Formulary Updates

December 2023

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for August 2023. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in August 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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B. Changes to the Highmark Healthcare Reform Essential Formulary
C. Changes to the Highmark Core Formulary
D. Changes to the Highmark National Select Formulary
E. Updates to the Pharmacy Utilization Management Programs
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    2. Managed Prescription Drug Coverage (MRxC) Program
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Section II. Highmark Medicare Part D Formularies

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B. Changes to the Highmark Medicare Part D 5-Tier Closed Formularies
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As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (accessible via NaviNet® or our website). Click the **Pharmacy Program/Formularies** link from the menu on the left.

HIGHMARK

Important Drug Safety Updates

Albuterol Sulfate Inhalation by Cipla: Recall - Defective device

On July 6, 2023, Cipla Limited (BSE: 500087; NSE: CIPLA EQ; and hereafter referred to as "Cipla"), today announced that its wholly owned subsidiary Cipla US is voluntarily recalling six batches of Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 Metered Inhalation) manufactured in November 2021 to the consumer level.

There is a reasonable probability that failure to deliver the recommended dose to treat the respiratory symptoms of an acute asthma exacerbations such as wheezing coughing, shortness of breath and bronchospasms, due to device defect, may be life-threatening. There were no adverse events reported for Albuterol Sulfate Inhalation Aerosol 90 mcg related to this recall.

Tydemy by Lupin Pharmaceuticals: Recall - Out of specification test results

On July 28, 2023, Lupin Pharmaceuticals Inc. (Lupin) is voluntarily recalling two (2) lots of Tydemy (Drospirenone, Ethinyl Estradiol and Levomefolate Calcium Tablets 3mg/0.03mg/0.451 mg and Levomefolate Calcium Tablets 0.451 mg) to the patient (consumer/user) level due to out of specification (OOS) test results at the 12-month stability time point. Specifically, one lot (L200183) tested low for ascorbic acid (an inactive ingredient) and high for a known impurity.

To date, Lupin has received no reports of adverse events related to either recalled batches. Regardless, Lupin is recalling these two batches because if there were a significant reduction in the amount of inactive content (ascorbic acid), this could potentially impact the effectiveness of the product which could potentially result in unexpected pregnancy.

Highmark Formulary Update – August 2023

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 pleased 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 August 2023 unless otherwise noted.

Brand Name	Generic Name	Comments
Abrysvo	respiratory syncytial virus vaccine	Respiratory syncytial virus, prevention
Opill*	norgestrel	Pregnancy prevention
Opvee	nalmefene	Emergency opioid overdose reversal

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

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Inpefa	sotagliflozin	Farxiga, Jardiance
Lodoco	colchicine	rosuvastatin calcium, atorvastatin calcium, Repatha Sureclick
Miebo	perfluorohexyloctane	cyclosporine 0.05 % dropperette, single-use drop dispenser; Xiidra***
Ngenla	somatrogon-ghla	Genotropin, Norditropin Flexpro, Humatrope
Rolvedon	eflapegrastim-xnst	Fulphila, Ziextenzo
Suflave	PEG3350; sodium sulfate; potassium chloride; magnesium sulfate; sodium chloride	peg 3350-Electrolyte, Gavilyte-C, Gavilyte-G

Brand Name	Generic Name	Preferred Alternatives
Vevye*	cyclosporine	cyclosporine 0.05 % dropperette, single-use drop dispenser; Xiidra***
Yuflyma	adalimumab-aaty	Humira, adalimumab-adaz, Cyltezo, Hyrimoz
Litfulo	ritlecitinib	prescriber discretion

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

Table 3. Additions to the Specialty Tier Copay Option

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

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

Brand Name	Generic Name
Ngenla	somatrogon-ghla
Litfulo	ritlecitinib
Rolvedon	eflapegrastim-xnst
Yuflyma	adalimumab-aaty

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 August 2023, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Opill*	norgestrel	2	Pregnancy prevention
Opvee	nalmefene	2	Emergency opioid overdose reversal
Abrysvo	respiratory syncytial virus vaccine	3	Respiratory syncytial virus, prevention
Items listed below were not added to the formulary			
Inpefa	sotagliflozin	NF	Farxiga, Jardiance
Lodoco	colchicine	NF	rosuvastatin calcium, atorvastatin calcium, Repatha Sureclick
Miebo	perfluorohexyloctane	NF	cyclosporine 0.05 % dropperette, single-use drop dispenser
Ngenla	somatrogon-ghla	NF	Genotropin, Norditropin Flexpro, Humatrope

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Rolvedon	eflapegrastim-xnst	NF	Nivestym, Zarxio
Suflave	PEG3350; sodium sulfate; potassium chloride; magnesium sulfate; sodium chloride	NF	peg 3350-electrolyte, Gavilyte-C, Gavilyte-G
Vevye*	cyclosporine	NF	cyclosporine 0.05 % dropperette, single-use drop dispenser
Yuflyma	adalimumab-aaty	NF	Humira, Hadlima, adalimumab-fkjp
Litfulo	ritlecitinib	NF	prescriber discretion

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

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 August 2023 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Abrysvo	respiratory syncytial virus vaccine	3	Respiratory syncytial virus, prevention
Opill*	norgestrel	3	Pregnancy prevention
Opvee	nalmefene	3	Emergency opioid overdose reversal
Items listed below were not added to the formulary			
Inpefa	sotagliflozin	NF	Farxiga, Jardiance
Lodoco	colchicine	NF	rosuvastatin calcium, atorvastatin calcium, Repatha Sureclick
Miebo	perfluorohexyloctane	NF	cyclosporine 0.05 % dropperette, single-use drop dispenser; Xiidra
Ngenla	somatrogon-ghla	NF	Genotropin, Norditropin Flexpro, Humatrope
Rolvedon	eflapegrastim-xnst	NF	Nivestym
Suflave	PEG3350; sodium sulfate; potassium chloride; magnesium sulfate; sodium chloride	NF	peg 3350-Electrolyte, Gavilyte-C, Gavilyte-G
Vevye*	cyclosporine	NF	cyclosporine 0.05 % dropperette, single-use drop dispenser; Xiidra
Yuflyma	adalimumab-aaty	NF	Humira, Hadlima, adalimumab-fkjp
Litfulo	ritlecitinib	NF	prescriber discretion

