence	denosumab-bnht	alendronate sodium tablet, risedronate sodium tablet 5 mg, risedronate sodium tablet 150 mg
Hemiclor	chlorthalidone	chlorthalidone, hydrochlorothiazide tablet, indapamide
Khindivi	hydrocortisone oral solution	hydrocortisone tablets
Livmarli tablet	maralixibat	Prescriber Discretion
Lopressor oral solution	metoprolol tartrate	metoprolol tartrate tablets
Mezofy	aripiprazole	aripiprazole tablets
Qfitlia	fitusiran	Prescriber Discretion
Starjemza 45 mg/0.5 mL, 90 mg/mL	ustekinumab-hmny	Yesintek 45 mg/0.5ml, Yesintek 90 mg/ml, Stelara Syringe 45mg/0.5ml Stelara Vial 45mg/0.5ml, Stelara Syringe 90 mg/mL
Tryptyr	acoltremon	cyclosporine 0.05%
Vanrafia	atrasentan	irbesartan oral tablet, losartan oral tablet, valsartan oral tablet
Vykat XR	diazoxide choline	Prescriber Discretion
Vyvgart Hytrulo syringe	efgartigimod alfa and hyaluronidase-qvfc	Prescriber Discretion

Coverage may be contingent upon plan benefits.

Physicians may request coverage of these products using the Prescription Drug Medication Request Form. To access this form for your region, go to the [Provider Resource Center](#) and choose your region from the top right. Select **Resources & Education > Forms > Pharmacy Prior Authorization Forms and then scroll down to the **Prescription Drug Medication Request Form**.

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. Once on the page, click on Healthcare Reform, which is under the "Line of Business" header.

Brand Name	Generic Name
Atzumi	dihydroergotamine
Avmapki Fakzynja	avutometinib capsules;defactinib tablets
Bomynta	denosumab-bnht

Brekiya	dihydroergotamine mesylate
Bucapsol	bupirone hydrochloride
Conexence	denosumab-bnht
Khindivi	hydrocortisone oral solution
Livmarli tablet	maralixibat
Mezofy	aripiprazole
Qfitlia	fitusiran
Starjemza	ustekinumab-hmny
Vanrafia	atrasentan
Vykat XR	diazoxide choline
Vyvgart Hytrulo syringe	efgartigimod alfa and hyaluronidase-qvfc

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

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
mNexspike	COVID-19 Vaccine, mRNA	3	Individuals who have been previously vaccinated with any COVID-19 vaccine and are 65 years of age and older, or 12 through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
Nuvaxovid	COVID-19 Vaccine, Adjuvanted	3	Active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults 65 years and older.; Active immunization for individuals 12 through 64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
Items listed below were not added to the formulary			
Arbli	losartan potassium	NF	losartan potassium tablet, valsartan tablet, irbesartan
Atzumi	dihydroergotamine	NF	sumatriptan succinate tablet
Avmapki Fakzynja	avutometinib capsules; defactinib tablets	NF	Prescriber discretion
Blujepa	gepotidacin	NF	fosfomycin tromethamine
Bomynta	denosumab-bnht	NF	Prescriber Discretion
Brekiya	dihydroergotamine mesylate	NF	sumatriptan succinate tablet

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Bucapsol	bupirone hydrochloride	NF	bupirone tablets
Conexence	denosumab-bnht	NF	Prolia
Hemiclor	chlorthalidone	NF	chlorthalidone, hydrochlorothiazide tablet, indapamide
Khindivi	hydrocortisone oral solution	NF	hydrocortisone tablets
Livmarli tablet	maralixibat	NF	Prescriber Discretion
Lopressor oral solution	Metoprolol Tartrate	NF	metoprolol tartrate tablets
Mezofy	aripiprazole	NF	aripiprazole tablets
Qfitlia	fitusiran	NF	Prescriber Discretion
Starjemza 45 mg/0.5 mL, 90 mg/mL	ustekinumab-hmny	NF	Yesintek 45 mg/0.5 ml, Yesintek 90 mg/ml, Stelara Syringe (mL) 45mg/0.5ml, Stelara Vial (mL) 45mg/0.5ml, Stelara Syringe (mL) 90 mg/mL
Tryptyr	acoltremon	NF	cyclosporine 0.05%
Vanrafia	atrasentan	NF	irbesartan oral tablet, losartan oral tablet, valsartan tablet
Vykat XR	diazoxide choline	NF	Prescriber discretion
Vyvgart Hytrulo syringe	efgartigimod alfa and hyaluronidase-qvfc	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).**

C. Changes to the Highmark Core Formulary

The Core Formulary is a closed formulary for select Commercial plans. A list of drugs included on the Core 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			
mNexspike	COVID-19 Vaccine, mRNA	3	Individuals who have been previously vaccinated with any COVID-19 vaccine and are 65 years of age and older, or 12 through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
Nuvaxovid	COVID-19 Vaccine, Adjuvanted	3	Active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults 65 years and older.; Active immunization for individuals 12 through 64

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
			years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
Items listed below were not added to the formulary			
Arbli	losartan potassium	NF	losartan potassium tablet, valsartan tablet, irbesartan
Atzumi	dihydroergotamine	NF	sumatriptan succinate tablet, sumatriptan nasal spray
Avmapki Fakzynja	avutometinib capsules;defactinib tablets	NF	Prescriber discretion
Blujepa	gepotidacin	NF	prescriber discretion
Bomynta	denosumab-bnht	NF	Prescriber Discretion
Brekiya	dihydroergotamine mesylate	NF	sumatriptan succinate tablet, sumatriptan nasal spray
Bucapsol	buspirone hydrochloride	NF	buspirone tablets
Conexence	denosumab-bnht	NF	Prolia
Hemiclor	chlorthalidone	NF	chlorthalidone, hydrochlorothiazide tablet, indapamide
Khindivi	hydrocortisone oral solution	NF	hydrocortisone tablets
Livmarli tablet	maralixibat	NF	Prescriber Discretion
Lopressor oral solution	Metoprolol Tartrate	NF	metoprolol tartrate tablets
Mezofy	aripiprazole	NF	aripiprazole tablets
Qfitlia	fitusiran	NF	Prescriber Discretion
Starjemza 45 mg/0.5 mL, 90 mg/mL	ustekinumab-hmny	NF	Yesintek 45 mg/0.5ml, Yesintek 90 mg/ml, Stelara Syringe (mL) 45mg/0.5ml, Stelara Vial (mL) 45mg/0.5ml, Stelara Syringe (mL) 90 mg/mL
Tryptyr	acoltremon	NF	cyclosporine 0.05%
Vanrafia	atrasentan	NF	irbesartan oral tablet, losartan oral tablet, valsartan tablet
Vykat XR	diazoxide choline	NF	Prescriber discretion
Vyvgart Hytrulo syringe	efgartigimod alfa and hyaluronidase-qvfc	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).**

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)			
Vanrafia	atrasentan	2	To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN)
Items listed below were added to the formulary (Non-Preferred)			
Arbli*	losartan potassium	3	losartan potassium tablet, valsartan tablet, irbesartan
Atzumi*	dihydroergotamine	3	sumatriptan succinate tablet, sumatriptan nasal spray, zolmitriptan nasal spray
Avmapki Fakzinja*	avutometinib capsules;defactinib tablets	3	Prescriber discretion
Blujepa*	gepotidacin	3	Prescriber Discretion
Bomynta*	denosumab-bnht	3	Prescriber Discretion
Brekiya*	dihydroergotamine mesylate	3	sumatriptan succinate tablet, sumatriptan nasal spray, zolmitriptan nasal spray
Conexence*	denosumab-bnht	3	alendronate sodium tablet, risedronate sodium tablet 5 mg, risedronate sodium tablet 150 mg
Khindivi*	hydrocortisone oral solution	3	hydrocortisone tablets
Livmarli tablet	maralixibat	3	prescriber discretion
Lopressor oral solution*	Metoprolol Tartrate	3	metoprolol tartrate tablets
Mezofy*	aripiprazole	3	aripiprazole tablets
mNexspike*	COVID-19 Vaccine, mRNA	3	Comirnity, Spikevax
Nuvaxovid*	COVID-19 Vaccine, Adjuvanted	3	Comirnity, Spikevax
Starjemza 45 mg/0.5 mL*	ustekinumab-hmny	3	Yesintek 45 mg/0.5 ml, Stelara Syringe (mL) 45mg/0.5ml Stelara Vial (mL) 45mg/0.5ml
Starjemza 90 mg/mL*	ustekinumab-hmny	3	Yesintek 90 mg/ml, Stelara Syringe (mL) 90 mg/mL
Tryptyr*	acoltremon	3	cyclosporine 0.05%
Vykat XR 150 mg	diazoxide choline	3	prescriber discretion
Vykat XR 25 mg	diazoxide choline	3	prescriber discretion
Vykat XR 75 mg	diazoxide choline	3	prescriber discretion
Vyvgart Hytrulo	efgartigimod alfa and hyaluronidase-qvfc	3	prescriber discretion
Items listed below were not added to the formulary			

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Bucapsol 10 mg	bupirone hydrochloride	NF	bupirone tablets
Hemiclor	chlorthalidone	NF	chlorthalidone, hydrochlorothiazide tablet, indapamide
Qfitlia	fitusiran	NF	Alhemo, Hemlibra, Hymfavzi

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

Brand Name	Generic Name
Atzumi	dihydroergotamine
Avmapi Fakzynja	avutometinib capsules;defactinib tablets
Bomynta	denosumab-bnht
Brekiya	dihydroergotamine mesylate
Bucapsol	bupirone hydrochloride
Conexence	denosumab-bnht
Khindivi	hydrocortisone oral solution
Livmarli	maralixibat
Mezofy	aripiprazole
Qfitlia	fitusiran
Starjemza	ustekinumab-hmny
Vanrafia	atrasentan
Vykat XR	diazoxide choline
Vyvgart Hytrulo syringe	efgartigimod alfa and hyaluronidase-qvfc

