

Formulary Updates



Updated: April 2025

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Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for January 2025. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in January by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Please reference the guide below to navigate this communication:

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As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (PRC) (accessible via Availity® 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.



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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.

Important Drug Safety Updates

Ocaliva (obeticholic acid) by Intercept Pharmaceuticals: Drug Safety Communication – Serious Liver Injury Being Observed in Patients without Cirrhosis

On Dec. 12, 2024, the FDA issued a safety alert after it identified cases of serious liver injury among patients being treated for primary biliary cholangitis (PBC) with Ocaliva (obeticholic acid) who did not have cirrhosis of the liver. Ocaliva is a prescription medicine approved in May 2016 that has been shown to improve a certain liver test called alkaline phosphatase (ALP) in patients with PBC who have not responded well enough to another medicine called ursodeoxycholic acid. The FDA previously communicated about the risk of serious liver injury associated with Ocaliva in May 2021 (restriction of Ocaliva use in PBC patients with advanced cirrhosis). Additional communications about related safety issues for Ocaliva occurred in February 2018 (addition of Boxed Warning to highlight correct dosing of Ocaliva) and September 2017 (warning about serious liver injury with incorrect dosing). FDA is notifying health care professionals and patients of this new safety information, and that frequent liver test monitoring is necessary to identify worsening liver function and ensure appropriate discontinuation of Ocaliva. FDA will continue to monitor the medicine's safety and will follow up if additional information becomes available.

Astellas Pharma US, Inc. Issues Voluntary Nationwide Recall of One Lot of PROGRAF® 0.5mg (Tacrolimus) and One Lot of ASTAGRAF XL® 0.5mg (Tacrolimus Extended-Release Capsules) Because Bottles Shipped to U.S. May Contain Empty Capsules

On Dec. 23, 2024, Astellas Pharma US, Inc. (Head of US Commercial: Michael Petroutsas, "Astellas") is voluntarily recalling one lot of PROGRAF® 0.5mg (tacrolimus) and one lot of ASTAGRAF XL® 0.5mg (tacrolimus extended-release) capsules to the consumer level. These products are being recalled because bottles may contain empty capsules. Transplant patients who consume empty PROGRAF or ASTAGRAF XL capsules may experience initiation of rejection of the transplanted organ, tissue, or cells, due to underimmunosuppression. In the case of life-sustaining organ transplants such as a heart transplant (for which there is no permanent substitute such as hemodialysis in the case of a failed kidney transplant) if the transplant fails, the consequences of rejection initiated by ingesting empty capsules may be fatal. To date, Astellas has not received any reports of adverse events related to this recall.

FDA adds Boxed Warning about a rare but serious allergic reaction called anaphylaxis with the multiple sclerosis medicine glatiramer acetate (Copaxone, Glatopa)

On Jan. 22, 2025, the FDA released a Drug Safety Communication warning about the risk of a rare but serious allergic reaction, called anaphylaxis, with the medicine glatiramer acetate (Copaxone, Glatopa). Glatiramer acetate is used to treat patients with multiple sclerosis (MS). The FDA is adding the risk of anaphylaxis to a new *Boxed Warning* in the glatiramer acetate prescribing information. Anaphylaxis can occur after the first dose or after doses administered months or even years after starting treatment. Anaphylaxis symptoms generally occur within one hour of an injection and include hives, severe rash, wheezing or difficulty breathing and swelling of the face lips or throat. Anaphylaxis can result in hospitalization and death. Initial symptoms of anaphylaxis can overlap with the common immediate post-injection reactions. Compared to immediate post-injection reactions, anaphylaxis is rare, and its symptoms are typically more severe, worsen over time, and require treatment. Patients experiencing an anaphylactic reaction after glatiramer acetate is administered should stop taking glatiramer acetate and seek immediate medical attention by going to an emergency room or calling 911. Health care professionals should be aware of the new *Boxed Warning* and educate patients. To help FDA track safety issues with medicines, report side effects from glatiramer acetate or other medicines to the FDA MedWatch program.

Highmark Formulary Update – January 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 that the Highmark Comprehensive Closed/Incentive Formulary is a complete subset of the Open Formulary; therefore, all medications added to the Comprehensive Closed/Incentive Formulary are also added to the Open Formulary. These updates are effective on the dates noted throughout this document. For your convenience, you can search the following formularies online:

- [Highmark Comprehensive Formulary](#)
- [Highmark Healthcare Reform Comprehensive Formulary](#)

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

Table 1. Products Added

All products added to the formulary effective January 2025, unless otherwise noted.

Brand Name	Generic Name	Comments
Nemludio	nemolizumab	Treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Alhemo	concizumab-mtci	prescriber discretion
Alyftrek	vanzacaftor, tezacaftor, and deutevacaftor)	prescriber discretion
Attruby	acoramidis	prescriber discretion
Crenessity capsules	crinecerfont	hydrocortisone tablet, dexamethasone tablet, Prednisone tablet
Crenessity oral solution	crinecerfont	Prednisone solution, oral; dexamethasone solution, oral

Brand Name	Generic Name	Preferred Alternatives
Danziten	nilotinib	Imatinib mesylate, Tasigna
Emrosi	minocycline hydrochloride	Metronidazole Cream; Metronidazole 0.75 % Gel
vEnsacove	ensartinib	Xalkori, Alecensa
Imkeldi	imatinib	Imatinib mesylate, Tasigna
Opipza 2 mg 5mg, 10mg	aripiprazole	aripiprazole tablets
Revuforj 110 mg and 160mg	revumenib	prescriber discretion
Steqeyma 45 mg/0.5 mL, 90 mg/mL	ustekinumab-stba	Stelara Syringe 45mg/0.5mL; Stelara Vial 45mg/0.5mL, Stelara Syringe 90 Mg/mL
Tryngolza	olezarsen	prescriber discretion
Yesintek 45 mg/0.5 mL, 90 mg/mL	ustekinumab-kfce	Stelara syringe 45mg/0.5mL; Stelara vial 45mg/0.5mL, Stelara syringe 90 mg/mL

Coverage may be contingent upon plan benefits.

*Effective date to be determined.

Physicians may request coverage of these products using the Prescription Drug Medication Request Form. 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 **Formulary** page under **Policies & Programs** 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.

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

Brand Name	Generic Name
Alhemo	concizumab-mtci
Alyftrek	vanzacaftor, tezacaftor, and deuterivacaftor
Attruby	acoramidis
Crenessity capsules	crinecerfont
Crenessity oral solution	crinecerfont
Danziten	nilotinib
Emrosi	minocycline hydrochloride
Ensacove	ensartinib
Imkeldi	imatinib
Migergot	ergotamine/caffeine

Nemludio	nemolizumab
Opipza 2 mg, 5mg and 10mg	aripiprazole
Revuforj 110 mg and 160mg	revumenib
Steqeyma 45 mg/0.5 mL, 90 mg/mL	ustekinumab-stba
Tryngolza	olezarsen
Yesintek 45 mg/0.5 mL, 90 mg/mL	ustekinumab-kfce

B. Changes to the Highmark Healthcare Reform Essential Formulary

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

Table 1. Formulary Updates

All formulary changes effective January 2025, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Alyftrek	vanzacaftor, tezacaftor, and deutivacaftor	4	cystic fibrosis (CF) in patients aged 6 years and older who have at least one F508del mutation or another responsive mutation in the CFTR gene
Nemludio	nemolizumab	4	Treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.
Items listed below were not added to the formulary			
Alhemo	concizumab-mtci	NF	prescriber discretion
Attruby	acoramidis	NF	prescriber discretion
Crenessity capsules	crinecerfont	NF	Hydrocortisone Tablet, Dexamethasone Tablet, Prednisone Tablet
Crenessity oral solution	crinecerfont	NF	Prednisone Solution, Oral; Dexamethasone Solution, Oral
Danziten	nilotinib	NF	Imatinib Mesylate, Tasisa
Emrosi	minocycline hydrochloride	NF	Metronidazole cream; metronidazole 0.75 % gel
Ensacove	ensartinib	NF	Xalkori; Alecensa
Imkeldi	imatinib	NF	Imatinib Mesylate, Tasisa
Opipza 2 mg, 5mg and 10mg	aripiprazole	NF	aripiprazole tablets
Revuforj 110 mg, 160mg	revumenib	NF	prescriber discretion

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Steqeyma 45 mg/0.5 mL, 90 mg/mL	ustekinumab-stba	NF	Stelara syringe 45mg/0.5mL; Stelara vial 45mg/0.5mL, Stelara syringe 90 mg/mL
Tryngolza	olezarsen	NF	prescriber discretion
Yesintek 45 mg/0.5 mL, 90 mg/mL	ustekinumab-kfce	NF	Stelara syringe 45mg/0.5mL; Stelara vial 45mg/0.5mL, Stelara syringe 90 mg/mL

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

*Effective date to be determined.