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

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)			
Abrysvo	respiratory syncytial virus vaccine	2	Respiratory syncytial virus, prevention
Ngenla	somatrogon-ghla	2	Growth hormone
Items listed below were added to the formulary (Non-Preferred)			
Litfulo	ritlecitinib	3	prescriber discretion
Opill*	norgestrel	3	prescriber discretion
Opvee	nalmefene	3	prescriber discretion
Vevye*	cyclosporine	3	cyclosporine 0.05 % dropperette, single-use drop dispenser
Items listed below were not added to the formulary			
Rolvedon	eflapegrastim-xnst	NF	Fulphila, Ziextenzo
Inpefa	sotagliflozin	NF	Farxiga, Jardiance
Lodoco	colchicine	NF	rosuvastatin calcium, atorvastatin calcium
Miebo	perfluorohexyloctane	NF	cyclosporine 0.05 % dropperette, single-use drop dispenser
Suflave	PEG3350; sodium sulfate; potassium chloride; magnesium sulfate; sodium chloride	NF	PEG 3350-electrolyte, PEG3350-SOD SUL-NaCl-KCl-ASB-C
Yuflyma	adalimumab-aaty	NF	Humira, Cyltezo, adalimumab-adaz

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
Litfulo	ritlecitinib
Ngenla	somatrogon-ghla
Rolvedon	eflapegrastim-xnst
Yuflyma	adalimumab-aaty

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Lupkynis (voclosporin) – Commercial and Healthcare Reform	09/082023	Policy revised for Lupkynis (voclosporin) to remove step requirement of trial/failure/contraindication to two standard of care drug classes: corticosteroid, antimalarial, or immunosuppressive.
Human Growth Hormone – Delaware Commercial and Healthcare Reform	TBD	Policy revised to add Humatrope (somatropin) as a preferred product for all formularies, excluding the National Select Formulary.
Human Growth Hormone – Commercial and Healthcare Reform	TBD	Policy revised to add Humatrope (somatropin) as a preferred product for all formularies, excluding the National Select Formulary.
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Commercial and Healthcare Reform	08/18/2023	Policy revised for Koselugo (selumetinib) to update age requirement to match FDA label of pediatrics only (ages 2 to 17 years).
Bylvay (odevixibat) – Commercial and Healthcare Reform	08/18/2023	Policy revised for Bylvay (odevixibat) for progressive familial intrahepatic cholestasis (PFIC) to remove requirement that the member is not exclusively on liquid food. New indication added for Alagille syndrome (ALGS) to require age, FDA-approved diagnosis confirmed by genetic testing, elevated serum bile acid levels above reference range, attestation the member experiences cholestatic pruritus explained only by liver disease, and the member does not have cirrhosis, portal hypertension, or history of hepatic decompensation.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	08/15/2023	New criteria created for Litfulo (ritlecitinib) for alopecia areata (AA) to require age, diagnosis based on FDA-approved indication, current episode lasting 6 months or more without spontaneous re-growth, and trial/failure to systemic therapy or high potency topical corticosteroids or contraindication to all. Reauthorization criteria for attestation of disease stability or beneficial response to therapy. Policy revised to add Yuflyma (adalimumab-aaty) as a target adding to current adalimumab biosimilar and Humira (adalimumab) criteria. Policy revised to add new strength of Cosentyx (secukinumab) to quantity limitations allowing for 1 x 300 mg pen or syringe every 4 weeks in adult plaque psoriasis (PsO), psoriatic arthritis, and ankylosing

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		spondylitis. For adult PsO loading dose, 5 x 300 mg pens or syringed allowed within the first 4 weeks of therapy.
Chronic Inflammatory Diseases – Commercial National Select Formulary	08/15/2023	Policy revised for Cosentyx (secukinumab) for plaque psoriasis and psoriatic arthritis to move to a step 3a non-preferred agent directed to two step 1 or 2 agents. New criteria created for Litfulo (ritlecitinib) for alopecia areata (AA) to require age, diagnosis based on FDA-approved indication, current episode lasting 6 months or more without spontaneous re-growth, and trial/failure to systemic therapy or high potency topical corticosteroids or contraindication to all. Reauthorization criteria for attestation of disease stability or beneficial response to therapy. Criteria combined with J-0266. Policy revised to add Yuflyma (adalimumab-aaty) as a target adding to current adalimumab biosimilar and Humira (adalimumab) criteria. Policy updated to add preferred adalimumab products (Cyltezo (adalimumab-adbm) and Hyrimoz (adalimumab-adaz)) and non-preferred adalimumab products (Abrilada (adalimumab-afzb), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Idacio (adalimumab-aacf), Yuflyma (adalimumab-aaty), and Yusimry (adalimumab-aqvh)). Non-preferred adalimumab products are directed to preferred adalimumab products. Policy revised to add new strength of Cosentyx (secukinumab) to quantity limitations allowing for 1 x 300 mg pen or syringe every 4 weeks in adult plaque psoriasis (PsO), psoriatic arthritis, and ankylosing spondylitis. For adult PsO loading dose, 5 x 300 mg pens or syringes allowed within the first 4 weeks of therapy.
Empaveli (pegcetacoplan) – Commercial and Healthcare Reform	08/18/2023	Policy revised for Empaveli (pegcetacoplan) to remove "documentation" of hemoglobin level and removed signs/symptoms of paroxysmal nocturnal hemoglobinuria (PNH) and replaced with meeting one (1) of the criteria: elevated lactate dehydrogenase (LDH) greater than or equal to 1.5 times the upper limit of normal (ULN), history of a thromboembolic event, or clinical findings of systemic complications. Reauthorization revised to ask for one (1) of the following: achieved hemoglobin stabilization or an increase from