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Anti-Angiogenesis and VEGF Kinase Inhibitors – Commercial and Healthcare Reform	07/18/2025	Policy revised for Cabometyx (cabozantinib) to require age and diagnosis based on FDA-approved expanded indications for pancreatic neuroendocrine tumors and extra-pancreatic neuroendocrine tumors.
Anti-Obesity – Administrative Services Only (ASO) Commercial	07/18/2025	Policy revised for all targets for continuation and maintenance therapy to specify that comorbidities are required at baseline. Policy revised to add heart failure with preserved ejection fraction as an obesity related comorbidity.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Anti-Obesity – Fully Insured Commercial and Healthcare Reform	07/18/2025	<p>Policy revised for Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide) for maintenance therapy to specify that two comorbidities are required at baseline. For Saxenda (liraglutide) and Wegovy (semaglutide) for maintenance approval in pediatric patients, required weight loss revised to a 5% reduction in BMI. For Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide), allowable comorbidities updated to the following clinical manifestations of excess adiposity: chronic, severe knee or hip pain; atrial fibrillation; coronary artery disease; heart failure with preserved ejection fraction; heart failure with reduced ejection fraction; hypertension; myocardial infarction; peripheral arterial disease; peripheral vascular disease; pulmonary arterial hypertension; recurrent deep vein thrombosis or pulmonary thromboembolic disease; stroke; prediabetes demonstrated by an A1c of 5.7% to 6.4%, fasting plasma glucose of 100 mg/dl to 125 mg/dl, or oral glucose tolerance test of 140 to 199 mg/dl, high triglycerides (≥ 150 mg/dl), and low high-density lipoprotein (< 40 mg/dl for men, or < 50 mg/dl for women); idiopathic intracranial hypertension; lower limb lymphedema; male hypogonadism; microalbuminuria with reduced estimated glomerular filtration rate; metabolic dysfunction-associated steatotic liver disease with hepatic fibrosis; obstructive sleep apnea; polycystic ovarian syndrome, anovulation, or oligo-menorrhea; recurrent or chronic urinary incontinence; reduced lung and/or diaphragmatic compliance resulting in hypoventilation, breathlessness, or wheezing; significant, age-adjusted limitations of mobility and/or other basic activities of daily living.</p>
Apomorphine Products – Commercial and Healthcare Reform	07/18/2025	<p>Policy updated for Onapgo (apomorphine hydrochloride) injection to remove therapeutic failure or intolerance to generic apomorphine hydrochloride injection.</p>

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
BCR-ABL Kinase Inhibitors – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy revised to add generic nilotinib as a target and for brand Tassigna (nilotinib) and Danziten (nilotinib) to require therapeutic failure or intolerance to generic nilotinib for initial and reauthorization.
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Commercial and Healthcare Reform	07/18/2025	Policy revised to add Avmapki Fakzynja Co-Pack (avutometinib; defactinib) to require age and diagnosis based on FDA-approved indication.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	04/25/2025	Policy revised to update Tremfya (guselkumab) for CD requires received or currently undergoing IV induction therapy or using Tremfya SC for induction dosing.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy revised for Rinvoq ER (upadacitinib) to add new indication giant cell arteritis to require diagnosis and age based on FDA approved indication, prescribed in consultation with a rheumatologist, and therapeutic failure, intolerance or contraindication to a systemic corticosteroid. Policy revised to add ustekinumab-aekn as a non-preferred ustekinumab product.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	06/16/2025	Policy revised to add Yesintek (ustekinumab-kfce) as a preferred ustekinumab product.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	06/20/2025	Policy revised for Tremfya (guselkumab) to remove maintenance dosing criteria for ulcerative colitis and Crohn's disease.
Chronic Inflammatory Diseases – Commercial National Select Formulary	04/25/2025	Policy revised to update Tremfya (guselkumab) for CD requires received or currently undergoing IV induction therapy or using Tremfya SC for induction dosing.
Chronic Inflammatory Diseases – Commercial National Select Formulary	Effective upon completion of internal review and implementation.	Policy revised for Rinvoq ER (upadacitinib) to add new indication giant cell arteritis to require diagnosis and age based on FDA approved indication, prescribed in consultation with a rheumatologist, and therapeutic failure, intolerance or contraindication to a systemic corticosteroid. Policy revised to add ustekinumab-aekn as a non-preferred ustekinumab product.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Chronic Inflammatory Diseases – Commercial National Select Formulary	06/16/2025	Policy revised to add Yesintek (ustekinumab-kfce) as a preferred ustekinumab product.
Chronic Inflammatory Diseases – Commercial National Select Formulary	06/20/2025	Policy revised for Tremfya (guselkumab) to remove maintenance dosing criteria for ulcerative colitis and Crohn's disease.
Clotting Factor Products – Commercial and Healthcare Reform	07/18/2025	Policy revised to add Qfitlia (fitusiran) requiring age, diagnosis based on FDA-approved indication, severe disease confirmed by factor levels, previously taken a factor replacement therapy if no documented history of inhibitors, and documentation of antithrombin (AT) activity >60% prior to treatment. For reauthorization, disease stability, improvement, or delayed disease progression, and documentation of AT activity 15%-35. If AT < 15%, the member is undergoing dose reduction and if AT >35% the member is undergoing dose escalation. Quantity limit exception for 1 pen/vial per month allowed if AT >35% after 6 months or the member has not achieved satisfactory bleed control. Initial authorization and quantity limit duration is 6 months; reauthorization duration is 12 months.
Denosumab Products for Oncology – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy revised to add Bomynta (denosumab-bnht) to require age and diagnosis based on FDA-approved indication and therapeutic failure/intolerance to Xgeva (denosumab). Policy revised for Osenvelt (denosumab-bmwo), Wyost (denosumab-bbdz), and Xbryk (denosumab-dssb) to require therapeutic failure or intolerance to Xgeva (denosumab).
Dificid (fidaxomicin) – Commercial and Healthcare Reform	07/18/2025	Policy revised for Dificid (fidaxomicin) to include reauthorization requiring the member to have a recurrence of Clostridium difficile (C. difficile) with an episode of symptom onset (for example, unexplained or new onset loose bowel movements) and one of the following: a

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		positive nucleic acid amplification test (NAAT) or polymerase chain reaction (PCR) result for <i>C. difficile</i> , a positive glutamate dehydrogenase (GDH) test result, a positive enzyme immunoassay (EIA) for <i>C. difficile</i> toxin, or a positive stool culture for <i>C. difficile</i> .
Dihydroergotamine Products – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy revised to add Atzumi (dihydroergotamine mesylate) nasal powder and Brekiya (dihydroergotamine mesylate) autoinjector to require FDA-approved indication and that the member requires a non-oral route of administration. For Atzumi, the member must experience therapeutic failure, contraindication, or intolerance to generic sumatriptan nasal spray and zolmitriptan nasal spray. For Brekiya, the member must experience therapeutic failure, contraindication or intolerance to generic sumatriptan injection and contraindication or intolerance to generic dihydroergotamine injection.
Dupixent (dupilumab) – Commercial and Healthcare Reform	07/18/2025	Policy revised for Dupixent (dupilumab) to add new indication of chronic spontaneous urticaria (CSU) to require diagnosis and age based on FDA approved indication, therapeutic failure, contraindication or intolerance to a second-generation non-sedating H1 antihistamine at the maximum recommended dose and reauthorization requiring the member has improved CSU symptoms.
Duvyzat (givinostat) – Commercial and Healthcare Reform	07/18/2025	Policy revised for Duvyzat (givinostat) to require that the member is stable on corticosteroid therapy for at least 6 months for initial and reauthorization criteria. For reauthorization, the member continues to be ambulatory.
Experimental and Investigational Products – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	New policy for experimental and investigational products. Leqembi (lecanemab) subcutaneous (SC) added with criteria that no exception will be made for experimental and investigational products.
Eysuvis – Commercial and Healthcare Reform	TERMED 7/1/2025	Policy terminated, criteria moved to J-0845.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Filspari (sparsentan) and Vanrafia (atrasentan) – Commercial and Healthcare Reform	07/18/2025	Policy revised to add Vanrafia (atrasentan) as a target requiring FDA-approved age, diagnosis of primary immunoglobulin A nephropathy, proteinuria ≥ 0.5 g/day, and concurrent use of or intolerance/contraindication to an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB). For reauthorization, the member must experience a decrease in proteinuria from baseline and be concurrently using, or have intolerance/contraindication to, an ACE or ARB. For all targets, initial authorization duration extended to 12 months.
Hydrocortisone Products – Commercial and Healthcare Reform	07/18/2025	Policy revised for Khindivi (hydrocortisone) oral solution to ensure that members have a diagnosis of adrenocortical insufficiency. The member is between the age of 5 and 17 years of age. The prescriber attests that the member is not experiencing adrenal stress or acute events and have experienced therapeutic failure or intolerance to generic hydrocortisone tablets.
Gonadotropin-Releasing Hormone (GnRH) Agonists – Commercial and Healthcare Reform	07/18/2025	Policy revised to add Lutrate Depot (leuprolide acetate) as a target requiring FDA-approved diagnosis and trial/failure of Eligard (leuprolide acetate). Reauthorization requires positive clinical response and continued need for therapy.
Interleukin (IL)-5 Antagonists – Commercial and Healthcare Reform	07/18/2025	Policy revised for Nucala (mepolizumab) to include chronic obstructive pulmonary disease (COPD) with an initial authorization requiring all of the following: the member is 18 years of age and older, a diagnosis of COPD (ICD: 10: J41-J44), a post-bronchodilator FEV1 $\leq 80\%$ predicted, a blood eosinophil count of ≥ 300 cells/mcL or the member is currently taking daily or alternate-day oral corticosteroids, a modified Medical Research Council dyspnea scale score of ≥ 2 , the member meets one of the following criteria: an exacerbation history of at least two moderate exacerbations resulting in