C. Changes to the Highmark Core Formulary

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

Table 1. Formulary Updates

All formulary changes effective January Year unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Alyftrek	vanzacaftor, tezacaftor, and deutevacaftor	4	cystic fibrosis (CF) in patients aged 6 years and older who have at least one F508del mutation or another responsive mutation in the CFTR gene
Nemluvio	nemolizumab	4	Treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.
Items listed below were not added to the formulary			
Alhemo	concizumab-mtci	NF	prescriber discretion
Attruby	acoramidis	NF	prescriber discretion
Crenessity capsules	crinecerfont	NF	Hydrocortisone Tablet, Dexamethasone Tablet, Prednisone Tablet
Crenessity oral solution	crinecerfont	NF	Prednisone Solution, Oral; Dexamethasone Solution, Oral
Danziten	nilotinib	NF	Imatinib Mesylate, Tassigna
Emrosi	minocycline hydrochloride	NF	Metronidazole cream; metronidazole 0.75 % gel

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Ensacove	ensartinib	NF	Xalkori; Alecensa
Imkeldi	imatinib	NF	Imatinib Mesylate, Tasisna
Opipza 2 mg, 5mg and 10mg	aripiprazole	NF	aripiprazole tablets
Revuforj 110 mg, 160mg	revumenib	NF	prescriber discretion
Steqeyma 45 mg/0.5 mL, 90 mg/mL	ustekinumab-stba	NF	Stelara syringe 45mg/0.5mL; Stelara vial 45mg/0.5mL, Stelara syringe 90 mg/mL
Tryngolza	olezarsen	NF	prescriber discretion
Yesintek 45 mg/0.5 mL, 90 mg/mL	ustekinumab-kfce	NF	Stelara syringe 45mg/0.5mL; Stelara vial 45mg/0.5mL, Stelara syringe 90 mg/mL

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

*Effective date to be determined.

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)			
Nemluvio	nemolizumab	2	Treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.
Attruby	acoramidis	2	Cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM)
Danziten	nilotinib	2	Leukemia

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Revuforj	revumenib	2	Relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year and older.
Items listed below were added to the formulary (Non-Preferred)			
Alhemo*	concizumab-mtci	3	prescriber discretion
Alyftrek*	vanzacaftor, tezacaftor, and deutivacaftor	3	prescriber discretion
Crenessity capsules*	crinecerfont	3	hydrocortisone tablet, dexamethasone tablet, prednisone tablet
Crenessity oral solution*	crinecerfont	3	prednisone solution, oral; dexamethasone solution, oral
Ensacove *	ensartinib	3	Xalkori; Alecensa
Steqeyma 45 mg/0.5 mL, 90 mg/mL*	ustekinumab-stba	3	Stelara syringe 45mg/0.5mL; Stelara vial 45mg/0.5mL; Stelara syringe 90 mg/mL
Tryngolza*	olezarsen	3	provider discretion
Yesintek 45 mg/0.5 mL, 90 mg/mL*	ustekinumab-kfce	3	Stelara syringe 45mg/0.5mL; Stelara vial 45mg/0.5mL; Stelara syringe 90 mg/mL
Emrosi*	minocycline hydrochloride	3	metronidazole cream; metronidazole 0.75 % gel
Imkeldi*	imatinib	3	Imatinib Mesylate, Tasigna
Items listed below were not added to the formulary			
Opipza	aripiprazole	NF	aripiprazole tablets

Formulary options: **Tier 1:** Generic drugs; **Tier 2:** Preferred Brand drugs; **Tier 3:** Non-Preferred Brand drugs; **Non-formulary (NF).**

*Effective date and final formulary position to be determined.

Table 2. Additions to the Specialty Tier Copay Option

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

Brand Name	Generic Name
Alhemo	concizumab-mtci
Alyftrek	vanzacaftor, tezacaftor, and deutivacaftor
Attruby	acoramidis
Crenessity capsules	crinecerfont
Crenessity oral solution	crinecerfont
Danziten	nilotinib

Emrosi	minocycline hydrochloride
Ensacove	ensartinib
Imkeldi	imatinib
Migergot	ergotamine/caffeine
Nemludio	nemolizumab
Opipza 2 mg, 5mg and 10mg	aripiprazole
Revuforj 110 mg and 160mg	revumenib
Steqeyma 45 mg/0.5 mL and 90 mg/mL	ustekinumab-stba
Tryngolza	olezarsen
Yesintek 45 mg/0.5 mL and 90 mg/mL	ustekinumab-kfce

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors – Commercial and Healthcare Reform	02/14/2025	Policy revised for heterozygous familial hypercholesterolemia and hypercholesterolemia with ASCVD, policy revised to require a < 50% reduction in baseline LDL despite use with a maximally tolerated statin or current LDL ≥ 70 or non-HDL ≥ 100 or if the member is very high risk, LDL ≥ 55 or non-HDL ≥85. For primary hyperlipidemia, current LDL ≥ 70 or non-HDL ≥ 100 or < 50% reduction in baseline LDL despite use with maximally tolerated statin.
ALK-Targeting Kinase Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised to add Ensacove (ensartinib) to require use in adult patients with ALK-positive locally advanced or metastatic NSCLC who have not previously received an ALK-inhibitor.
Anti-Angiogenesis and VEGF Kinase Inhibitors – Commercial and Healthcare Reform	02/14/2025	Policy revised for Lenvima (lenvatinib) to require use as first-line treatment in unresectable hepatocellular carcinoma per FDA-approved indication.
Anti-Obesity – Fully Insured Commercial and Healthcare Reform	01/29/2025	Policy revised for Zepbound (tirzepatide) for maintenance removing requirement for concurrent use with positive airway pressure and current body mass index. Requiring need for continued therapy. For both Wegovy (semaglutide) for cardiovascular disease and Zepbound (tirzepatide) for obstructive sleep apnea, if the member has type 2 diabetes, therapeutic failure to a diabetes GLP-1 RA.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
BCR-ABL Kinase Inhibitors – Commercial and Healthcare Reform	02/14/2025	Policy revised to include Danziten (nilotinib) requiring diagnosis based on FDA-approved indication and require trial/failure to brand Tasigna (nilotinib). Policy revised to include Imkeldi (imatinib) to require diagnosis and age based on FDA-approved indication, and therapeutic failure, intolerance, or inability to swallow generic imatinib tablets.
Benlysta (belimumab) – Commercial and Healthcare Reform	TBD	Policy revised for Benlysta (belimumab) to remove prescriber attestation of positive anti-nuclear antibody (ANA) titer or anti-double stranded DNA antibody (anti-dsDNA) and inclusion of the member meets one of the following criteria: diagnosis is confirmed by a renal biopsy or the member has a contraindication to a renal biopsy and meets the following criteria: the member is positive for autoantibodies relevant to systemic lupus erythematosus (SLE) and the member has laboratory findings specific to lupus nephritis (LN).
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Commercial and Healthcare Reform	02/14/2025	Policy revised for Braftovi (encorafenib) to require age and diagnosis based on expanded FDA-approved indication for metastatic colorectal cancer.
Cablivi (caplacizumab-yhdp) – Commercial and Healthcare Reform	02/14/2025	Policy revised for Cablivi (caplacizumab-yhdp) requiring an additional specialist requirement and that the total treatment duration will be limited to 58 days beyond the last therapeutic plasma exchange. Reauthorization requiring that the request is for a new episode of acquired thrombotic thrombocytopenic purpura (aTTP) and that the member has not experienced ≥ 2 recurrences of aTTP after initial course of therapy. Initial and reauthorization durations extended to 60 days with a maximum of 3 courses per lifetime.
CFTR Modulators – Commercial and Healthcare Reform	TBD	Policy revised to include Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor tablets) requiring diagnosis based on FDA-approved indication.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	02/14/2025	Policy revised for Bimzelx (bimekizumab-bkzx) to add new indication hidradenitis suppurativa (HS) to require diagnosis and age based on FDA-approved indication, prescribed in consultation with a dermatologist and therapeutic failure or intolerance to at least two