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		baseline, decrease from baseline in the number of transfusions, or decrease from baseline in the LDH levels or reduction of hemolysis.
Evrysdi (risdiplam) – Commercial and Healthcare Reform	08/18/2023	Policy revised for Evrysdi (risdiplam) to clarify that member has spinal muscular atrophy (SMA) classified as one (1) of the following: 1) presymptomatic SMA (infants up to 6 weeks of age), 2) infantile-onset (type 1 SMA), or 3) later-onset (type 2 or type 3 SMA). In reauthorization criteria the member is not using Evrysdi (risdiplam) concomitantly with Spinraza (nusinersen) and meets one (1) of the following: the member has not previously received gene replacement therapy for the treatment of SMA or the member has received gene replacement therapy and has experienced a decline in clinical status since receipt of gene replacement therapy.
Glatiramer Acetate – Commercial and Healthcare Reform	01/01/2024	Policy revised for brand Copaxone (glatiramer acetate) 20 mg to require a step through generic glatiramer or Glatopa (glatiramer acetate) for initial and reauthorization.
Human Growth Hormone – Commercial and Healthcare Reform	09/07/2023	Policy revised for Genotropin, Humatrope, Norditropin, Omnitrope, and Zomacton (somatropin) to require diagnosis of small for gestational age, failure to have catch-up growth by 2 years of age, birth weight and birth crown-heel length at least 2 standard deviations below the gestational age-appropriate mean, and if the request is for a non-preferred growth hormone product, the member has had trial/failure of a preferred product. For reauthorization, clinical documentation indicating a growth velocity of at least 2 cm/year, and bone age of 14 years or less and chronological age greater than 14 years if the member is female; bone age of 16 years or less and chronological age greater than 16 years if the member is male; or the member is female with chronological age 14 years or less or the member is male with chronological age 16 years or less. For all somatropin products, Skytrofa (lonapegsomatropin-tcgd), and Sogroya (somapacitan-beco), policy revised for pediatric growth hormone deficiency to require clinical documentation of a height at least 2 standard deviations below the mean. Policy revised to add Ngenla (somatrogon-ghla) as a non-preferred

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		product for initial authorization and reauthorization for growth hormone deficiency requiring FDA-approved diagnosis with appropriate documentation, age, and therapeutic failure or intolerance to all of the preferred products. Humatrope added as a preferred product.
Human Growth Hormone – Delaware Commercial and Healthcare Reform	09/07/2023	For all somatropin products, Skytrofa (lonapegsomatropin-tcgd), and Sogroya (somapacitan-beco), policy revised for pediatric growth hormone deficiency to require clinical documentation of a height at least 2 standard deviations below the mean. Policy revised to add Ngenla (somatrogon-ghla) as a non-preferred product for initial authorization and reauthorization for growth hormone deficiency requiring FDA-approved diagnosis with appropriate documentation, age, and therapeutic failure or intolerance to all of the preferred products. Humatrope added as a preferred product.
Keveyis (dichlorphenamide) – Commercial and Healthcare Reform	08/18/2023	Policy revised for Keveyis (dichlorphenamide) that if the request is for brand Keveyis, the member has tried and failed dichlorphenamide in initial authorization and reauthorization. Added "related variants" to primary hyperkalemic periodic paralysis and primary hypokalemic periodic paralysis.
KIT and PDGFR Tyrosine Kinase Inhibitors – Commercial and Healthcare Reform	08/18/2023	Policy revised to consolidate existing Qinlock (ripretinib) criteria from J-0276; terming J-0276. Policy revised for Ayvakit (avapritinib) to require age and diagnosis based on FDA-approved expanded indication.
Lodoco (colchicine) – Commercial and Healthcare Reform	TBD	New policy created for Lodoco (colchicine) requiring age, diagnosis based on FDA-approved indication, using Lodoco (colchicine) to reduce the risk of myocardial infarction, stroke, coronary revascularization, or cardiovascular death, and trial/failure/contraindication to statins and Repatha (evolocumab). Reauthorization to require positive response to therapy.
Market Watch Programs – Delaware	08/31/2023	Policy revised to add Atropine sulfate (atropine sulfate) 1% preservative free dropperette to the list of high-cost low value medications with generic atropine sulfate 1% drops listed as a therapeutic alternative. Policy revised to add Zolpidem Capsules 7.5 mg to the list of high cost, low value medications with zolpidem tablet 5 mg,