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		<p>treatment with systemic corticosteroids and/or antibiotics in the previous year, one severe exacerbation resulting in hospitalization or observation in the emergency department for over 24 hours in the previous year, or GOLD group E and the member has inadequate symptom control despite regular treatment for at least 3 months with triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (LAMA/LABA/ICS), unless intolerant of, or has contraindications to these agents. Policy updated to include when a benefit, reauthorization may be approved when one (1) of the following criteria is met: The prescriber attests that the member has experienced a reduction in symptoms of chronic obstructive pulmonary disease (COPD), the prescriber attests that the member has experienced an improvement in exercise tolerance, the prescriber attests that the member has experienced delayed disease progression, or the prescriber attests that the member has experienced a reduction in the number of exacerbations.</p>
Interleukin-1 β blockers – Commercial and Healthcare Reform	07/18/2025	Policy revised for Ilaris (canakinumab) to remove criteria from Adult-Onset Still's Disease requiring failure of a nonsteroidal anti-inflammatory drug, corticosteroid and disease-modifying antirheumatic drug (DMARD), and remove criterion from systemic juvenile idiopathic arthritis (SJIA) requiring failure of a DMARD.
Isturisa (osilodrostat) – Commercial and Healthcare Reform	07/18/2025	Policy revised for Isturisa (osilodrostat) to require diagnosis of Cushing's syndrome.
Leqembi SC (lecanemab-irmb) – Commercial and Healthcare Reform – Delaware	Effective upon completion of internal review and implementation.	New policy for subcutaneous (SC) Leqembi (lecanemab-irmb) for Delaware Commercial Fully Insured and Delaware Healthcare Reform plans requiring diagnosis of Alzheimer's disease with mild cognitive impairment or mild dementia, the member has completed the required

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		<p>number of initiation intravenous (IV) infusions per FDA labeling, prior to initiation of IV Leqembi there was documentation of baseline functional and/or cognitive status including both the clinical dementia rating-global score (CDR-GS) and the mini-mental state examination (MMSE) score of ≥ 19, prior to initiation of IV Leqembi the member has not experienced localized superficial siderosis, \geq ten brain microhemorrhages, or brain hemorrhage greater than one centimeter, the member is not taking anticoagulant or antiplatelet agents (except for aspirin), the prescriber has ruled out all other possible causes of cognitive impairment or dementia, and prior to initiation of IV Leqembi the member has undergone ApoE ϵ4 genetic testing. Reauthorization requires documentation that the member has stable or improved disease, documentation that the member has not progressed to moderate or severe disease as indicated by MMSE score ≥ 19 and CDR-GS ≤ 1 or CDR-Sum of Boxes ≤ 9, and the member has obtained the required number of brain MRIs per FDA labeling.</p>
Livmarli (maralixibat) – Commercial and Healthcare Reform	07/18/2025	<p>Policy revised to include newly FDA-approved Livmarli (maralixibat) tablets. In addition to existing prior authorization, if the request is for the tablets, for either diagnosis, the member must be ≥ 25 kg and be able to swallow tablets. Quantity limit approval criteria added for tablets to allow for maximum maintenance dosing per FDA labeling.</p>
Market Watch Programs – Delaware	Effective upon completion of internal review and implementation.	<p>Policy revised to add target of Hemiclor (chlorthalidone) with alternatives of chlorthalidone, hydrochlorothiazide, and indapamide. Policy revised to add target of Bucapsol (buspirone HCl) with alternative of buspirone tablets. Policy revised to add target of Khindivi (hydrocortisone) with alternative of hydrocortisone tablets.</p>
Market Watch Programs – New York,	Effective upon completion of	<p>Policy revised to add target of Hemiclor (chlorthalidone) with alternatives of</p>

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Pennsylvania, and West Virginia	internal review and implementation.	chlorthalidone, hydrochlorothiazide, and indapamide. Policy revised to add target of Bucapsol (buspirone HCl) with alternative of buspirone tablets. Policy revised to add target of Khindivi (hydrocortisone) with alternative of hydrocortisone tablets.
Miebo (perfluorohexyloctane) – Commercial and Healthcare Reform	TERMED 7/1/2025	Policy terminated, criteria moved to J-0845.
Ongentys (opicapone) – Commercial and Healthcare Reform	07/18/2025	Policy revised for reauthorization of Ongentys (opicapone) to require use as an adjunct to carbidopa/levodopa.
Dry Eye Disease Products – Commercial and Healthcare Reform	07/02/2025	Policy revised to move Eysuvis (loteprednol etabonate), Miebo (perfluorohexyloctane), and Tyrvaya (varenicline) to this policy. Policy criteria changed for Cequa (cyclosporine), Miebo (perfluorohexyloctane), Tyrvaya (varenicline), and Vevye (cyclosporine) to require verification of pharmacy claims or documented chart notes for trial of cyclosporine and Xiidra (lifitegrast). Policy revised to require age of 18 years of age or older for Eysuvis (loteprednol etabonate) and 16 years of age or older for Restasis (cyclosporine).
Dry Eye Disease Products – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy revised to add Tryptyr (acoltremon) requiring FDA approved diagnosis and age and therapeutic failure, contraindication, or intolerance to artificial tears, cyclosporine, and Xiidra (lifitegrast). Use must be verified by pharmacy claims or documented chart notes for cyclosporine and Xiidra.
Opzelura (ruxolitinib) – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy revised for Opzelura (ruxolitinib) to change initial authorization duration to 16 weeks.
Denosumab Products for Bone Disease and Evenity (romosozumab-aqqg) – Commercial and Healthcare Reform		Policy revised to add Conexence (denosumab-bnht) 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,

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		and is not using product with other injectable osteoporosis medications. Conexence requires trial and failure of Prolia (denosumab).
Denosumab Products for Bone Disease and Evenity (romosozumab-aqqg) – Commercial and Healthcare Reform	06/03/2025	Policy revised for Jubbonti (denosumab-bbdz) to require diagnosis based on FDA-approved indication and trial/failure/contraindication to Prolia (denosumab). Use for osteoporosis or osteopenia (including glucocorticoid-induced osteoporosis) must be supported by lab values such as T-score or FRAX calculator, and trial/failure/contraindication to one bisphosphonate.
Omalizumab Products (Syringe and Autoinjector) – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy revised to include Omlyclo (omalizumab-igec), a new interchangeable biosimilar to Xolair. For all four FDA-approved indications (asthma, chronic spontaneous urticaria [CSU], chronic rhinosinusitis with nasal polyps [CRSwNP] and IgE-mediated food allergy), in addition to existing criteria, initial authorization as well as reauthorizations, if the request is for Xolair, the member must have experienced therapeutic failure or intolerance to plan-preferred Omlyclo.
Omalizumab Products (Syringe and Autoinjector) – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy revised to include Omlyclo (omalizumab-igec), a new interchangeable biosimilar to Xolair. For all four FDA-approved indications (asthma, chronic spontaneous urticaria [CSU], chronic rhinosinusitis with nasal polyps [CRSwNP] and IgE-mediated food allergy), initial authorization as well as reauthorizations, in addition to existing criteria, if the request is for Omlyclo, the member must have experienced therapeutic failure or intolerance to plan-preferred Xolair.
Rezdiffra (resmetirom) – Commercial and Healthcare Reform	07/18/2025	Policy revised to require prescription by a gastroenterologist or hepatologist and require liver biopsy or non-invasive test with imaging.
Rivfloza (nedosiran) – Commercial and Healthcare Reform	07/18/2025	Policy revised to update age limit to 2 years of age or older for expanded indication of Rivfloza (nedosiran).