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		step 1 or 2 agents for HS. Criteria revised for Sotyktu (deucravacitinib), Entyvio SC (vedolizumab), Zymfentra SC (infliximab-dyyb), Omvoh SC (mirikizumab-mrkz) and Velsipity (etrasimod) to update from double step directed to step 1 agents to a double step directed to step 1 and 2 agents.
Chronic Inflammatory Diseases – Commercial National Select Formulary	02/14/2025	Policy revised for Bimzelx (bimekizumab-bkzx) to add new indication hidradenitis suppurativa (HS) to require diagnosis and age based on FDA-approved indication, prescribed in consultation with a dermatologist and therapeutic failure or intolerance to at least two step 1 or 2 agents for HS. Policy revised to move Velsipity (etrasimod) to step 1 preferred agent.
Clotting Factor Products – Commercial and Healthcare Reform	TBD	Policy revised to add new product Alhemo (concizumab-mtci) requiring age, diagnosis based on FDA-approved indication, presence of inhibitors defined as ≥ 0.6 Bethesda units/mL. Reauthorization requiring therapeutic response, and documentation of Alhemo (concizumab-mtci) plasma concentration levels ≥ 200 ng/mL on consecutive measurements, or attestation benefits outweigh risks, and alternative therapies are not appropriate if < 200 ng/mL on two consecutive measurements. Initial authorization duration of 6 months, reauthorization duration of 12 months.
Crenessity (crinecerfont) – Commercial and Healthcare Reform	02/14/2025	New policy created for Crenessity (crinecerfont) requiring age, FDA-approved diagnosis, and either supraphysiological glucocorticoid dosing or high levels of androstenedione or 17-hydroxyprogesterone. Reauthorization requiring a reduction in daily glucocorticoid dose or improvement or stabilization in androgen levels. Initial authorization duration of 6 months and reauthorization duration of 12 months. Quantity limit exception to allow 300 mg per day with concomitant moderate cytochrome P450 3A4 (CYP3A4) inducers or 400 mg per day with concomitant strong CYP3A4 inducers per FDA-labeled population.
Cystic Fibrosis Inhaled Medications –	02/14/2025	Policy updated to include National Select formulary.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Commercial and Healthcare Reform		
Cystic Fibrosis Inhaled Medications – Commercial National Select Formulary	TERMED 02/05/2025	Policy terminated
Dihydroergotamine and Ergotamine Products – Commercial and Healthcare Reform	TBD	Policy revised to add Migergot (ergotamine tartrate and caffeine) to require FDA-approved diagnosis and that the member has significant nausea and vomiting requiring a non-oral route and trial of sumatriptan nasal spray or injection and zolmitriptan nasal spray if using to abort vascular headache.
Drug Shortages Step Therapy Exceptions – Commercial and Healthcare Reform	02/14/2025	New policy created for any policies with step therapy or non-formulary medications to allow temporary step therapy exception where the preferred product(s) are experiencing a current shortage as evidenced by the American Society of Health-System Pharmacists (ASHP) Drug Shortage Bulletin, Food and Drug Administration (FDA) Drug Shortage Database, FDA CBER-Regulated Products Shortage Database, or documentation of shortage from the manufacturer or wholesaler (specifically, ordering invoices). If the ASHP Drug Shortage Bulletin lists available products on a lower tier than the requested drug requiring step therapy, the member has experienced therapeutic failure, intolerance, or contraindication to available preferred products. If the requested product requires a clinical prior authorization or formulary exception, all clinical/formulary criteria in applicable policies are met. A 3-12 month authorization may be granted.
Gattex (teduglutide) – Commercial and Healthcare Reform	02/14/2025	Policy revised for Gattex (teduglutide) reauthorization requiring use of parenteral/intravenous nutrition or trial/failure of Gattex discontinuation.
Hetlioz (tasimelteon) – Commercial and Healthcare Reform	02/14/2025	Policy revised for Smith-Magenis Syndrome to require deletion of chromosome 17p11.2 or variant in the RAI1 gene. Policy revised for non-24-hour sleep-wake disorder to change the daily sleep log requirement to 14 days and require therapeutic failure, intolerance, or contraindication to melatonin.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Homozygous Familial Hypercholesterolemia – Commercial and Healthcare Reform	02/14/2025	Policy revised for Juxtapid (lomitapide) to require LDL > 70 mg/dL or LDL > 55 mg/dL if atherosclerotic cardiovascular disease (ASCVD) or major ASCVD risk factors.
Lupkynis (voclosporin) – Commercial and Healthcare Reform	TBD	Policy revised for Lupkynis (voclosporin) to remove prescriber attestation of positive anti-nuclear antibody (ANA) titer or anti-double stranded DNA antibody (anti-dsDNA) and inclusion of the member meets one of the following criteria: diagnosis is confirmed by a renal biopsy or the member has a contraindication to a renal biopsy and meets the following criteria: the member is positive for autoantibodies relevant to systemic lupus erythematosus (SLE) and the member has laboratory findings specific to lupus nephritis (LN).
Market Watch Programs – Delaware	TBD	Policy revised to add Dolobid (brand) to high cost, low value table. The alternatives are ibuprofen, meloxicam tablets, and naproxen tablets. Policy also revised to include Tramadol 75 mg tablets and Tramadol 100 mg tablets. The alternative is tramadol 50 mg tablets.
Market Watch Programs – New York, Pennsylvania, and West Virginia	TBD	Policy revised to add Dolobid (brand) to high-cost, low-value table. The alternatives are ibuprofen, meloxicam tablets, and naproxen tablets. Policy also revised to include Tramadol 75 mg tablets and Tramadol 100 mg tablets. The alternative is tramadol 50 mg tablets.
Nemludio (nemolizumab-ilto) – Commercial and Healthcare Reform	02/14/2025	Policy revised for Nemludio (nemolizumab-ilto) for new indication in atopic dermatitis (AD) requiring age, FDA-approved diagnosis, and trial/failure to one topical corticosteroid or topical calcineurin inhibitor or severe AD with severely damaged skin or large body surface area (BSA) involvement where topical therapy is not appropriate. Reauthorization requiring positive clinical response and member assessed for dose de-escalation. Quantity limit exception allowed for induction dose.
Orserdu (elacestrant) – Commercial and Healthcare Reform	02/14/2025	Policy revised for Orserdu (elacestrant) to require that disease harbors an ESR1 mutation, as detected by an FDA-approved test.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Oxervate (cenegermin-bkbj) – Commercial and Healthcare Reform	02/14/2025	Policy revised for Oxervate (cenegermin-bkbj) to remove fundoscopic examination requirement in initial and reauthorization criteria. Policy revised to extend authorization duration from 8 weeks to 12 weeks to allow for specialty pharmacy dispensing and shipping of medication.
PCSK9 Inhibitors – Commercial and Healthcare Reform	02/14/2025	Policy revised for homozygous familial hypercholesterolemia to require LDL >115 if less than 17 years of age or LDL > 70 if over 18 years of age or LDL < 55 if over 18 years of age with atherosclerotic cardiovascular disease (ASCVD) or major ASCVD risk factors. For heterozygous familial hypercholesterolemia and hypercholesterolemia with ASCVD, policy revised to require a < 50% reduction in baseline LDL despite use with a maximally tolerated statin or current LDL ≥ 70 or non-HDL ≥ 100 or if the member is very high risk, LDL ≥ 55 or non-HDL ≥85. For primary hyperlipidemia, requiring a baseline untreated LDL ≥ 190 or a coronary artery calcium score ≥ 1,000. Also for primary hyperlipidemia, current LDL ≥ 70 or non-HDL ≥ 100 or < 50% reduction in baseline LDL despite use with maximally tolerated statin. Reauthorization criteria for all diagnoses also updated to require the above LDL levels prior to start of therapy.
Pretomanid – Commercial and Healthcare Reform	02/14/2025	Policy revised for pretomanid to include trail/failure/contraindication to isoniazid and a rifamycin antibiotic (rifampin, rifabutin or rifapentine) for treatment intolerant or multidrug resistant tuberculosis.
Revuforj (revumenib) – Commercial and Healthcare Reform	02/14/2025	New policy for Revuforj (revumenib) requiring diagnosis based on FDA-approved indication.
Testosterone (Androgens) – Commercial and Healthcare Reform	02/14/2025	Policy updated to clarify the provider submits documentation (specifically, laboratory results or chart notes) for testosterone products of low testosterone levels or the member is not producing any testosterone. Attestation (yes/no) via survey is no longer acceptable.
Thiola (tiopronin) and Thiola EC (tiopronin) – Commercial and Healthcare Reform	02/14/2025	Policy revised to add Venxxiva (tiopronin) to require diagnosis based on FDA-approved indication, one 24-hour urine collection with urinary cystine excretion of > 400 mg/day, therapeutic failure to increased fluid intake,