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		zolpidem tablet 10 mg listed as a therapeutic alternative. Policy revised to add baclofen suspension 25 mg/5 mL (generic to Fleqsuvy) to the list of high cost, low value medications with baclofen tablets or tizanidine tablets listed as therapeutic alternatives.
Market Watch Programs – NY, PA, and WV	08/31/2023	Policy revised to add Atropine sulfate (atropine sulfate) 1% preservative free dropperette to the list of high-cost low value medications with generic atropine sulfate 1% drops listed as a therapeutic alternative. Policy revised to add Zolpidem Capsules 7.5 mg to the list of high cost, low value medications with zolpidem tablet 5 mg, zolpidem tablet 10 mg listed as a therapeutic alternative. Policy revised to add baclofen suspension 25 mg/5 mL (generic to Fleqsuvy) to the list of high cost, low value medications with baclofen tablets or tizanidine tablets listed as therapeutic alternatives.
Miebo (perfluorohexyloctane) – Commercial and Healthcare Reform	08/18/2023	New policy created for Miebo (perfluorohexyloctane) requiring age, FDA-approved diagnosis, trial/failure/contraindication to artificial tears, Restasis (cyclosporine), and Xiidra (lifitegrast). Reauthorization requiring attestation of positive clinical response. Authorization duration of 12 months.
Non-Preferred Baclofen Products – Commercial and Healthcare Reform	08/18/2023	Policy revised to add baclofen suspension, a new generic to Fleqsuvy, as a target. Criteria for initial authorization as well as reauthorization, mirror that of Fleqsuvy.
Ofev (nintedanib) and Esbriet (pirfenidone) – Commercial and Healthcare Reform	08/18/2023	Policy revised for idiopathic pulmonary fibrosis to remove that the medication is being prescribed by a pulmonologist, for systemic sclerosis-associated interstitial lung disease to remove the medication is being prescribed by a pulmonologist or rheumatologist, and for chronic fibrosing interstitial lung disease with progressive phenotype to remove the medication is being prescribed by a pulmonologist.
Ophthalmic Cyclosporine for Dry Eye Disease – Commercial and Healthcare Reform	TBD	Policy revised to add Vevye (cyclosporine) requiring age, FDA-approved diagnosis, trial/failure/contraindication to artificial tears, brand or generic Restasis (cyclosporine), and brand Xiidra (lifitegrast). Expanded Cequa (cyclosporine) step to trial/failure/contraindication to brand or generic Restasis (cyclosporine). Reauthorization

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		requires attestation of positive clinical response. Authorization duration of 12 months.
Oral Hypomethylating Agents – Commercial and Healthcare Reform	08/18/2023	Policy revised for Inqovi (decitabine/cedazuridine) to remove requirement for either de novo or secondary myelodysplastic syndrome.
Palynziq (pegvaliase-pqpz) – Commercial and Healthcare Reform	08/18/2023	Policy revised for Palynziq (pegvaliase-pqpz) to specify generic sapropterin dihydrochloride as drug to try and fail as existing management, removed "documentation" for Phe levels, and that member is not using in combination with Kuvan or Javygtor (sapropterin dihydrochloride).
PARP Inhibitors – Commercial and Healthcare Reform	08/18/2023	Policy revised for Lynparza (olaparib) to require age, diagnosis based on FDA-approved expanded indication and supported by companion diagnostic test. Policy revised for Talzenna (talazoparib) to require age and diagnosis based on FDA-approved expanded indication, and for breast cancer indication, specified use as a single agent.
PCSK9 Inhibitors – Commercial and Healthcare Reform	08/18/2023	Policy revised for Praluent (alirocumab) and Repatha (evolocumab) to update reauthorization criteria for indications of Hypercholesterolemia with ASCVD and Primary Hyperlipidemia, Not Associated with ASCVD, HeFH, or HoFH to require 30% reduction in LDL-C from baseline.
Pylera (bismuth subcitrate potassium, metronidazole, tetracycline) – Commercial and Healthcare Reform	08/18/2023	Policy revised for Pylera (bismuth subcitrate potassium, metronidazole, tetracycline hydrochloride) to require previous treatment with first-line lansoprazole or omeprazole, amoxicillin or metronidazole, and clarithromycin without *Helicobacter pylori* eradication. If the request is for brand Pylera, the member has tried/failed its generic.
Rezurock (belumosudil) – Commercial and Healthcare Reform	08/18/2023	Policy reauthorization criteria revised for Rezurock (belumosudil) to require prescriber attestation that the member has experienced disease improvement or delayed disease progression
Strensiq (asfotase alfa) – Commercial and Healthcare Reform	08/18/2023	Policy revised for Strensiq (asfotase alfa) to add additional prescriber options such as geneticist or metabolic disorder sub-specialist. Added clarification to refer to laboratory reference range for serum alkaline phosphatase (ALP) and plasma pyridoxal-5'-phosphate (PLP).
Viberzi (eluxadoline) – Commercial National Select Formulary	07/31/2023	Policy revised for Viberzi to update from a double step to a single step through any of the following:

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		anti-diarrheal, anti-spasmodic, or tricyclic antidepressant.
Zyclara (imiquimod) – Commercial and Healthcare Reform	08/18/2023	Policy revised to remove Aldara (imiquimod) 5% brand since no longer available on the market. Policy revised for Zyclara (imiquimod) 2.5% and 3.75% to add reauthorization criteria requiring attestation of positive clinical response to therapy and that the member requires additional courses of treatment.

*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
Mesalamine Ulcerative Colitis Treatments – Commercial and Healthcare Reform	10/1/2023	Policy revised for Asacol HD (mesalamine) and Pentasa (mesalamine) to require trial/failure to two plan-preferred generic mesalamine products: mesalamine 0.375 g ER capsules, mesalamine 400 mg DR capsules, mesalamine 1.2 g DR tablets, or mesalamine 4 g/60 mL enema (non-kit). For Asacol HD, Canasa, Rowasa, and Pentasa, reauthorization duration extended to 6 months.
Beta Blocker Management – Commercial and Healthcare Reform	01/01/2024	Policy revised for multi-source brand non-preferred beta blockers to require therapeutic failure or intolerance to its AB-rated generic equivalent in initial and reauthorization.
Bystolic (nebivolol) - Healthcare Reform Essential Formulary	01/01/2024	Policy revised if request is for brand Bystolic (nebivolol) to require trial/failure to generic nebivolol in reauthorization.
Colony-Stimulating Factors – Commercial and Healthcare Reform	09/20/2023	Policy revised to add Rolvedon (eflapegrastim-xnst) requiring FDA-approved diagnosis; therapeutic failure or intolerance to two of the following: Neulasta (pegfilgrastim), Fulphila (pegfilgrastim-jmdb), or Ziextenzo (pegfilgrastim-bmez); and to require Rolvedon to not be used with other colony-stimulating factor products. Reauthorization criteria added requiring FDA-approved diagnosis and Rolvedon not to be used with other colony-stimulating factor products.
Egrifta SV (tesamorelin) – Commercial and Healthcare Reform	08/18/2023	Policy revised for Egrifta SV (tesamorelin) to require that females have a waist circumference of 94 cm or greater and males have a waist