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Savella (milnacipran) – Commercial and Healthcare Reform	07/18/2025	Policy revised for Savella (milnacipran) to require an additional step through plan preferred pregabalin.
Sucraid (sacrosidase) – Commercial and Healthcare Reform	07/18/2025	Policy revised for Sucraid (sacrosidase) to add genetic testing indicating a mutation in the sucrase-isomaltase gene as an option to support the diagnosis of congenital sucrase-isomaltase deficiency.
Testosterone (Androgens) – Commercial and Healthcare Reform		Policy revised for testosterone to include in the reauthorization that the provider submits documentation of a testosterone level within the past 12 months and meets 1 of the following criteria: the member's testosterone level is within normal limit or the member's testosterone is out of normal limit and the provider attests the dosage is being adjusted if the member has hypogonadism.
Thrombopoiesis Stimulating Agents – Commercial and Healthcare Reform	07/18/2025	Policy revised for brand Promacta (eltrombopag olamine) and Alvaiz (eltrombopag choline) to require intolerance to generic eltrombopag olamine if brand is requested.
Transthyretin Amyloid Cardiomyopathy (ATTR-CM) TTR Stabilizers – Commercial and Healthcare Reform	07/18/2025	Policy revised for all targets requiring documentation of cardiac involvement supported by cardiac magnetic resonance, echocardiography, or serum cardiac biomarkers. Policy revised for all targets to require that scintigraphy be used with radiotracers resulting in a heart to lung contralateral of greater than 1.5 or visual grade 2 to 3. For all targets, initial and reauthorization criteria revised to require that the member is not simultaneously utilizing transthyretin-lowering agents other than the requested drug.
Transthyretin-Directed Antisense Oligonucleotides – Commercial and Healthcare Reform	07/18/2025	Policy revised to remove Tegsedi (inotersen) as it is off-market. Policy revised to state member is not simultaneously utilizing transthyretin-lowering agents other than the requested drug.
Tyvaya (varenicline solution) – Commercial and Healthcare Reform	TERMED 7/1/2025	Policy terminated, criteria moved to J-0845.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Ustekinumab Biosimilars – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy revised to add new product Starjemza (ustekinumab-hmny) subcutaneous (SC) injection requiring age, FDA-approved diagnosis, specialist, dosing based on FDA-approved weight). For psoriatic arthritis, trial/failure to one nonsteroidal anti-inflammatory drug (NSAID), non-biologic DMARD, or local glucocorticoid injection depending on disease classification. For plaque psoriasis, trial/failure to phototherapy or systemic therapy, or contraindication to all. For Crohn's disease and ulcerative colitis, if the request is for SC, prescriber attestation of ustekinumab IV induction dose received within 2 months or currently undergoing induction. Reauthorization of positive clinical response to therapy. Non-preferred ustekinumab products are directed to preferred products Stelara (ustekinumab) and Yesintek (ustekinumab-fkce).
Veozah (fezolinetant) – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy revised for Veozah (fezolinetant) to require step through generic hormone therapy product or a plan preferred non-hormonal product, and that the member received baseline hepatic laboratory tests prior to initiation of Veozah for initial criteria. Reauthorization revised to require that the member has had periodic hepatic laboratory tests confirming continuation of therapy is appropriate.
Vorango (vorasidenib) – Commercial and Healthcare Reform	07/18/2025	Policy revised for Vorango (vorasidenib) to include revised FDA-approved indication for diagnosis of Grade 2 astrocytoma or Grade 2 oligodendroglioma with susceptible isocitrate dehydrogenase (IDH)-1 or IDH2 mutation, as detected by an FDA-approved test.
Vowst (fecal microbiota spores, live-brpk) – Commercial and Healthcare Reform	07/18/2025	Policy revised for Vowst (fecal microbiota spores, live-brpk) to require diagnosis of <i>Clostridioides difficile</i> infection (CDI) confirmed by positive stool test.
Voydeya (danicipan) – Commercial and Healthcare Reform	07/18/2025	Policy revised for Voydeya (danicipan) reauthorization to require continued use in combination with ravulizumab or

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		eculizumab and updated criterion to be a decrease in reticulocyte count.
Vtama (tapinarof) and Zoryve (roflumilast) – Commercial and Healthcare Reform	07/18/2025	Policy revised for Zoryve (roflumilast) topical foam to add new indication of plaque psoriasis requiring age, diagnosis, and trial/failure/contraindication to one generic formulary vitamin D analog or psoriasis on the face.
Vykat XR (diazoxide choline) –Commercial and Healthcare Reform	07/18/2025	New policy created for Vykat XR (diazoxide choline) to require that the member must be 4 years of age or older, have a diagnosis of Prader-Willi syndrome (PWS) confirmed by documentation of genetic analysis with identification of abnormal DNA methylation of chromosome 15q11.2-q13, and the member is experiencing hyperphagia due to the PWS diagnosis. For reauthorization, the prescriber attests that the member has experienced a decrease in hyperphagic and food-related behaviors.
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) – Commercial and Healthcare Reform	07/18/2025	New policy created for the prefilled syringe formulation of Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) requiring diagnosis based on FDA-approved indication of generalized myasthenia gravis (gMG), age greater than 18, the member has the Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV, the member has a Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score of five (5) or greater at initiation, the member has experienced therapeutic failure, contraindication to all, or intolerance to at least two different agents from two different classes, used alone or in combination: acetylcholinesterase inhibitors, systemic steroids, non-steroidal immunosuppressants, and the member is not concurrently receiving a complement inhibitor (for example, Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), Zilbrysq (zilucoplan) or intravenous immunoglobulin (IVIG)) within four weeks of starting Vyvgart Hytrulo. For reauthorization, the

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		<p>member has experienced one of the following: the member has experienced improvement in signs and symptoms of gMG (for example, speech, swallowing, mobility, and/or respiratory function) or the member has experienced a decrease in the number of exacerbations of gMG. For chronic inflammatory demyelinating polyneuropathy (CIDP), the member has a diagnosis based on the FDA-approved indication supported by diagnostic criteria, is at least 18 years of age and trial/failure to a systemic corticosteroid or an immune globulin or contraindication to all. Reauthorization requires improvement in fictional ability or strength from baseline.</p>
<p>Welireg (belzutifan) – Commercial and Healthcare Reform</p>	<p>07/18/2025</p>	<p>Policy revised for Welireg (belzutifan) to require diagnosis of advanced renal cell carcinoma with a clear cell component based on updated FDA-approved indication. Policy revised to require age and diagnosis of pheochromocytoma or paraganglioma based on expanded FDA-approved indication.</p>
<p>Xenazine (tetrabenazine) – Commercial and Healthcare Reform</p>	<p>07/18/2025</p>	<p>Policy revised for Xenazine (tetrabenazine) requiring members to be 18 years of age or older.</p>
<p>Xolair (omalizumab) Syringe and Autoinjector Omalizumab Products (Syringe and Autoinjector)</p>	<p>07/18/2025</p>	<p>Policy updated for Xolair (omalizumab) to require the member has inadequate symptom control despite regular treatment with medium- or high-dose inhaled corticosteroids (ICS) and at least one additional asthma controller (for example, long-acting beta-2 agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), with or without oral corticosteroids (OCS), unless intolerant of, or has contraindications to all of these agents and the member will continue treatment with medium- or high-dose ICS and at least one additional asthma controller (for example, LABA, LTRA, or theophylline), with or without OCS, while using Xolair.</p>

*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	Effective upon completion of internal review and implementation.	Policy terminated
Atypical Antipsychotics – Commercial	Effective upon completion of internal review and implementation.	Policy revised to add Mezofy (aripiprazole) oral film requiring age of 13 years or older, diagnosis of schizophrenia and either prescriber attestation that the member has inability to swallow oral tablets or experienced trial and failure to plan preferred aripiprazole tablets.
Atypical Antipsychotics – Healthcare Reform	Effective upon completion of internal review and implementation.	Policy revised to add Mezofy (aripiprazole) oral film requiring age of 13 years or older, diagnosis of schizophrenia and either prescriber attestation that the member has inability to swallow oral tablets or experienced trial and failure to plan preferred aripiprazole tablets.
Benzodiazepines for Emergency Use – Commercial and Healthcare Reform	05/28/2025	Policy revised to change age limit for Valtoco (diazepam) to 2 years of age or older.
Brand Reliever Inhalers – Commercial and Healthcare Reform	07/18/2025	Policy updated to require the member to experience a therapeutic failure or intolerance to all of the following being utilized as needed for Airsupra (budesonide and albuterol): an inhaled corticosteroid-formoterol combination product and an inhaled corticosteroid and albuterol product.
Bucapsol (buspirone) – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy created to require members meet the following criteria for coverage of Bucapsol (buspirone): member must have a diagnosis of generalized anxiety disorder (ICD-10: F41), the member is unable to swallow tablets and the prescriber attests that the member lacks the ability to crush tablets. For reauthorization, the prescriber attests that the member has experienced

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		positive clinical response to therapy and the member continues to be unable to swallow tablets.
Bucapsol (buspirone) – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy created to require members meet the following criteria for coverage of Bucapsol (buspirone): member must have a diagnosis of generalized anxiety disorder (ICD-10: F41) and the member is unable to swallow tablets. For reauthorization, the prescriber attests that the member has experienced positive clinical response to therapy and the member continues to be unable to swallow tablets.
Colony-Stimulating Factors – Commercial and Healthcare Reform	07/18/2025	Policy revised for Releuko (filgrastim-ayow) to align with FDA-approved indication. Therapeutic failure or intolerance to Nivestym (filgrastim-aafi) required when using to mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
Digitized Inhalers – Commercial and Healthcare Reform	Termed 7/1/2025	Policy terminated
Direct Oral Anticoagulants (DOACs) – Commercial and Healthcare Reform	07/18/2025	Policy revised for Pradaxa (dabigatran etexilate) capsules for initial and reauthorization to require trial/failure/contraindication to plan-preferred Eliquis (apixaban) in pediatric patients.
Edarbi (azilsartan) – Healthcare Reform Essential Formulary	Effective upon completion of internal review and implementation.	Policy terminated.
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) for Diabetes – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy revised for all targets to require documentation of diabetes diagnosis.
Insomnia Medications – Commercial and Healthcare Reform	Effective upon completion of internal review and implementation.	Policy revised to remove Zolpimist (zolpidem tartrate) nasal spray as it is no longer on market and to add Doral (quazepam) requiring diagnosis, step through quazepam and two of the following plan preferred agents