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		<p>dietary modifications, and urine alkalinization, and the member has experienced therapeutic failure or intolerance to generic tiopronin. Reauthorization requires urine cystine concentration decrease from baseline or production of cystine stones decrease.</p>
<p>Tryngolza (olezarsen) – Commercial and Healthcare Reform</p>	<p>TBD</p>	<p>New policy created for Tryngolza (olezarsen) requiring age of 18 years and older, the member has a diagnosis of familial chylomicronemia syndrome (FCS), determined by one of the following: genetic test demonstrating biallelic pathogenic variants in at least one gene causing FCS or genetic test results are inconclusive, and the member meets one of the following: FCS score ≥ 10, NAFCS score ≥ 45, history of pancreatitis, history of eruptive xanthomas, history of lipemia retinalis, and the prescriber provides documentation the member has a fasting triglyceride level ≥ 880 mg/dL, and the prescriber attests the member will use Tryngolza in combination diet. Reauthorization requiring the prescriber provides documentation of improvement in triglycerides from baseline. Initial authorization duration of 6 months. Reauthorization duration of 12 months.</p>
<p>Ustekinumab Biosimilars – Commercial and Healthcare Reform</p>	<p>TBD</p>	<p>Policy revised to add new products Steqeyma (ustekinumab-stba) and Yesintek (ustekinumab-kfce) subcutaneous (SC) injection requiring age, FDA-approved diagnosis, specialist, dosing based on FDA-approved weight, and trial/failure to Stelara (ustekinumab). 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.</p>
<p>Voquezna (vonoprazan) Products – Commercial and Healthcare Reform</p>	<p>02/14/2025</p>	<p>Policy revised for Voquezna (vonoprazan) in erosive esophagitis(EE) to update maintenance/reauthorization to remove step through omeprazole and pantoprazole, while</p>

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		adding the requirement that the member has responded to an initial treatment course and continues to have EE that requires treatment for maintenance. For non-erosive gastroesophageal reflux disease (NERD), reauthorization added requiring additional therapy is required, the member has experienced symptom control during the initial 4-week treatment course, and no more than one 20-week reauthorization was received in the past 365 days. Reauthorization duration for NERD updated to 20 weeks.
Vtama (tapinarof) and Zoryve (roflumilast) – Commercial and Healthcare Reform	02/14/2025	Policy revised for Vtama (tapinarof) in atopic dermatitis (AD) requiring age, FDA-approved diagnosis, and trial/failure/contraindication to generic topical tacrolimus or pimecrolimus. Reauthorization of positive clinical response to therapy. For plaque psoriasis, step through topical corticosteroid removed.
Transthyretin Amyloid Cardiomyopathy (ATTR-CM) TTR Stabilizers – Commercial and Healthcare Reform	02/14/2025	Policy revised to add Attruby (acoramidis) requiring age, prescriber specialty, diagnosis based on FDA-approved indication supported by biopsy or scintigraphy, New York Heart Association (NYHA) Class I, II, or III, and not using with other transthyretin-lowering agents. Reauthorization asking for improvement or delayed disease progression in cardiac involvement and continues not using with other transthyretin-lowering agents.

*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
Acute Migraine Therapies – Commercial and Healthcare Reform	TBD	Policy revised to add ergotamine tartrate/caffeine and revise Ergomar (ergotamine tartrate) criteria requiring trial of all three plan-preferred generic triptans (sumatriptan, rizatriptan, and zolmitriptan) when used to abort a vascular headache or trial of three generic prophylactic migraine medications

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		when used for prevention of vascular headache.
Atypical Antipsychotics – Commercial	02/14/2025	Policy revised to include Opipza (aripiprazole oral film). For diagnoses of Gilles de la Tourette's syndrome (6 years and older), schizophrenia (13 years and older), and irritability with autistic disorder (6 years and older), member must have the specified diagnosis, in addition the prescriber must attest to one of the following: the member has an inability to swallow tablets or the member has experienced a therapeutic failure or intolerance to generic aripiprazole tablets. For a diagnosis of adjunctive treatment of major depressive disorder (MDD), the member is 18 years or older, the member has a diagnosis of MDD, the member is being prescribed Opipza as an adjunct to a currently used antidepressant, the member has experienced therapeutic failure, contraindication, or intolerance to one other generic antidepressant in addition to the antidepressant currently being used to treat MDD, and the prescriber must attest to one of the following: the member has an inability to swallow tablets or the member has experienced a therapeutic failure or intolerance to generic aripiprazole tablets.
Atypical Antipsychotics – Healthcare Reform	02/14/2025	Policy revised to include Opipza (aripiprazole oral film). For diagnoses of Gilles de la Tourette's syndrome (6 years and older), schizophrenia (13 years and older), and irritability with autistic disorder (6 years and older), member must have the specified diagnosis, in addition the prescriber must attest to one of the following: the member has an inability to swallow tablets or the member has experienced a therapeutic failure or intolerance to generic aripiprazole tablets. For a diagnosis of adjunctive treatment of major depressive disorder (MDD), the member is 18 years or older, the member has a diagnosis of MDD, the member is being prescribed Opipza as an adjunct to a currently used antidepressant, the member has experienced therapeutic failure, contraindication, or intolerance to one other generic antidepressant in addition to the