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		circumference of 95 cm or greater. For reauthorization, removing the requirement of prescriber attestation that the member has not developed a comorbid diagnosis of diabetes. Initial reauthorization duration updated to 6 months; reauthorization duration of 12 months.
Generic Step Therapy Edit – Commercial	TBD	Policy revised for multi-source brand statins and SSRIs/SNRIs to require trial/failure of the AB-rated generic. For brand statins only, requiring trial/failure of two additional generic statins of the same potency as the requested product, if available. For multi-source brand statins, reauthorization revised to require trial/failure of the AB-rated generic. Automatic approval criteria removed for brand statins only. For brand SSRI/SNRI only, requiring trial/failure of one additional plan-preferred, generic SSRI/SNRI. For multi-source brand SSRI/SNRI, reauthorization revised to require trial/failure of the AB-rated generic. Automatic approval criteria for brand SSRI/SNRI requires one (1) paid claim for two brand or generic SSRI/SNRI within the past 720 days.
Generic Step Therapy Edit – Select Healthcare Reform Plans	01/01/2024	Policy revised for multi-source brand statins to require trial/failure of the AB-rated generic and trial/failure of two additional generic statins of the same potency as the requested product, if available. Reauthorization revised to require trial/failure of the AB-rated generic for multi-source brands. Automatic approval criteria removed.
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) for Diabetes - Commercial and Healthcare Reform	09/15/2023	New policy for Adlyxin (lixisenatide), Bydureon BCise (exenatide extended-release), Byetta (exenatide), Mounjaro (tirzepatide), Ozempic (semaglutide), Rybelsus (semaglutide), Trulicity (dulaglutide), and Victoza (liraglutide) to require use for an FDA-approved indication. Limitations of coverage to exclude a sole diagnosis of obesity and to require meeting criteria in policy J-0661, if applicable. Automatic approval criteria to allow for automatic adjudication if there is a claim for one (1) anti-diabetes medication, excluding glucagon-like peptide-1 receptor agonists, in the prescription drug claims history within the previous 720 days.
Latuda (lurasidone) – Healthcare Reform	01/01/2024	Criteria revised for 01/01/2024; policy will only apply to brand Latuda; lurasidone will no longer be subject to step therapy or require a prior authorization. Removed all criteria stating that if the

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		request is for brand Latuda, the member has experienced therapeutic failure or intolerance to generic lurasidone.
Non-Preferred Atypical Antipsychotic Medications – Healthcare Reform Essential Formulary	01/01/2024	Criteria revised for 01/01/2024; policy will only apply to brand Latuda and brand Saphris; lurasidone and asenapine will no longer be subject to step therapy or require a prior authorization.
Non-Preferred Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Commercial and Healthcare Reform	08/18/2023	Policy revised to add Inpefa (sotagliflozin) to require diagnosis of heart failure and trial/failure/contraindication to Jardiance (empagliflozin) and Farxiga (dapagliflozin). Or require diagnosis of type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factor(s) and trial/failure/contraindication to all of the following drug-containing products: dapagliflozin (Farxiga or Xigduo XR), and empagliflozin (Jardiance, Synjardy, or Synjardy XR).
Opioid Dependence Therapy – Commercial and Healthcare Reform	08/18/2023	Policy revised due to quantity limits on substance use disorder (SUD) medications being removed due to differing prescribing considerations given additional certifications needed for prescribing of SUD medications.
Proton Pump Inhibitors (PPIs) – Commercial and Healthcare Reform	TBD	Policy revised for brand non-preferred proton pump inhibitors to require trial/failure to generic lansoprazole delayed-release 30 mg capsule. Initial authorization and reauthorization criteria updated to add if the request is for a multi-source brand, trial/failure to an AB-rated generic equivalent, or if the request is for a single-source brand, trial/failure to a generic agent with the same active ingredient(s).
Proton Pump Inhibitors (PPIs) – Commercial National Select Formulary	TBD	Policy revised for brand non-preferred proton pump inhibitors to require trial/failure to generic lansoprazole delayed-release 30 mg capsule. Initial authorization and reauthorization criteria updated to add if the request is for a multi-source brand, trial/failure to an AB-rated generic equivalent, or if the request is for a single-source brand, trial/failure to a generic agent with the same active ingredient(s).