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		(zolpidem tartrate tablets, zolpidem tartrate ER, eszopiclone and zaleplon). Policy revised for Belsomra (suvorexant), Dayvigo (lemborexant) and Quviviq (daridorexant) to require members to be 18 years of age or older.
Liquid Formulations of Anti-Hypertensive Medications – Commercial and Healthcare Reform	Effective Upon Completion Of Internal Review And Implementation.	Policy revised to add Arbli (losartan potassium) and Lopressor (metoprolol tartrate) oral solution requiring FDA approved age and diagnosis, inability to swallow tablets whole, therapeutic failure or intolerance to a plan-preferred alternative tablet or capsule with the same active ingredient and reauthorization requiring prescriber attestation that the member has experienced positive clinical response to therapy and continued inability to swallow tablets whole.
Non-Preferred Inhaler Products – Commercial and Select Healthcare Reform	07/18/2025	Policy revised to include the authorized generic of umeclidinium/vilanterol to require a diagnosis of chronic obstructive pulmonary disease (COPD) and if the request is for umeclidinium/vilanterol, the member has experienced therapeutic failure or intolerance to brand Anoro Ellipta (umeclidinium/vilanterol).
Non-Preferred Selective Serotonin Reuptake Inhibitors (SSRIs) – Commercial and Healthcare Reform	07/18/2025	Policy revised to include escitalopram oral solution, 10 mg/10 mL. Member must have an FDA approved diagnosis and be 12 years or older for a major depressive disorder diagnosis (MDD) or 18 years or older for a generalized anxiety disorder (GAD) diagnosis. In addition, the member must have experienced therapeutic failure or intolerance to plan-preferred escitalopram oral solution 5 mg/5 mL and the member has an inability to swallow tablets. For reauthorization, the prescriber attests that the member has experienced positive clinical response to therapy and the member continues to have an inability to swallow tablets.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Non-preferred Statins – Healthcare Reform Essential	07/18/2025	Policy revised to include age of 18 years or older for Roszet (rosuvastatin/ezetimibe)
Topical Acne Products – Commercial and Healthcare Reform	07/01/2025	Policy revised to add Evoclin (clindamycin phosphate) 1% foam to require diagnosis, age and trial and failure to 1 plan preferred generic from 2 different therapeutic categories (topical retinoids and topical antibiotics).
Yupelri (revefenacin) – Commercial and Healthcare Reform	07/18/2025	Policy revised to remove age limit from automatic approval criteria.

*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

No changes at this time.

4. Quantity Level Limit (QLL) Programs*

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

Drug Name	Retail Edit Limit	Mail Edit Limit
Atzumi (dihydroergotamine)	12 nasal powder/devices per 30 days	36 nasal powder/devices per 90 days
Avmapki Fakzynja (avutometinib capsules;defactinib tablets)	1 carton (24 Avmapki capsules, 42 Fakzynja tablets) per 28 days	3 cartons (72 Avmapki capsules; 126 Fakzynja tablets) per 84 days
Brekiya (dihydroergotamine mesylate)	24 autoinjectors per 28 days	72 autoinjectors per 84 days
Eohilia (budesonide oral suspension)	180 single-dose stick packs (1800 mL) per 365 days	180 single-dose stick packs (1800 mL) per 365 days
Firvanq (vancomycin) oral solution	2100 mL per 30 days	6300 mL per 90 days
mNexspike (COVID-19 Vaccine, mRNA)	6 doses per 720 days	
Nuvaxovid (COVID-19 Vaccine, Adjuvanted)	6 doses per 720 days	
Paxlovid (nirmatrelvir/ritonavir) 150 mg - 100 mg	22 tablets per 180 days	22 tablets per 180 days
Qfitlia (fitusiran)	1 pen/vial per 56 days	1 pen/vial per 56 days
Starjemza (ustekinumab-hmny) 45 mg/0.5 mL	1 syringe or vial (0.5 mL) per 84 days	1 syringe or vial (0.5 mL) per 84 days

Drug Name	Retail Edit Limit	Mail Edit Limit
Starjemza (ustekinumab-hmny) 90 mg/mL	1 syringe (1 mL) per 84 days	1 syringe (1 mL) per 84 days
Tryptyr (acoltremon)	60 vials per 25 days	180 vials per 75 days
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)	4 prefilled syringes (1,000 mg efgartigimod alfa and 10,000 units hyaluronidase per 5 mL) per 28 days	12 prefilled syringes (1,000 mg efgartigimod alfa and 10,000 units hyaluronidase per 5 mL) per 84 days
Zyvox (linezolid) powder for suspension	900 mL per 30 days	2700 mL per 90 days

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

Drug Name	Retail Edit Limit	Mail Edit Limit
Blujepa (gepotidacin)	10 tablets	10 tablets
Valtoco (diazepam)	5 blister packs	5 blister packs
Xenleta (lefamulin acetate) tablets	10 tablets	10 tablets

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
Ambien (zolpidem tartrate)	1 tablet per day
Ambien CR (zolpidem tartrate) extended release	1 tablet per day
Arbli (losartan potassium)	11 mL per day
Bucapsol (buspirone hydrochloride) 10 mg	5 capsules per day
Bucapsol (buspirone hydrochloride) 15 mg	4 capsules per day
Bucapsol (buspirone hydrochloride) 7.5 mg	2 capsules per day
Flurazepam hcl	1 capsule per day
Hemiclor (chlorthalidone)	8 tablets per day
Livmarli (maralixibat) tablet	1 tablet per day
Lopressor (Metoprolol Tartrate Oral Solution)	45 mL per day
Mezofy (aripiprazole)	1 oral film per day
Vancocin (vancomycin) 125 mg capsules	16 capsules per day
Vancocin (vancomycin) 250 mg capsules	8 capsules per day
Vanrafia (atrasentan)	1 tablet per day
Vykat XR (diazoxide choline) 150 mg	3 extended-release tablets per day
Vykat XR (diazoxide choline) 25 mg	4 extended-release tablets per day

Drug Name	Daily Limit
Vykat XR (diazoxide choline) 75 mg	7 extended-release tablets per day
Zyvox (linezolid) tablets	2 tablets 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
Arbli	losartan potassium	valsartan tablet, losartan, irbesartan
Blujepa	gepotidacin	prescriber discretion
Conexence	denosumab-bnht	Prolia
Hemiclor	chlorthalidone	chlorthalidone, hydrochlorothiazide, indapamide
Lopressor	Metoprolol Tartrate Oral Solution	metoprolol tartrate tablets
Qamzova	meloxicam	ibuprofen tablets, meloxicam tablets, naproxen sodium tablets
Tryptyr	acoltremon	cyclosporine dropperette, Xiidra

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

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
Blujepa	gepotidacin	prescriber discretion

Table 3. Products Not Added*

Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Preferred Alternatives
Arbli	losartan potassium	valsartan tablet, losartan, irbesartan
Atzumi	dihydroergotamine	sumatriptan tablets, zolmitriptan tablets, sumatriptan nasal spray
Bomynta	denosumab-bnht	Xgeva
Brekiya	dihydroergotamine mesylate	sumatriptan tablets, zolmitriptan tablets, sumatriptan nasal spray
Bucapsol	bupirone hydrochloride	bupirone tablets
Conexence	denosumab-bnht	Prolia
Hemiclor	chlorthalidone	chlorthalidone, hydrochlorothiazide, indapamide
Imaavy	nipocalimab-aahu	prescriber discretion
Jobevne	bevacizumab-nwgd	prescriber discretion
Livmarli tablet	maralixibat	prescriber discretion
Lopressor oral solution	Metoprolol Tartrate Oral Solution	metoprolol tartrate tablets
Qamzova	meloxicam	ibuprofen tablets, meloxicam tablets, naproxen sodium tablets
Starjemza	ustekinumab-hmny	Stelara
Tryptyr	acoltremon	cyclosporine dropperette, Xiidra
Uplizna	inebilizumab-cdon	prescriber discretion
Vanrafia	atrasentan	irbesartan oral tablet, losartan oral tablet, valsartan oral tablet
Vykat XR	diazoxide choline	prescriber discretion
Vyvgart Hytrulo	efgartigimod alfa and hyaluronidase-qvfc	prescriber discretion

*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
Atzumi*	dihydroergotamine
Avmapki Fakzynja	avutometinib capsules;defactinib tablets
Bomynta*	denosumab-bnht
Brekiya*	dihydroergotamine mesylate
Bucapsol*	bupirone hydrochloride
Emrelis	telisotuzumab vedotin-tllv
Imaavy*	nipocalimab-aahu
Jobevne*	bevacizumab-nwgd
Khindivi	hydrocortisone oral solution
Livmarli*	maralixibat
Mezofy	aripiprazole
Penpulimab-kcqx	Penpulimab-kcqx
Starjemza*	ustekinumab-hmny
Uplizna*	inebilizumab-cdon
Vanrafia*	atrasentan
Vykat XR*	diazoxide choline
Vyvgart Hytrulo*	efgartigimod alfa and hyaluronidase-qvfc

* Pertains only to Incentive and Compass Formularies

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Administrative Prior Authorizations for Medicare Part D Plans – Medicare	07/18/2025	Policy updated to include Jubbonti (denosumab-bbdz) and Administrative changes to II. BvD section H.
Administrative Prior Authorizations for Medicare Part D Plans – Medicare	05/15/2025	Policy revised to add products Kisunla (donanemab) and Leqembi (lecanemab-irmb) to II. BvD section M. Incident to Provider Services.
Amvuttra (vutrisiran) – Medicare	TERMED 7/1/2025	Policy terminated (combined with J-0945).
Amyloid beta-Directed Antibodies for Alzheimer’s Disease – Medicare	05/15/2025	Policy revised to add language that the product has determined to be eligible for coverage under part D per policy J-0030.
Amyloid beta-Directed Antibodies for	Effective Upon Completion Of	Policy revised to add subcutaneous (SC) Leqembi (lecanemab-irmb) requiring that