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		antidepressant currently being used to treat MDD, and the prescriber must attest to one of the following: the member has an inability to swallow tablets or the member has experienced a therapeutic failure or intolerance to generic aripiprazole tablets.
Butalbital Combination Products – Commercial and Healthcare Reform	02/14/2025	Policy revised to remove off-market products Bupap (butalbital-acetaminophen), Esgic capsules (butalbital-acetaminophen-caffeine), and Zebutal (butalbital-acetaminophen-caffeine).
Gemtesa (vibegron) – Commercial and Healthcare Reform	02/14/2025	Policy revised for Gemtesa (vibegron) for new indication to require overactive bladder symptoms in adult males on pharmacological therapy for benign prostatic hyperplasia, failure on Myrbetriq (mirabegron), or Myrbetriq is inappropriate for the member because of high blood pressure or drug interaction(s) with Myrbetriq, and failure on one of the three agents (oxybutynin, tolterodine, trospium), or antimuscarinics are inappropriate because of the side effects . Reauthorization criterion requires attestation that the member has experienced positive clinical response to therapy.
Intraocular Pressure Reducing Agents – Commercial and Healthcare Reform	01/01/2025	Policy revised for Cosopt (dorzolamide/timolol) to no longer target the generic dorzolamide/timolol product. For Cosopt/Cosopt PF (dorzolamide/timolol), removed requirement for trial/failure of individual components. For generic Cosopt PF (dorzolamide/timolol), requiring trial/failure to generic dorzolamide/timolol non-preservative free.
Lyrica/Lyrica CR (pregabalin/pregabalin ER) – Commercial and Healthcare Reform	02/14/2025	In addition to current criteria, policy revised for Lyrica (pregabalin) to require an age of 18 years and older for a diagnosis of fibromyalgia.
Methotrexate Injections – Commercial and Healthcare Reform	02/14/2025	Policy revised to remove discontinued medication, Reditrex (methotrexate).
Minocycline Products – Commercial and Healthcare Reform	TBD	Policy revised to add Emrosi (minocycline ER) to require diagnosis and age per FDA-approved indication, failure on topical metronidazole or azelaic acid, failure on generic IR minocycline, and generic doxycycline monohydrate IR-DR

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		40 mg. Reauthorization requires clinical improvement or response to therapy.
Minocycline Products – Commercial National Select Formulary	TBD	Policy revised to add Emrosi (minocycline ER) to require diagnosis and age per FDA-approved indication, failure on topical metronidazole or azelaic acid, failure on generic IR minocycline and generic doxycycline monohydrate IR-DR 40 mg. Reauthorization requires clinical improvement or response to therapy.
Non-Preferred Bupropion Products – Commercial and Healthcare Reform	TBD	Policy revised to remove automatic approval criteria.
Non-Preferred Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) – Commercial and Healthcare Reform	TBD	Policy revised to add brand Victoza (liraglutide) as a target requiring diagnosis of type 2 diabetes and therapeutic failure, intolerance, or contraindication to generic liraglutide and two plan preferred products (Mounjaro (tirzepatide), Ozempic (semaglutide) or Rybelsus (semaglutide), or Trulicity (dulaglutide). Reauthorization requires that the member still requires continued therapy and has therapeutic failure, intolerance, or contraindication to generic liraglutide and two plan preferred products (Mounjaro (tirzepatide), Ozempic (semaglutide) or Rybelsus (semaglutide), or Trulicity (dulaglutide).
Non-Preferred Ranolazine Products – Commercial and Healthcare Reform	02/14/2025	Policy revised to remove brand Ranexa (ranolazine) as a target.
Non-Preferred Tramadol Products – Commercial and Healthcare Reform	02/14/2025	Policy revised to include Tramadol 75 mg tablets as a target. Members must have a diagnosis of pain (ICD-10: R52) and also have experienced therapeutic failure or intolerance to plan-preferred generic tramadol hydrochloride 50 mg. No change to current reauthorization criteria.
Non-Stimulant Treatment of ADHD – Commercial and Healthcare Reform	12/23/2024	Policy revised to remove generic atomoxetine as a target.
Non-Stimulant Treatment of ADHD – Commercial and Healthcare Reform	TBD	Policy revised to remove Kapvay (clonidine ER) (brand and generic) tablets as targets. Brand Strattera no longer requires therapeutic failure or intolerance to generic guanfacine ER or generic clonidine ER tablets. The member must

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		have experienced therapeutic failure or intolerance to generic atomoxetine. Automatic approval criteria remains the same for brand Intuniv. For brand Strattera, there must be a claim for amphetamine, methamphetamine, or methylphenidate, as well as generic atomoxetine in the member's prescription drug claims history within the previous 180 days. For Qelbree, there must be a claim for amphetamine, methamphetamine, or methylphenidate, a claim for generic guanfacine ER or generic clonidine ER, as well as a claim for generic atomoxetine in the member's prescription drug claims history within the previous 180 days.
Topical Corticosteroids – Commercial and Healthcare Reform	02/14/2025	Policy revised to remove desonide 0.05% lotion and fluticasone propionate 0.05% lotion as step therapy qualifiers
Topical Corticosteroids – Commercial and Healthcare Reform	TBD	Policy revised to add Tovet emollient (clobetasol dipropionate) 0.05% foam and clobetasol emollient 0.05% foam as targets to align with criteria for other high potency topical corticosteroids. Added desonide 0.05% lotion and fluticasone propionate 0.05% lotion as targets to align with criteria for other low to medium topical corticosteroids.
Xeloda (capecitabine) – Commercial and Healthcare Reform	TBD	Policy revised for Xeloda (capecitabine) to add generic capecitabine as a target. Automatic approval criteria to include generic capecitabine.

*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*

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

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

Drug Name	Retail Edit Limit	Mail Edit Limit
Alyftrek vanzacaftor, tezacaftor, and deutivacafto	1 carton per 28 days	3 cartons per 84 days
Cablivi (caplacizumab-yhdp)	174 kits per 720 days	174 kits per 720 days
Crenessity (crinecerfont) oral solution	120 mL (4 x 30 mL bottles) per 25 days	360 mL (12 x 30 mL bottles) per 75 days
Ergotamine tartrate-caffeine	40 tablets per 21 days	120 tablets per 63 days
Mavenclad	40 tablets per 720 days	40 tablets per 720 days
Migergot	20 suppositories per 21 days	60 suppositories per 63 days
Opill (norgestrel)	366-day supply in 270 days	366-day supply in 270 days
Steqeyma (ustekinumab-stba) 45 mg/0.5 mL	1 syringe (0.5 mL) per 84 days	1 syringe (0.5 mL) per 84 days
Steqeyma (ustekinumab-stba) 90 mg/mL	1 syringe (1 mL) per 84 days	1 syringe (1 mL) per 84 days
Tryngolza (olezarsen)	1 autoinjector per 28 days	3 autoinjectors per 84 days
Yesintek (ustekinumab-kfce) 45 mg/0.5 mL	1 syringe (0.5 mL) per 84 days	1 syringe (0.5 mL) per 84 days
Yesintek (ustekinumab-kfce) 90 mg/mL	1 syringe (1 mL) per 84 days	1 syringe (1 mL) per 84 days

*Effective date to be determined.

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

Drug Name	Retail Edit Limit	Mail Edit Limit
Climara 0.1 mg/day patch	16 patches (4 boxes)	48 patches (12 boxes)
Dotti 0.1 mg patch	32 patches (4 boxes)	96 patches (12 boxes)
Estradiol 0.1 mg patch (1/wk)	16 patches (4 boxes)	48 patches (12 boxes)
Estradiol 0.1 mg patch (2/wk)	32 patches (4 boxes)	96 patches (12 boxes)
Lyllana 0.1 mg patch	32 patches (4 boxes)	96 patches (12 boxes)
Minivelle 0.1 mg patch	32 patches (4 boxes)	96 patches (12 boxes)
Vivelle-dot 0.1 mg patch	32 patches (4 boxes)	96 patches (12 boxes)

*Effective date to be determined.