*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
Abrysvo (respiratory syncytial virus vaccine)	1 dose per 185 days	1 dose per 185 days
Miebo (perfluorohexyloctane)	1 bottle (3 mL) per 30 days	3 bottles (9 mL) per 90 days
Vevye (cyclosporine)*	1 bottle per 50 days	2 bottles per 90 days
Yuflyma (adalimumab-aaty)	Two (2) prefilled syringes or autoinjectors per 28 days	6 syringes or autoinjectors every 84 days
Abrysvo (respiratory syncytial virus vaccine)	1 dose per 185 days	1 dose per 185 days
Eligard (Leuprorelin) 22.5 mg	1 kit per 90 days	1 kit per 90 days
Eligard (Leuprorelin) 30 mg	1 kit per 120 days	1 kit per 120 days
Eligard (Leuprorelin) 45 mg	1 kit per 180 days	1 kit per 180 days
Eligard (Leuprorelin) 7.5 mg	1 kit per 30 days	3 kits per 90 days
Lupron Depot (leuprolide acetate) 11.25 mg	1 kit per 90 days	1 kit per 90 days
Lupron Depot (leuprolide acetate) 22.5 mg	1 kit per 84 days	1 kit per 84 days
Lupron Depot (leuprolide acetate) 3.75 mg	1 kit per 30 days	3 kits per 90 days
Lupron Depot (leuprolide acetate) 30 mg	1 kit per 112 days	1 kit per 112 days
Lupron Depot (leuprolide acetate) 45 mg	1 kit per 168 days	1 kit per 168 days
Lupron Depot (leuprolide acetate) 7.5 mg	1 kit per 28 days	3 kits per 84 days
Lupron Depot Ped (leuprolide acetate) 30 mg	1 kit per 84 days	1 kit per 84 days
Lupron Depot Ped (leuprolide acetate) 7.5 mg, 11.25 mg, 15 mg	1 kit per 30 days	3 kits per 90 days
Miebo (perfluorohexyloctane)	1 bottle (3 mL) per 30 days	3 bottles (9 mL) per 90 days
Palynziq (Pegvaliase) 10MG/0.5ML	15 mL per 30 days	45 mL per 90 days
Palynziq (Pegvaliase) 2.5 MG/0.5ML	4 mL per 30 days	12 mL per 90 days

Drug Name	Retail Edit Limit	Mail Edit Limit
Palynziq (Pegvaliase) 20 MG/ML	90 mL per 30 days	270 mL per 90 days
Prevymis (letermovir)	210 tablets per 365 days	210 tablets per 365 days
Vevye (cyclosporine)	1 bottle per 50 days	2 bottles per 90 days
Vyleesi (bremelanotide)	8 autoinjectors per 30 days	24 autoinjectors per 90 days
Yuflyma (adalimumab-aaty)	Two (2) prefilled syringes or autoinjectors per 28 days	6 syringes or autoinjectors every 84 days
Zeposia (ozanimod) capsule dose pack	1 pack (all Zeposia starter pack quantities) per 365 days	1 pack (all Zeposia starter pack quantities) per 365 days
Zoladex (Goserelin) 10.8 mg	1 implant per 84 days	1 implant per 84 days
Zoladex (Goserelin) 3.6 mg	1 implant per 28 days	3 implants per 84 days

*Effective date to be determined.

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

No changes at this time

*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
Bylvay (odevixibat) 200 mcg pellets	36 pellets per day
Bylvay (odevixibat) 400 mcg capsules	18 capsules per day
Bylvay (odevixibat) 600 mcg pellets	12 pellets per day
Bylvay (odevixibat) 1,200 mcg capsules	6 capsules per day
Inpefa (sotagliflozin)	1 tablet per day
Litfulo (ritlecitinib)	1 capsule (50 mg) per day
Lodoco (colchicine 0.5 mg tablets)	1 tablet per day
Talzenna (talazoparib tosylate) 0.1 mg capsules	1 capsule per day
Talzenna (talazoparib tosylate) 0.35 mg capsules	1 capsule 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.

Brand Name	Generic Name	Comments
Abrysvo	respiratory syncytial virus vaccine	Respiratory syncytial virus, prevention

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

Brand Name	Generic Name	Preferred Alternatives
Inpefa	sotagliflozin	Invokana*, Jardiance
Lodoco	colchicine	rosuvastatin, atorvastatin, Repatha Sureclick
Opvee	nalmefene	naloxone syringe
Suflave	PEG3350; sodium sulfate; potassium chloride; magnesium sulfate; sodium chloride	peg-electrolyte soln, peg 3350-electrolytes, GaviLyte-C
Vevye	cyclosporine	cyclosporine 0.05% eye emuls; Xiidra 5% eye drops; Restasis 0.05% eye emulsion

***Incentive Formulary Only

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

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

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

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

Brand Name	Generic Name	Comments
Abrysvo	respiratory syncytial virus vaccine	Respiratory syncytial virus, prevention

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

No changes 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
Inpefa	sotagliflozin	Invokana, Jardiance
Lodoco	colchicine	rosuvastatin, atorvastatin, Repatha Sureclick
Miebo	perfluorohexyloctane	cyclosporine 0.05% eye emuls; Xiidra 5% eye drops; Restasis 0.05% eye emulsion
Ngenla	somatrogon-ghla	Genotropin Miniquick 0.2 Mg, Omnitrope 5 Mg/1.5 Ml Crtg**
Opvee	nalmefene	naloxone syringe
Rolvedon	eflapegrastim-xnst	prescriber discretion
Suflave	PEG3350; sodium sulfate; potassium chloride; magnesium sulfate; sodium chloride	peg-electrolyte soln, peg 3350-electrolytes, GaviLyte-C
Vevye	cyclosporine	cyclosporine 0.05% eye emuls; Xiidra 5% eye drops; Restasis 0.05% eye emulsion
Yuflyma	adalimumab-aaty	Humira

*Physicians may request coverage of these products using the Prescription Drug Medication Request Form.
** Venture and Fundamental Formularies Only

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

Brand Name	Generic Name
Brixadi	buprenorphine (monthly)
Brixadi	buprenorphine (weekly)
Columvi	glofitamab-gxbm
Elevidys	delandistrogene moxeparvovec-rokl