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Alzheimer's Disease – Medicare	Internal Review And Implementation.	the member has a diagnosis of Alzheimer's disease classified as mild cognitive impairment or mild dementia, the member has completed the required number of initiation intravenous (IV) infusions of Leqembi per FDA labeling, the prescriber has ruled out all other possible causes of cognitive impairment or dementia, prior to initiation of IV Leqembi the member has confirmed presence of amyloid beta pathology via Positron Emission Tomography (PET) imaging and a baseline brain MRI, and the member meets criteria outlined in the Medicare national coverage determination 200.3. Reauthorization requiring that at treatment initiation the member had mild cognitive impairment or mild dementia stage of Alzheimer's disease, the member continues to meet criteria outline in the Medicare national coverage determination 200.3, the member has obtained all required brain MRIs per FDA labeling, the member has experienced reduction from baseline in amyloid beta plaque levels via PET imaging, and the member has demonstrated positive clinical response as evidenced by slowed decline in cognition.
Anti-Angiogenesis and VEGF Kinase Inhibitors – Medicare	07/18/2025	Policy revised for Cabometyx (cabozantinib) to require diagnosis based on FDA-approved expanded indications for pancreatic neuroendocrine tumors and extra-pancreatic neuroendocrine tumors.
Atypical Antipsychotics – Medicare	06/02/2025	Policy revised for all diagnoses for Opipza: criteria was changed from therapeutic failure or intolerance to generic aripiprazole tablets to intolerance to generic aripiprazole tablets.
Atypical Antipsychotics – Medicare	Effective upon completion of internal review and implementation.	Policy revised to add Mezofy (aripiprazole) oral film to require a diagnosis of schizophrenia and either prescriber attestation that the member has inability to swallow oral tablets or the member has experienced intolerance to generic aripiprazole tablets.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
BCR-ABL Kinase Inhibitors – Medicare	Effective upon completion of internal review and implementation.	Policy revised to add generic nilotinib as a target and for brand Tasisa (nilotinib) to require intolerance to generic nilotinib.
Benzodiazepines for Emergency Use – Medicare	05/28/2025	Policy revised to remove age limits for Valtoco (diazepam) and Nayzilam (midazolam).
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Medicare	07/18/2025	Policy revised to add Avmapki Fakzynja Co-Pack (avutometinib; defactinib) to require diagnosis based on FDA-approved indication.
Bucapsol (buspirone) – Medicare	07/18/2025	Policy created to require members meet the following criteria for coverage of Bucapsol (buspirone): member must have a diagnosis of generalized anxiety disorder and the member is unable to swallow tablets.
Chronic Inflammatory Diseases – Medicare	07/01/2025	Authorization duration revised for adalimumab products and ustekinumab products to end of plan year.
Chronic Inflammatory Diseases – Medicare	Effective upon completion of internal review and implementation.	Policy revised for Rinvoq ER (upadacitinib) to require new indication giant cell arteritis, and therapeutic failure, intolerance or contraindication to a systemic corticosteroid. Policy revised to add ustekinumab-aekn as a non-preferred ustekinumab product.
Chronic Inflammatory Diseases – Medicare	06/20/2025	Policy revised for Tremfya (guselkumab) to remove maintenance dosing criteria for ulcerative colitis and Crohn's disease.
Complement Inhibitors for Geographic Atrophy – Medicare	07/18/2025	Policy revised to include Izervay (avacincaptad pegol) in the reauthorization criteria that the member has experienced a decrease in growth lesion(s) from baseline and updated the authorization duration to remove additional courses of Izervay exceeding a total cumulative duration of 12 months will not be granted.
Conjupri (levamlodipine) – Medicare	TERMED 7/2/2025	Policy terminated
Denosumab Products for Bone Disease – Medicare	06/03/2025	Policy revised for Jubbonti (denosumab-bbdz) to require diagnosis based on FDA-approved indication and trial/failure/contraindication to Prolia (denosumab). Use for osteoporosis or

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		osteopenia (including glucocorticoid-induced osteoporosis) must be supported by lab values such as T-score or FRAX calculator, and trial/failure/contraindication to one bisphosphonate.
Denosumab Products for Bone Disease – Medicare	Effective upon completion of internal review and implementation.	Policy revised to add Conexence (denosumab-bnht) 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, and trial/failure/contraindication to one bisphosphonate. Conexence requires trial and failure of Prolia (denosumab).
Denosumab Products for Oncology – Medicare	Effective upon completion of internal review and implementation.	Policy revised to add Bomynta (denosumab-bnht) to require diagnosis based on FDA-approved indication and therapeutic failure/intolerance to Xgeva (denosumab). Policy revised for Osenvelt (denosumab-bmwo), Wyost (denosumab-bbdz), and Xbryk (denosumab-dssb) to require therapeutic failure or intolerance to Xgeva (denosumab).
Digitized Inhalers – Medicare	Termed 7/1/2025	Policy terminated
Disease-Modifying Medications for Generalized Myasthenia Gravis – Medicare	07/18/2025	Policy revised to include Imaavy (nipocalimab-aahu) requiring that the member has a diagnosis of generalized myasthenia gravis (gMG), the member has one of the following subtypes of gMG: anti-acetylcholine receptor antibody positive (AChR Ab+) or anti-muscle-specific tyrosine kinase antibody positive (MuSK Ab+) and the member has experienced therapeutic failure, contraindication, or intolerance to generic pyridostigmine. For reauthorization, the prescriber must attest that the member has experienced improvement in the signs and symptoms of gMG or the prescriber attests that the member has experienced a decrease in the number of exacerbations of gMG.
Dupixent (dupilumab) – Medicare	Effective Upon Completion Of Internal Review	Policy revised for Dupixent (dupilumab) to add new indication of chronic spontaneous urticaria (CSU) to require diagnosis based

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
	And Implementation.	on FDA approved indication, therapeutic failure, contraindication or intolerance to a second-generation non-sedating H1 antihistamine at the maximum recommended dose and reauthorization requiring the member has improved CSU symptoms.
Emrelis (telisotuzumab vedotin-tllv) – Medicare	07/18/2025	New policy for Emrelis (telisotuzumab vedotin-tllv) to require diagnosis based on FDA-approved indication.
Ergotamines – Medicare	Effective upon completion of internal review and implementation.	Policy revised to add Atzumi (dihydroergotamine mesylate) nasal powder and Brekiya (dihydroergotamine mesylate) autoinjector to require FDA-approved indication and that the member requires a non-oral route of administration. For Atzumi, the member must experienced therapeutic failure, contraindication, or intolerance to generic sumatriptan nasal spray. For Brekiya, the member must experience therapeutic failure, contraindication or intolerance to generic sumatriptan injection and contraindication or intolerance to generic dihydroergotamine injection.
Ergotamines – Medicare	04/28/2025	Policy revised to change examples of generic prophylactic migraine medications to topiramate, propranolol, and timolol).
Fabhalta (iptacopan) – Medicare	Effective upon completion of internal review and implementation.	Policy revised for a diagnosis of Complement 3 Glomerulopathy (C3G), the requirement for an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73m ² has been removed.
Fecal Microbiota Products – Medicare	Effective upon completion of internal review and implementation.	Policy revised for Rebyota (fecal microbiota, live-jslm) and Vowst (fecal microbiota spores, live-brpk) requiring a diagnosis of <i>Clostridioides difficile</i> infection (CDI) confirmed by positive stool test, and recurrent infection defined ≥ 2 total CDI episodes.
Filspari (sparsentan) and Vanrafia (atrasentan) – Medicare	07/18/2025	Policy revised to add Vanrafia (atrasentan) as a target requiring diagnosis of primary immunoglobulin A nephropathy, proteinuria ≥ 0.5 g/day, and concurrent use of or intolerance/contraindication to an angiotensin converting enzyme (ACE)

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		inhibitor or angiotensin receptor blocker (ARB). For reauthorization, the member must experience a decrease in proteinuria from baseline and be concurrently using, or have intolerance/contraindication to, an ACE or ARB.
Gattex (teduglutide) – Medicare	07/18/2025	Policy revised for Gattex (teduglutide) reauthorization requiring use of parenteral/intravenous nutrition or trial/failure of Gattex discontinuation.
Hydrocortisone Products – Medicare	Effective upon completion of internal review and implementation.	Policy revised for Khindivi (hydrocortisone) oral solution to ensure that members have a diagnosis of adrenocortical insufficiency. The member is between the age of 5 and 17 years of age. The prescriber attests that the member is not experiencing adrenal stress or acute events and member has experienced intolerance to generic oral hydrocortisone tablets.
Injectable Octreotide Products – Medicare	07/18/2025	Policy revised to add octreotide acetate extended release as a target mirroring criteria for Sandostatin (octreotide) LAR.
Interleukin (IL)-5 Antagonists – Medicare	Effective upon completion of internal review and implementation.	Policy revised to include chronic obstructive pulmonary disease (COPD) for Nucala (mepolizumab) with an initial authorization requiring all of the following: a diagnosis of COPD, a blood eosinophil count of ≥ 300 cells/mcL or the member is currently taking daily or alternate-day oral corticosteroids and the member has inadequate symptom control despite regular treatment for at least 3 months with triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (LAMA/LABA/ICS), unless intolerant of, or has contraindications to these agents. Policy updated to include when a benefit, reauthorization of Nucala may be approved when one (1) of the following criteria is met: The prescriber attests that the member has experienced a reduction in symptoms of chronic obstructive pulmonary disease (COPD), the prescriber attests that the member has experienced an improvement in exercise tolerance, the prescriber attests