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

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

Drug Name	Daily Limit
Attruby (acoramidis)	4 tablets per day
Crenessity (crinicerfont) 25 mg, 50mg, 100 mg capsules	2 capsules per day
Danziten (nilotinib)	4 tablets per day
Emrosi (minocycline hydrochloride)	1 capsule daily
Ensacove (ensartinib)	2 tablets per day
Imkeldi (imatinib)	10 mL per day
Jatenzo (testosterone undecanoate) 158 mg	4 capsules per day
OPIPZA (aripiprazole) 2 mg	1 oral film/day
OPIPZA (aripiprazole) 5 mg and 10 mg	3 oral films/day
Oracea (doxycycline monohydrate)	1 capsule per day
Revuforj (revumenib) 110 mg	4 tablets per day
Revuforj (revumenib) 160 mg	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 Incentive 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:

[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.

Brand Name	Generic Name	Comments
None 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
Azmiro syringe	testosterone cypionate	testosterone cypionate oil 200 mg/mL
Rapiblyk	landiolol	prescriber discretion

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.

Brand Name	Generic Name	Comments
None 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
None at this time.		

Table 3. Products Not Added*

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

Brand Name	Generic Name	Preferred Alternatives
Alyftrek	vanzacaftor, tezacaftor, and deuterivacaftor	prescriber discretion
Attruby	acoramidis	prescriber discretion
Azmiro syringe	testosterone cypionate	testosterone cypionate oil 200 mg/mL
Crelessness capsules	crinicerfont	prednisone tablet, dexamethasone tablet, hydrocortisone tablet
Crelessness oral solution	crinicerfont	prednisone solution, dexamethasone solution
Emrosi	minocycline hydrochloride	metronidazole cream; metronidazole lotion
Rapiblyk	landiolol	prescriber discretion
Steqeyma	ustekinumab-stba	Stelara
Tryngolza	olezarsen	prescriber discretion
Venxxiva Delayed release tablet	tiopronin	tiopronin tablet** prescriber discretion***
Yesintek	ustekinumab-kfce	Stelara

*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**.

** Venture only

***Performance and Fundamental only

C. Additions to the Specialty Tier

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

Brand Name	Generic Name
Alyftrek*	vanzacaftor, tezacaftor, and deutivacaftor
Attruby*	acoramidis
Bizengri	zenocutuzumab-zbco
Crenessity*	crinecerfont
Danziten	nilotinib
Emrosi*	minocycline hydrochloride
Ensacove	ensartinib
Imkeldi	imatinib
Kebilidi	eladocagene exuparvovec-tneq
Nemluvio**	nemolizumab
Opdivo Qvantig	nivolumab and hyaluronidase-nvhy
Opipza	aripiprazole
Revuforj	revumenib
Steqeyma*	ustekinumab-stba
Tryngolza*	olezarsen
Unloxcyt	cosibelimab-lpdl
Venxxiva delayed release tablet*	tiopronin
Yesintek *	ustekinumab-kfce
Ziihera	zanidatamab-hrii

*Pertains only to Incentive and Compass Formularies

** Pertains only to Venture, Performance and Fundamental

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors – Medicare	02/14/2025	Policy revised for heterozygous familial hypercholesterolemia and hypercholesterolemia with ASCVD, policy revised to require a < 50% reduction in baseline LDL despite use with a maximally tolerated statin or current LDL ≥ 70 or non-HDL ≥ 100 or if the member is very high risk, LDL ≥ 55 or non-HDL ≥85. For primary hyperlipidemia, current LDL ≥ 70 or non-HDL ≥ 100 or < 50% reduction in baseline LDL despite use with maximally tolerated statin.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Administrative Prior Authorizations for Medicare Part D Plans – Medicare	02/14/2025	Policy revised to add Vyalev (foscarbidopa/foslevodopa) as a target for Drugs Administered via Infusion Pump review. Policy revised to add additional criteria for Hepatitis B approval under Part B of not previously received a complete Hepatitis B vaccination series or Hepatitis B vaccination history is unknown. Policy revised to add Velphoro as an oral-only renal dialysis drugs that has no other form of administrations to renal dialysis drug review.
ALK Targeting Kinase Inhibitors – Medicare	TBD	Policy revised to add Ensacove (ensartinib) to require use in patients with ALK-positive locally advanced or metastatic NSCLC who have not previously received an ALK-inhibitor.
Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor tablets) – Medicare	02/14/2025	New policy created for Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor tablets) requiring diagnosis based on FDA-approved indication.
Anti-Angiogenesis and VEGF Kinase Inhibitors – Medicare	02/14/2025	Policy revised for Fotivda (tivozanib), Lenvima (lenvatinib), Stivarga (regorafenib), and Votrient (pazopanib) to remove age limitations.
Anti-Angiogenesis and VEGF Kinase Inhibitors – Medicare	TBD	Policy revised for Inlyta (axitinib) to require use as a single agent per FDA-approved indication. Policy revised for Lenvima (lenvatinib) to require use as first-line treatment for hepatocellular carcinoma per FDA-approved indication. Policy revised for Nexavar (sorafenib) to require diagnosis of advanced renal cell carcinoma per FDA-approved indication.
Atypical Antipsychotics – Medicare	TBD	Policy revised to include Opipza (aripiprazole oral film). For diagnoses of Gilles de la Tourette's syndrome, schizophrenia, and irritability with autistic disorder, member must have the specified diagnosis, in addition the prescriber must attest to one of the following: the member has an inability to swallow tablets or the member has experienced a therapeutic failure or intolerance to generic aripiprazole tablets. For a diagnosis of adjunctive treatment of major depressive disorder (MDD), the member has a diagnosis of MDD, the member is being prescribed Opipza as an adjunct to a currently used antidepressant, the member has experienced therapeutic failure, contraindication, or intolerance to one other generic antidepressant in addition to the antidepressant currently being used to treat MDD, and the prescriber must attest

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		to one of the following: the member has an inability to swallow tablets or the member has experienced a therapeutic failure or intolerance to generic aripiprazole tablets.
BCR-ABL Kinase Inhibitors – Medicare	02/14/2025	Policy revised to include Danziten (nilotinib) requiring diagnosis based on FDA-approved indication. Policy revised to include Imkeldi (imatinib) to require diagnosis based on FDA-approved indication, and therapeutic failure, intolerance, or inability to swallow generic imatinib tablets.
Benlysta (belimumab) – Medicare	TBD	Policy revised for Benlysta (belimumab) to remove prescriber attestation of positive anti-nuclear antibody (ANA) titer or anti-double stranded DNA antibody (anti-dsDNA) and inclusion of the member meets one of the following criteria: diagnosis is confirmed by a renal biopsy or the member has a contraindication to a renal biopsy and meets the following criteria: the member is positive for autoantibodies relevant to systemic lupus erythematosus (SLE) and the member has laboratory findings specific to lupus nephritis (LN).
Bizengri (zenocutuzumab-zbco) – Medicare	02/14/2025	New policy for Bizengri (zenocutuzumab-zbco) requiring diagnosis based on FDA-approved indication.
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Medicare	02/14/2025	Policy revised for Braftovi (encorafenib) to require diagnosis based on expanded FDA-approved indication for metastatic colorectal cancer.
Cabliivi (caplacizumab-yhdp) – Medicare	02/14/2025	Policy revised for Cabliivi (caplacizumab-yhdp) to remove age restriction.
Cabliivi (caplacizumab-yhdp) – Medicare	TBD	Policy revised for Cabliivi (caplacizumab-yhdp) requiring the total treatment duration will be limited to 58 days beyond the last therapeutic plasma exchange. Reauthorization requiring that the request is for a new episode of acquired thrombotic thrombocytopenic purpura (aTTP) and that the member has not experienced ≥ 2 recurrences of a TTP after initial course of therapy. Reauthorization duration extended to 60 days with a maximum of 3 courses per lifetime.
Chronic Inflammatory Diseases – Medicare	TBD	Policy revised for Bimzelx (bimekizumab-bkzx) to add new indication hidradenitis suppurativa (HS) to require diagnosis and age based on FDA-approved indication, and therapeutic failure or