Epkinly	epcoritamab-bysp
Litfulo	ritlecitinib
Miebo*	perfluorohexyloctane
Ngenla*	somatrogon-ghla
Roctavian	valoctocogene roxaparvovec-rvox
Rolvedon*	eflapegrastim-xnst
Rystiggo	rozanolixizumab-noli
Vyjuvek	beremagene geperpavec-svdt
Vyvgart Hytrulo	efgartigimod alfa and hyaluronidase-qvfc
Xacduro	sulbactam/durlobactam
Yuflyma*	adalimumab-aaty

* Medicare Incentive and Compass only; OFF for 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
Lupkynis (voclosporin) – Medicare	09/08/2023	Policy revised for Lupkynis (voclosporin) to remove step requirement of trial/failure/contraindication to two standard of care drug classes: corticosteroid, antimalarial, or immunosuppressive.
Administrative Prior Authorizations for Medicare Part D Plans – Medicare	08/18/2023	Policy revised to update CMS Local Coverage Article A52509 hyperlink under Intravenous Immune Globulin section. Local Coverage Article A52509 updated BvD review to include diagnosis Activated Phosphoinositide 3-kinase Delta Syndrome. Prednisone products added as target for BvD transplant review. Lamzede(velmanase alfa) and Rystiggo(rozanolixizumab) added as targets for BvD infusion pump review.
Ancobon (flucytosine) – Medicare	01/01/2025	Policy created for Ancobon (flucytosine) to require diagnosis by susceptible strain and trial and failure of generic flucytosine.
Banzel (rufinamide) – Medicare	01/01/2025	Policy revised to add step through generic rufinamide for request for brand Banzel (rufinamide).
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Medicare	01/01/2025	Policy revised for Koselugo (selumetinib) to update age requirement to match FDA label of pediatrics only (ages 2 to 17 years).
Bylvay (odevixibat) – Medicare	08/18/2023	Policy revised for Bylvay (odevixibat) for new indication of Alagille syndrome (ALGS) to require FDA-approved diagnosis, and the member does not have cirrhosis, portal hypertension, or history of hepatic decompensation.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Chronic Inflammatory Diseases – Medicare	08/18/2023	New criteria created for Litfulo (ritlecitinib) for alopecia areata (AA) to require age, diagnosis based on FDA-approved indication, and trial/failure to an intralesional corticosteroid, or high potency topical corticosteroid, or contraindication to all. Policy revised to add Yuflyma (adalimumab-aaty) as a target adding to current adalimumab biosimilar and Humira (adalimumab) criteria. Criteria combined with J-0296. Policy revised to add new strength of Cosentyx (secukinumab) to quantity limitations allowing for 1 x 300 mg pen or syringe every 4 weeks in adult plaque psoriasis (PsO), psoriatic arthritis, and ankylosing spondylitis. For adult PsO loading dose, 5 x 300 mg pens or syringes allowed within the first 4 weeks of therapy.
Columvi (glofitamab-gxbm) – Medicare	08/18/2023	Policy created for Columvi (glofitamab-gxbm) to require that the member has a diagnosis of relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma and has received at least two lines of prior therapy. Quantity limits for Columvi (glofitamab-gxbm) added per FDA-approved dosing.
Combination Prescription Drug Safety – Medicare	01/01/2024	Policy revised to include additional benzodiazepines: Ativan (lorazepam), chlordiazepoxide, estazolam, lorazepam intensol, Loreev XR (lorazepam ER), Klonopin (clonazepam), oxazepam, Restoril (temazepam), Tranxene (clorazepate), and Valium (diazepam).
Disease-Modifying Medications for Generalized Myasthenia Gravis – Medicare	08/18/2023	Title of policy changed to Disease-Modifying Medications for Generalized Myasthenia Gravis - Medicare. Policy revised to include Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) and Rystiggo (rozanolixizumab-noli). The criteria for Vyvgart will be revised to include Vyvgart Hytrulo. A new section is added for criteria for Rystiggo: the product has been determined to be eligible for coverage under Part D per policy J-0030, the member has a diagnosis of generalized myasthenia gravis (gMG); the member is either anti-acetylcholine receptor (AChR) antibody positive (Ab+) OR anti-muscle-specific tyrosine kinase (MuSK) Ab+; and, the member has experienced therapeutic failure,

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		contraindication, or intolerance to generic pyridostigmine. Reauthorization will remain the same for Vyvgart, Vyvgart Hytrulo, or Rystiggo.
Egrifta SV (tesamorelin) – Medicare	01/01/2025	Policy revised for Egrifta SV (tesamorelin) to require that the member continues to receive antiretroviral therapy for human immunodeficiency virus (HIV) infection and that the member has experienced a reduction in visceral adipose tissue (e.g., reduction in minimum waist circumference, waist to hip ratio, or reduction in body mass index from baseline) for reauthorization.
Empaveli (pegcetacoplan) – Medicare	01/01/2024	Policy revised for Empaveli (pegcetacoplan) to remove signs/symptoms of paroxysmal nocturnal hemoglobinuria (PNH) and replaced with meeting one (1) of the criteria: anemia secondary to PNH, elevated lactate dehydrogenase (LDH) greater than or equal to 1.5 times the upper limit of normal (ULN), history of a thromboembolic event, or clinical findings of systemic complications. Reauthorization revised to ask for one (1) of the following: achieved hemoglobin stabilization or an increase from baseline, decrease from baseline in the number of transfusions, or decrease from baseline in the LDH levels or reduction of hemolysis.
Epkinly (epcoritamab-bysp) – Medicare	08/18/2023	Policy created for Epkinly (epcoritamab-bysp) to require that the member has a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), or high-grade B-cell lymphoma (HGBL), and has received at least two prior lines of therapy.
Evrysdi (risdiplam) – Medicare	01/01/2025	Policy revised for Evrysdi (risdiplam) to add that the member meets one (1) of the following in initial authorization and reauthorization: the member has not previously received gene replacement therapy for the treatment of spinal muscular atrophy (SMA), or the member has received gene replacement therapy and has experienced a decline in clinical status since receipt of gene replacement therapy. In reauthorization added that the member is not using Evrysdi (risdiplam) concomitantly with Spinraza (nusinersen).