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		that the member has experienced delayed disease progression, or the prescriber attests that the member has experienced a reduction in the number of exacerbations.
Interleukin-1 β blockers – Medicare	07/18/2025	Policy revised for Ilaris (canakinumab) to remove criterion from Adult-Onset Still's Disease and systemic juvenile idiopathic arthritis (SJIA) requiring failure of a disease-modifying antirheumatic drug (DMARD).
Intravitreal Corticosteroid Implants – Medicare	Effective upon completion of internal review and implementation.	Policy revised to include Dextenza (dexamethasone ophthalmic insert). Requiring FDA-approved indications ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis, and if the request is for a pediatric member, the prescriber attests that the member does not require sedation for insertion procedure
Journavx (suzetrigine) – Medicare	05/28/2025	Policy revised to address a CMS concern: the prescriber attests that the treatment of pain is not amenable to conservative measures such as acetaminophen, NSAIDs, and non-pharmacologic measures was changed to the prescriber attests that alternative therapies for the treatment of pain (for example, NSAIDs) have been explored. Likewise, for reauthorization, the prescriber attests that the treatment of the new episode of pain is not amenable to conservative measures such as acetaminophen, NSAIDs, and non-pharmacologic measures was changed to the prescriber attests that alternative therapies for the treatment of the new episode of acute pain (for example, NSAIDs) have been explored.
Livmarli (maralixibat) – Medicare	Effective upon completion of internal review and implementation.	Policy revised to require genetic testing demonstrating a <i>JAGGED1</i> or <i>NOTCH2</i> deletion or mutation to confirm diagnosis of Alagille syndrome. In addition, if the member has Alagille syndrome, they will be using either Livmarli oral solution 9.5 mg/mL or oral tablets. If the member has progressive familial intrahepatic cholestasis (PFIC), the member will be using either

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		Livmarli oral solution 19.5 mg/mL or oral tablets.
Lyrica/Lyrica CR (pregabalin/pregabalin ER) – Medicare	Effective upon completion of internal review and implementation.	Policy revised to remove steps through duloxetine, gabapentin, and anti-epileptic drugs. Policy revised to add if the request is for brand Lyrica (pregabalin), the member has experienced intolerance to generic pregabalin. For Lyrica CR (pregabalin extended release), the member has experienced therapeutic failure or intolerance to generic pregabalin immediate release. If the request is for brand Lyrica CR (pregabalin ER), the member has experienced intolerance to generic pregabalin ER.
Mesalamine Ulcerative Colitis Treatments – Medicare	Effective upon completion of internal review and implementation.	New policy created for non-preferred mesalamine products: Apriso (mesalamine) Brand, Canasa (mesalamine), Delzicol (mesalamine) Brand, Lialda (mesalamine) Brand, mesalamine 800 mg DR tablet, Pentasa (mesalamine), Rowasa (mesalamine) Brand, sfRowasa (mesalamine) Brand; requiring FDA-approved diagnosis and trial/failure to one preferred product: Generic Mesalamine 4 g/60 mL enema, Generic Mesalamine 400 mg DR capsules, Generic Mesalamine 1.2 g DR tablets, Pentasa 250 mg capsule. Reauthorization requiring disease stability or beneficial response to therapy and attestation additional courses for UC treatment are necessary. Auth durations: 6 weeks (Mesalamine 800 mg DR, Canasa, Rowasa, sfRowasa), 8 weeks (Pentasa), and 6 months (Apriso, Delzicol, Lialda).
Namenda (memantine) and Namzaric (memantine/donepezil) – Medicare	04/28/2025	Policy revised for Namzaric (donepezil/memantine) to require the member experienced intolerance to generic memantine and donepezil.
Non-Preferred Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs) – Medicare	Effective upon completion of internal review and implementation.	Policy was updated to include Paxil CR (paroxetine) extended-release tablets, Bisdelle (paroxetine capsules), and Paxil (paroxetine) immediate release tablets or solution to require FDA indication as well as if the request is for Paxil CR (paroxetine)

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		extended-release tablets or Paxil (paroxetine) immediate release tablets or solution, the member has experienced intolerance to at least two other antidepressants (for example: SSRI or SNRI) and the member will be counseled regarding the risk-benefit profile regarding the use of paroxetine and its potential anticholinergic adverse effects
Omalizumab Products – Medicare	Effective upon completion of internal review and implementation.	Policy revised to include Omlyclo (omalizumab-igec), a new interchangeable biosimilar to Xolair. For all four FDA-approved indications (asthma, chronic spontaneous urticaria [CSU], chronic rhinosinusitis with nasal polyps [CRSwNP] and IgE-mediated food allergy), in addition to existing criteria, initial authorization as well as reauthorizations, if the request is for Xolair, the member must have experienced therapeutic failure or intolerance to plan-preferred Omlyclo.
Omalizumab Products – Medicare	Effective upon completion of internal review and implementation.	Policy updated for Xolair (omalizumab) to require the member has inadequate symptom control despite regular treatment with medium- or high-dose inhaled corticosteroids (ICS) and at least one (1) additional asthma controller (for example, long-acting beta-2 agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), with or without oral corticosteroids (OCS), unless intolerant of, or has contraindications to all of these agents and the member will continue treatment with medium- or high-dose ICS and at least one (1) additional asthma controller (for example, LABA, LTRA, or theophylline), with or without OCS, while using Xolair.
Omega-3 Fatty Acid Products – Medicare	07/18/2025	Policy revised for Lovaza (omega-3-acid ethyl esters) to remove age criteria.
Onpattro (patisiran) – Medicare	Effective upon completion of internal review and implementation.	Policy terminated.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Opzelura (ruxolitinib) – Medicare	Effective upon completion of internal review and implementation.	Policy revised for Opzelura (ruxolitinib) to change initial authorization duration to 16 weeks.
Programmed Death Receptor Therapies – Medicare	Effective upon completion of internal review and implementation.	Policy updated to include Penpulimab-kcqx. Criteria added for recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC): member has FDA-approved diagnosis, member will be using Penpulimab-kcqx as first-line treatment, the member is using Penpulimab-kcqx in combination with either cisplatin + gemcitabine or carboplatin + gemcitabine, and determined eligible for coverage under Part D per policy J-0030. Criteria added for metastatic non-keratinizing NPC with disease progression: member has FDA-approved diagnosis, member has experienced disease progression on or after platinum-based therapy and at least one other prior line of therapy, Penpulimab-kcqx will be used as a single agent, and determined eligible for coverage under Part D per policy J-0030.
Programmed Death Receptor Therapies – Medicare	07/18/2025	Policy revised for Imfinzi (durvalumab) to require diagnosis based on FDA-approved expanded indication for muscle invasive bladder cancer. Policy revised for Opdivo (nivolumab) to require diagnosis based on FDA-approved expanded indication for first-line treatment of hepatocellular carcinoma, and revised indication for colorectal cancer. Policy revised for Zynyz (retifanlimab-dlwr) to require diagnosis based on FDA-approved expanded indication for squamous cell carcinoma of the anal canal. Policy revised for Opdivo (nivolumab) and Opdivo Qvantig (nivolumab and hyaluronidase-nvhy) to require that the member's tumors express PD-L1 (greater than or equal to 1) when used in combination with chemotherapy and/or ipilimumab for esophageal squamous cell carcinoma or when used in combination with chemotherapy for gastric cancer, gastroesophageal junction cancer, or

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		esophageal adenocarcinoma per updated FDA-approved indications.
Qalsody (tofersen) – Medicare	Effective upon completion of internal review and implementation.	Policy revised for Qalsody (tofersen) to adjust to proper induction therapy of three vials (45 mL) within the first 42 days (6 weeks) of therapy
Savella (milnacipran) – Medicare	Effective upon completion of internal review and implementation.	Policy revised for Savella (milnacipran) to require step through duloxetine and pregabalin.
Sirturo (bedaquiline) – Medicare	07/18/2025	Policy updated to include the member has experienced therapeutic failure, contraindication, or intolerance to two of the following: isoniazid, rifampin, rifabutin, or rifapentine, or a fluoroquinolone and the member is using Sirturo (bedaquiline) in combination with at least two other drugs for tuberculosis.
Steroidogenesis Inhibitors – Medicare	07/18/2025	Policy revised for Isturisa (osilodrostat) to require diagnosis of Cushing's syndrome.
Sucraid (sacrosidase) – Medicare	07/18/2025	Policy revised for Sucraid (sacrosidase) to add genetic testing indicating a mutation in the sucrase-isomaltase gene as an option to support the diagnosis of congenital sucrase-isomaltase deficiency.
Thrombopoiesis Stimulating Agents – Medicare	Effective upon completion of internal review and implementation.	Policy revised for Promacta (eltrombopag olamine) to require intolerance to generic eltrombopag olamine if brand is requested.
Transthyretin-Directed Antisense Oligonucleotides – Medicare	Effective upon completion of internal review and implementation.	Policy terminated.
Transthyretin-Directed Antisense Oligonucleotides – Medicare	07/18/2025	Policy revised to remove Tegsedi (inotersen) as it is off-market.
Transthyretin-Mediated Amyloidosis (ATTR) – Medicare	Effective upon completion of internal review and implementation.	Policy revised to add Onpattro (patisiran) and Wainua (eplontersen) as targets, mirroring criteria for Amvuttra (vutrisiran) for treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis.
Transthyretin-Mediated Amyloidosis (ATTR) – Medicare	07/02/2025	Policy revised to add Amvuttra (vutrisiran) as a target. Initial and reauthorization criteria for Amvuttra to treat cardiomyopathy added mirroring criteria for Attruby