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		intolerance to at least two preferred biologic products for HS.
Crenessity (crinecerfont) – Medicare	02/14/2025	New policy created for Crenessity (crinecerfont) requiring FDA-approved diagnosis, and either supraphysiological glucocorticoid dosing or high levels of androstenedione or 17-hydroxyprogesterone. Reauthorization requiring a reduction in daily glucocorticoid dose or improvement or stabilization in androgen levels. Initial authorization duration of 6 months and reauthorization duration of 12 months.
Eculizumab Products – Medicare	TBD	Policy revised for Epysqli (eculizumab-aagh) and Bkmev (eculizumab-aeeb) to add new indication of generalized myasthenia gravis (gMG), to require diagnosis based on FDA-approved indication, therapeutic failure, contraindication or intolerance to generic pyridostigmine and reauthorization requires improvement in signs and symptoms of gMG or decrease in number of exacerbations.
Hetlioz and Hetlioz LQ (tasimelteon) – Medicare	02/14/2025	Policy revised for non-24-hour sleep-wake disorder to change the daily sleep log requirement to 14 days and to remove the requirement that the member is totally blind.
Hetlioz and Hetlioz LQ (tasimelteon) – Medicare	TBD	Policy revised for Smith-Magenis Syndrome to require deletion of chromosome 17p11.2 or variant in the RAI1 gene.
Homozygous Familial Hypercholesterolemia – Medicare	02/14/2025	Policy revised for Evzeeka (evinacumab-dgnb) to require LDL > 115 mg/dL for members 17 years of age or younger or LDL > 70 mg/dL if 18 years of age or older or LDL > 55 mg/dL if 18 years of age and older and atherosclerotic cardiovascular disease (ASCVD) or major ASCVD risk factors. Policy revised for Juxtapid (lomitapide) to require LDL > 70 mg/dL or LDL > 55 mg/dL if ASCVD or major ASCVD risk factors.
Iluvien (fluocinolone acetonide intravitreal implant) – Medicare	02/14/2025	New policy created for Iluvien (fluocinolone acetonide intravitreal implant) requiring FDA-approved diagnosis. For reauthorization, requiring improved or stabilized visual acuity and at least 36 months have elapsed since the prior treatment of the same eye. Authorization duration of 12 months.
Interferons – Medicare	02/14/2025	Policy revised to remove discontinued medication, Intron A (interferon alfa-2b).

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Kebilidi (eladocagene exuparvovec-tneq) – Medicare	TBD	New policy created for Kebilidi (eladocagene exuparvovec-tneq) requiring FDA-approved diagnosis genetically confirmed with biallelic mutations in the DOPA decarboxylase (DDC) gene and the member has achieved skull maturity assessed by neuroimaging.
Lupkynis (voclosporin) – Medicare	TBD	Policy revised for Lupkynis (voclosporin) to remove 18 years of age or older and prescriber attestation of positive anti-nuclear antibody (ANA) titer or anti-double stranded DNA antibody (anti-dsDNA) and inclusion of the member meets one of the following criteria: diagnosis is confirmed by a renal biopsy or the member has a contraindication to a renal biopsy and meets the following criteria: the member is positive for autoantibodies relevant to systemic lupus erythematosus (SLE) and the member has laboratory findings specific to lupus nephritis (LN).
Methotrexate Injections – Medicare	02/14/2025	Policy revised to remove discontinued medication, Reditrex (methotrexate).
Nemludio (nemolizumab-ilto) – Medicare	TBD	Policy revised for Nemludio (nemolizumab-ilto) for new indication in atopic dermatitis (AD) requiring FDA-approved diagnosis, and trial/failure to one topical corticosteroid or topical calcineurin inhibitor or severe AD with severely damaged skin or large body surface area (BSA) involvement where topical therapy is not appropriate. Documentation that the prescribed dose for AD is consistent with FDA-approved dosing. Quantity limit exception allowed for induction dose.
Oral Rosacea Medications – Medicare	TBD	Policy revised to add Oracea (doxycycline monohydrate) to require diagnosis per FDA-approved indication, failure on topical metronidazole and if the request is for brand Oracea failure on generic doxycycline monohydrate IR-DR 40 mg.
Oral Rosacea Medications – Medicare	02/14/2025	Policy created for Emrosi (minocycline ER) to require diagnosis per FDA-approved indication, failure on topical metronidazole and failure on generic doxycycline monohydrate IR-DR 40 mg.
Orserdu (elacestrant) – Medicare	TBD	Policy revised for Orserdu (elacestrant) to require that ESR1 mutation is detected by an FDA-approved test.
Orserdu (elacestrant) – Medicare	02/14/2025	Policy revised for Orserdu (elacestrant) to require that disease harbors an ESR1 mutation.

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Oxervate (cenegermin-bkbj) – Medicare	02/14/2025	Policy revised Oxervate (cenegermin-bkbj) to extend authorization duration from 8 weeks to 12 weeks to allow for specialty pharmacy dispensing and shipping of medication.
PCSK9 Therapies – Medicare	02/14/2025	Policy revised for homozygous familial hypercholesterolemia to require LDL >115 if less than 17 years of age or LDL > 70 if over 18 years of age or LDL < 55 if over 18 years of age with atherosclerotic cardiovascular disease (ASCVD) or major ASCVD risk factors. For heterozygous familial hypercholesterolemia and hypercholesterolemia with ASCVD, policy revised to require a < 50% reduction in baseline LDL despite use with a maximally tolerated statin or current LDL ≥ 70 or non-HDL ≥ 100 or if the member is very high risk, LDL ≥ 55 or non-HDL ≥85. For primary hyperlipidemia, current LDL ≥ 70 or non-HDL ≥ 100 or < 50% reduction in baseline LDL despite use with maximally tolerated statin.
PCSK9 Therapies – Medicare	01/22/2025	Policy revised for Praluent (alirocumab) to remove step through Repatha (evolocumab) for diagnosis of Primary Hyperlipidemia, Not Associated with ASCVD (atherosclerotic cardiovascular disease), HeFH (heterozygous familial hypercholesterolemia), or HoFH (homozygous familial hypercholesterolemia).
Pretomanid – Medicare	TBD	Policy revised for pretomanid to require a diagnosis of pulmonary tuberculosis (TB) classified as pre-extensively drug resistant (XRD) TB or XRD-TB and for the member to experience failure, contraindication, or intolerance to isoniazid or a rifamycin antibiotic, and experience failure, contraindication, or intolerance to 1 fluoroquinolone antibiotic or amikacin, kanamycin, or capreomycin. The member must also take pretomanid with bedaquiline and linezolid. For a diagnosis of pulmonary TB classified as treatment tolerant or nonresponsive multidrug resistant (MDR) TB, the member must experience therapeutic failure, contraindication, or intolerance to isoniazid or a rifamycin antibiotic and to take pretomanid with bedaquiline and linezolid.
Pretomanid – Medicare	TBD	Policy updated for treatment intolerant or nonresponsive multidrug resistant tuberculosis for the member to experience failure, contraindication,