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		(acoramidis), Vyndaqel (tafamidis meglumine), and Vyndamax (tafamidis). Policy revised for all targets to require that scintigraphy be used with radiotracers resulting in a heart to lung contralateral of at least 1.5 or visual grade 2 to 3. Limitation of coverage excluding use in primary amyloidosis removed.
Tyrvaya (varenicline solution) – Medicare	TERMED 7/1/2025	Policy terminated, criteria moved to J-1138.
Uplizna (inebilizumab-cdon) – Medicare	07/18/2025	Policy revised for Uplizna (inebilizumab-cdon) to add new indication of diagnosis of Immunoglobulin G4-related disease (IgG4-RD), determined to be eligible for coverage under Part D per policy J-0030, and the prescriber attests the member has involvement of one of the following organs/sites: pancreas, bile ducts/biliary tree, orbits, lungs, kidneys, lacrimal glands, major salivary glands, retroperitoneum, aorta, pachymeninges, or thyroid gland. Removed neuromyelitis optica spectrum disorder (NMOSD) wording in reauthorization to include only the prescriber attests the member has experienced a decrease in the number of relapse(s).
Uplizna (inebilizumab-cdon) – Medicare	Effective upon completion of internal review and implementation.	Policy revised for Uplizna (inebilizumab-cdon) to add quantity limits for neuromyelitis optica spectrum disorder (NMOSD) and Immunoglobulin G4-related disease (IgG4-RD) for induction therapy six (6) single-dose vials within the first two weeks of therapy and maintenance therapy three (3) single-dose vials every 6 months.
Ustekinumab Biosimilars – Medicare	Effective upon completion of internal review and implementation.	Policy revised to add new products Starjemza (ustekinumab-hmny) subcutaneous (SC) injection and intravenous (IV) infusion requiring age, FDA-approved diagnosis, dosing based on FDA-approved weight, and trial/failure to Stelara (ustekinumab). For plaque psoriasis, trial/failure to phototherapy or systemic therapy, or contraindication to all. For Crohn's disease and ulcerative colitis, if the request is for an ustekinumab SC

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		biosimilar, prescriber attestation of ustekinumab IV induction dose received within 2 months or currently undergoing induction.
Vancocin (vancomycin) Oral Capsules – Medicare	Effective upon completion of internal review and implementation.	Policy terminated.
Voranigo (vorasidenib) – Medicare	07/18/2025	Policy revised for Voranigo (vorasidenib) to include revised FDA-approved indication for diagnosis of Grade 2 astrocytoma or Grade 2 oligodendroglioma with susceptible isocitrate dehydrogenase (IDH)-1 or IDH2 mutation, as detected by an FDA-approved test.
Voydeya (danicipan) – Medicare	Effective upon completion of internal review and implementation.	Policy revised for Voydeya (danicipan) reauthorization to require continued use in combination with ravulizumab or eculizumab
Voydeya (danicipan) – Medicare	07/18/2025	Policy revised for Voydeya (danicipan) to update reauthorization criterion to be a decrease in reticulocyte count.
Vtama (tapinarof) and Zoryve (roflumilast) – Medicare	Effective upon completion of internal review and implementation.	Policy revised for Zoryve (roflumilast) topical foam to add new indication of plaque psoriasis requiring diagnosis and trial/failure to one generic formulary medium to ultrahigh potency topical corticosteroid or psoriasis on facial or intertriginous areas, and trial/failure/contraindication to one generic formulary vitamin D analog or psoriasis on the face.
Vykat XR (diazoxide choline) – Medicare	07/18/2025	New policy created for Vykat XR (diazoxide choline) to require that the member has a diagnosis of Prader-Willi syndrome (PWS) confirmed by documentation of genetic analysis with identification of abnormal DNA methylation of chromosome 15q11.2-q13, and the member is experiencing hyperphagia due to the PWS diagnosis. For reauthorization, the prescriber attests that the member has experienced a decrease in hyperphagic and food-related behaviors.
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) – Medicare	07/18/2025	Policy updated to include the prefilled syringe formulation of Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) requiring diagnosis based on FDA-

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		approved indication of generalized myasthenia gravis (gMG) and the member has experienced therapeutic failure, contraindication, or intolerance to generic pyridostigmine. For reauthorization, the member meets one of the following: the member has experienced improvement in signs and symptoms of gMG (for example, speech, swallowing, mobility, and/or respiratory function) or the member has experienced a decrease in the number of exacerbations of gMG. For chronic inflammatory demyelinating polyneuropathy (CIDP) the member has an FDA-approved indication of CIDP supported by diagnostic criteria, and trial/failure to one (1) of the following or contraindication to all: systemic corticosteroid or an immune globulin. Reauthorization requires improvement in fictional ability or strength from baseline.
Welireg (belzutifan) – Medicare	07/18/2025	Policy revised for Welireg (belzutifan) to require diagnoses of advanced renal cell carcinoma with a clear cell component or pheochromocytoma or paraganglioma per updated FDA-approved indications.

*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
Brand Reliever Inhalers – Medicare	Effective upon completion of internal review and implementation.	Policy updated to require the member to experience a therapeutic failure or intolerance to all of the following for Airsupra (budesonide and albuterol): an inhaled corticosteroid-formoterol combination product and an inhaled corticosteroid and albuterol product being utilized as needed.
Colony-Stimulating Factors – Medicare	07/18/2025	Policy revised for Releuko (filgrastim-ayow) to align with FDA-approved indication. Therapeutic failure or intolerance to Nivestym (filgrastim-aafi) required when using to mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. Policy revised

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		for Fylnetra (pegfilgrastim-pbbk) to require diagnosis based on expanded FDA-approved indication for hematopoietic subsyndrome of acute radiation syndrome (H-ARS) and therapeutic failure or intolerance to Neulasta (pegfilgrastim) or Ziextenzo (pegfilgrastim-bmez). Policy revised for Udenyca (pegfilgrastim-cbvq) and Stimufend (pegfilgrastim-fpgk) to add Ziextenzo (pegfilgrastim-bmez) as a step therapy option for H-ARS.
Dry Eye Disease Products – Medicare	07/02/2025	Policy revised to move Miebo (perfluorohexyloctane) and Tyrvaya (varenicline) from J-1297 and J-1157 to this policy.
Dry Eye Disease Products – Medicare	Effective upon completion of internal review and implementation.	Policy revised to add Tryptyr (acoltremon) for dry eye disease and therapeutic failure, contraindication, or intolerance to Restasis (cyclosporine) or generic cyclosporine and Xiidra (lifitegrast).
Gonadotropin-releasing Hormone (GnRH) Agonists – Medicare	07/18/2025	Policy revised to add Lutrate Depot (leuprolide acetate) requiring FDA-approved diagnosis and trial/failure of leuprolide acetate depot 22.5 mg or Lupron Depot (leuprolide acetate).
Intravitreal Injections – Medicare	Effective upon completion of internal review and implementation.	Policy revised for Susvimo (ranibizumab injection) to include FDA-approved expanded indication for the treatment of patients with diabetic retinopathy (DR) who have previously responded to at least two intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor.
Miebo (perfluorohexyloctane) – Medicare	TERMED 7/1/2025	Policy terminated, criteria moved to J-1138.
Non-preferred Inhaler Products – Medicare	07/18/2025	Policy revised to include the authorized generic of umeclidinium/vilanterol to require a diagnosis of chronic obstructive pulmonary disease (COPD) and if the request is for umeclidinium/vilanterol, the member has experienced therapeutic failure or intolerance to brand Anoro Ellipta (umeclidinium/vilanterol).
Non-Preferred Rapid-Acting Insulins –	07/18/2025	Policy revised to add Merilog (insulin aspart-szjj) and Merilog Solostar (insulin aspart-szjj) as targets.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Medicare (Incentive Formulary)		

3. Quantity Level Limit (QLL) Program

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

Drug Name	Retail Quantity Limit (31 days)
Arbli (losartan potassium)	330 mL per 31 days
Atzumi (dihydroergotamine)	12 nasal powder/devices per 30 days
Avmapki Fakzynja (avutometinib capsules;defactinib tablets)	1 carton (24 Avmapki capsules, 42 Fakzynja tablets) per 28 days
Blujepa (gepotidacin)	10 tablets per 5 days
Brekiya (dihydroergotamine mesylate)	24 autoinjectors per 28 days
Bucapsol (buspirone hydrochloride) 10 mg	5 capsules per day
Bucapsol (buspirone hydrochloride) 15 mg	4 capsules per day
Bucapsol (buspirone hydrochloride) 7.5 mg	2 capsules per day
Conexence (denosumab-bnht)	1 syringe (60 mg/1 mL) per 180 days
Dextenza (dexamethasone ophthalmic insert)	2 implants (1 for each eye) per 30 days
Emrelis (telisotuzumab vedotin-tllv) 100 mg vial	2 vials per 14 days
Emrelis (telisotuzumab vedotin-tllv) 20 mg vial	10 vials per 14 days
Eohilia (budesonide oral suspension)	180 single-dose stick packs (1800 mL) per 365 days
Hemiclor (chlorthalidone)	8 tablets per day
Livmarli (maralixibat) 10, 15, 20 mg	2 tablets per day
Livmarli (maralixibat) 30 mg	1 tablet per day
Lopressor (Metoprolol Tartrate Oral Solution)	45 mL per day
Mezofy (aripiprazole)	1 film per day
Paxlovid (nirmatrelvir/ritonavir) 150 mg - 100 mg	99 tablets per 365 days
Penpulimab-kcqx (Penpulimab-kcqx)	2 single-dose vials (100 mg per 10 mL) per 21 days
Starjemza (ustekinumab-hmny) 130 mg/26 mL	8 vials (208 mL) per 365 days
Starjemza (ustekinumab-hmny) 45 mg/0.5 mL	1 syringe or 1 vial (0.5 mL) per 84 days
Starjemza (ustekinumab-hmny) 90 mg/mL	1 syringe (1 mL) per 56 days
Tryptyr (acoltremon)	60 vials per 30 days
Uplizna (inebilizumab-cdon)	3 single-dose vials (100 mg per 10 mL) per 180 days
Vanrafia (atrasentan)	One tablet per day

Drug Name	Retail Quantity Limit (31 days)
Vykat XR (diazoxide choline) 150 mg	3 extended-release tablets per day
Vykat XR (diazoxide choline) 25 mg	4 extended-release tablets per day
Vykat XR (diazoxide choline) 75 mg	7 extended-release tablets per day
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)	4 prefilled syringes (1,000 mg efgartigimod alfa and 10,000 units hyaluronidase per 5 mL) per 28 days