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		or intolerance to both isoniazid and a rifamycin antibiotic.
Programmed Death Receptor Therapies – Medicare	TBD	Policy revised to add Unloxcyt (cosibelimab-ipdl) requiring a diagnosis of cutaneous squamous cell carcinoma (CSCC) and one of the following: disease is classified as metastatic or the disease is classified as locally advanced, and the member is not a candidate for curative surgery or radiation.
Programmed Death Receptor Therapies – Medicare	02/14/2025	Policy revised for Imfinzi (durvalumab) to require diagnosis based on FDA-approved expanded indication for limited-stage small cell lung cancer. Policy revised for Tevimbra (tislelizumab-jsgr) to require diagnosis based on FDA-approved expanded indication for gastric or gastroesophageal junction adenocarcinoma. Policy revised to add new product Opdivo Qvantig (nivolumab and hyaluronidase-nvhy) to require diagnosis based on FDA-approved indications.
Revuforj (revumenib) – Medicare	02/14/2025	New policy for Revuforj (revumenib) requiring diagnosis based on FDA-approved indication.
Testosterone (Androgens) – Medicare	02/14/2025	Policy revised to add Azmiro (testosterone cypionate) requiring the member is male, diagnosis of hypogonadism due to double orchidectomy or testosterone deficiency, weight loss due to HIV infection, or on chronic steroids. For hypogonadism not due to double orchidectomy, requiring low testosterone levels per laboratory reference ranges.
Thiola (tiopronin) and Thiola EC (tiopronin) – Medicare	02/14/2025	Policy revised to add Venxxiva (tiopronin) to require diagnosis based on FDA-approved indication, one 24-hour urine collection with urinary cystine excretion of > 400 mg/day, member has failed urine alkalinization, and the member has experienced therapeutic failure or intolerance to generic tiopronin. Reauthorization requires urine cystine concentration decrease from baseline or production of cystine stones decrease.
Trodelvy (sacituzumab govitecan-hziy) – Medicare	02/14/2025	Policy revised for Trodelvy (sacituzumab govitecan-hziy) to remove criteria for urothelial cancer based on removal of FDA-approved indication.
Tryngolza (olezarsen) – Medicare	02/14/2025	New policy created for Tryngolza (olezarsen) requiring diagnosis of familial chylomicronemia syndrome (FCS), determined by one of the following: genetic test demonstrating biallelic

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		pathogenic variants in at least one gene causing FCS or genetic test results are inconclusive, and meets one of the following: the member has a FCS score ≥ 10 , NAFCS score ≥ 45 , the member has a history of pancreatitis, the member has a history of eruptive xanthomas, the member has a history of lipemia retinalis, and the member has a fasting triglyceride level ≥ 750 mg/dL which does not respond to standard lipid-lowering therapy, and the member will use Tryngolza in combination with diet. Reauthorization requiring the member has experienced improvement in triglycerides from baseline. Initial authorization duration of 6 months. Reauthorization duration of 12 months.
Ustekinumab Biosimilars – Medicare	TBD	Policy revised to add new products Steqeyma (ustekinumab-stba) and Yesintek (ustekinumab-kfce) 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 biosimilar, prescriber attestation of ustekinumab IV induction dose received within 2 months or currently undergoing induction.
Voquezna (vonoprazan) Products – Medicare	TBD	Policy revised for Voquezna (vonoprazan) in erosive esophagitis(EE) to update maintenance/reauthorization to remove step through omeprazole and pantoprazole, and add requirement that the member has responded to an initial treatment course and continues to have EE that requires treatment for maintenance. For non-erosive gastroesophageal reflux disease (NERD), reauthorization added requiring additional therapy is required and the member has experienced symptom control during the initial 4-week treatment course. Reauthorization duration for NERD updated to 20 weeks.
Vtama (tapinarof) and Zoryve (roflumilast) – Medicare	TBD	Policy revised for Vtama (tapinarof) in atopic dermatitis (AD) requiring FDA-approved diagnosis, trial/failure/contraindication to one generic formulary topical corticosteroid or facial or anogenital involvement, and

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		trial/failure/contraindication to generic topical tacrolimus or pimecrolimus.
Vyjuvek (beremagene geperpavec-svdt) – Medicare	02/14/2025	Policy revised for Vyjuvek (beremagene geperpavec-svdt) to update initial authorization duration to 6 months.
Transthyretin Amyloid Cardiomyopathy (ATTR-CM) TTR Stabilizers – Medicare	02/14/2025	Policy revised to add Attruby (acoramidis) requiring age, diagnosis based on FDA-approved indication supported by biopsy or scintigraphy and cardiac involvement, and not using with other transthyretin-lowering agents. Reauthorization asking for improvement or delayed disease progression in cardiac involvement and continues not using with other transthyretin-lowering agents.
Wegovy (semaglutide) – Medicare Incentive and Compass	01/01/2025	Policy revised for Wegovy (semaglutide) to remove requirement of concurrent use with a statin.
Wegovy (semaglutide) – Medicare Incentive and Compass	01/01/2025	Policy revised for reauthorization of Wegovy (semaglutide) in patients with atherosclerotic cardiovascular disease to require concurrent use with a plan to manage cardiovascular risk factors.
Wegovy (semaglutide) and Zepbound (tirzepatide) – Medicare Incentive and Compass	01/28/2025	Policy revised for Zepbound (tirzepatide) for initiation to require baseline apnea/hypopnea index with optimized guideline directed care. For reauthorization, requiring reduction in baseline (with optimized guideline directed care) apnea/hypopnea index and need for continued therapy.
Ziihera (zanidatamab-hrii) – Medicare	02/14/2025	New policy for Ziihera (zanidatamab-hrii) requiring diagnosis based on FDA-approved indication.

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

2. Updates to Step Therapy

No changes at this time.

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)
Alyftrek (vanzacaftor 10 mg, tezacaftor 50 mg, and deutivacaftor 125 mg)	1 carton (56-count) per 28 days
Alyftrek (vanzacaftor 4 mg, tezacaftor 20 mg, and deutivacaftor 50 mg)	1 carton (84-count) per 28 days

Drug Name	Retail Quantity Limit (31 days)
Attruby (acoramidis)	124 tablets per 31 days
Bizengri (zenocutuzumab-zbco)	2 vials (37.5 mL) per 14 days
Crenessity (crinecerfont) 100 mg capsules	4 capsules per day
Crenessity (crinecerfont) 25 mg, 50 mg capsules	2 capsules per day
Crenessity (crinecerfont) oral solution	4 mL per day
Danziten (nilotinib)	4 tablets per day
Emrosi (minocycline hydrochloride)	1 capsule per day
Ensacove (ensartinib)	2 tablets per day
Iluvien (fluocinolone acetonide intravitreal implant)	2 implants per 720 days
Imkeldi (imatinib)	10 mL per day
Kebilidi (eladocagene exuparvovec-tneq)	1 vial (2 mL) per lifetime
Opdivo Qvantig (nivolumab and hyaluronidase-nvhy)	2 vials (10 mL) per 21 days
Opipza (aripiprazole) 2 mg	1 oral film per day
Opipza (aripiprazole) 5 mg and 10 mg	3 oral films per day
Oracea (doxycycline monohydrate)	1 capsule per day
Revuforj (revumenib) 110 mg	4 tablets per day
Revuforj (revumenib) 160 mg	2 tablets per day
Steqeyma (ustekinumab-stba) 130 mg/26 mL	8 vials (208 mL) per 365 days
Steqeyma (ustekinumab-stba) 45 mg/0.5 mL	1 syringe (0.5 mL) per 84 days
Steqeyma (ustekinumab-stba) 90 mg/mL	1 syringe (1 mL) per 56 days
Tramadol HCl 75 mg oral tablets	155 tablets per 31 days
Tryngolza (olezarsen)	1 autoinjector (0.8 mL) per 28 days
Unloxcyt (Cosibelimab-lpdl)	4 cartons (20 mL) per 21 days
Yesintek (ustekinumab-kfce) 130 mg/26 mL	8 vials (208 mL) per 365 days
Yesintek (ustekinumab-kfce) 45 mg/0.5 mL	1 syringe (0.5 mL) per 84 days
Yesintek (ustekinumab-kfce) 90 mg/mL	1 syringe (1 mL) per 56 days