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Fleqsuvy (baclofen) and Lyvispah (baclofen) – Medicare	08/18/2023	Policy revised to add baclofen suspension, a new generic to Fleqsuvy, as a target. Criteria for initial authorization mirror that of Fleqsuvy.
Human Growth Hormone – Medicare	08/18/2023	For all somatropin products, Skytrofa (lonapegsomatropin-tcgd), and Sogroya (somapacitan-beco), policy revised for pediatric growth hormone deficiency to require clinical documentation of a height at least 2 standard deviations below the mean. Policy revised to add Ngenla (somatrogon-ghla) requiring FDA-approved diagnosis with appropriate documentation.
Keveyis (dichlorphenamide) – Medicare	08/18/2023	Policy revised for Keveyis (dichlorphenamide) that if the request is for brand Keveyis, the member has tried and failed dichlorphenamide in initial authorization and reauthorization.
KIT and PDGFR Tyrosine Kinase Inhibitors – Medicare	08/18/2023	Policy revised to consolidate existing Qinlock (ripretinib) criteria from J-0272; terming J-0272. Policy revised for Ayvakit (avapritinib) to require diagnosis based on FDA-approved expanded indication. Policy revised for Qinlock (ripretinib) to remove age requirement.
Lodoco (colchicine) – Medicare	09/29/2023	New policy created for Lodoco (colchicine) requiring age, diagnosis based on FDA-approved indication, using Lodoco (colchicine) to reduce the risk of myocardial infarction, stroke, coronary revascularization, or cardiovascular death, and trial/failure/contraindication to statins and Repatha (evolocumab).
Noxafil (posaconazole) – Medicare	01/01/2024	Policy revised to add Noxafil (posaconazole) intravenous (IV) injection requiring diagnosis based on FDA approved indication, for invasive Aspergillosis Infection treatment, trial/failure/contraindication to voriconazole, and if the request is for brand Noxafil IV injection, trial/failure to generic posaconazole IV injection.
Oral Hypomethylating Agents – Medicare	08/18/2023	Policy revised for Inqovi (decitabine/cedazuridine) to remove requirement for either de novo or secondary myelodysplastic syndrome.
Palynziq (pegvaliase-pqpz) – Medicare	08/18/2023	Policy revised for Palynziq (pegvaliase-pqpz) to specify sapropterin dihydrochloride as drug to try and fail as existing management.
PARP Inhibitors – Medicare	08/18/2023	Policy revised for both Lynparza (olaparib) and Talzenna (talazoparib) to require diagnosis based

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		on respective FDA-approved expanded indication. For Talzenna (talazoparib) use in breast cancer, specified use as a single agent. Policy revised for Lynparza (olaparib), Rubraca (rucaparib), Talzenna (talazoparib), and Zejula (niraparib) to remove requirement for age.
Rezurock (belumosudil) – Medicare	08/18/2023	Policy revised for Rezurock (belumosudil) to remove age requirement from criteria.
Rituximab Products – Medicare	01/01/2024	Policy revised for rituximab products for adults with B-cell Non-Hodgkin's Lymphoma (NHL) to require age and disease classified as relapsed or refractory and low grade or follicular. Age added for Chronic Lymphocytic Leukemia (CLL). For Rituxan (rituximab) in pediatrics with mature B-cell NHL and mature B-cell acute leukemia, requiring age of 6 months to 17 years.
Strensiq (asfotase alfa) – Medicare	01/01/2024	Policy revised for Strensiq (asfotase alfa) to add support for perinatal/infantile- and juvenile-onset hypophosphatasia (HPP) diagnosis including all of the following: ALPL gene mutation, serum alkaline phosphatase level (ALP) below the age-adjusted normal range per the laboratory reference range, and plasma pyridoxal-5'-phosphate (PLP) above the upper limit of normal per the laboratory reference range. Added that member has history of onset of signs and symptoms of HPP prior to 18 years of age.
Vyjuvek (beremagene geperpavec-svdt) – Medicare	08/18/2023	Policy created for Vyjuvek (beremagene geperpavec-svdt) to require the medication is prescribed by or in consultation with a dermatologist or wound care specialist with expertise in the management of dystrophic epidermolysis bullosa (DEB); the prescriber attests that the patient has a diagnosis of DEB confirmed by genetic testing; the prescriber attests that the patient has a mutation(s) in the *COL7A1* gene; the patient has one or more open wounds.
Zinplava (bezlotoxumab) – Medicare	08/18/2023	Policy revised for Zinplava (bezlotoxumab) to remove age requirement.

*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
Colony-Stimulating Factors – Medicare	01/01/2024	Policy revised to add Rolvedon (eflapegrastim-xnst) requiring FDA-approved diagnosis; therapeutic failure or intolerance to two of the following: Neulasta (pegfilgrastim), Fulphila (pegfilgrastim-jmdb), or Ziextenzo (pegfilgrastim-bmez).
Miebo (perfluorohexyloctane) – Medicare	08/18/2023	New policy created for Miebo (perfluorohexyloctane) requiring FDA-approved diagnosis, trial/failure/contraindication to brand or generic Restasis (cyclosporine) and Xiidra (lifitegrast). Authorization duration of 12 months.
Non-Preferred Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Medicare	08/18/2023	Policy revised to add Inpefa (sotagliflozin) to require diagnosis of heart failure and trial/failure/contraindication to Jardiance (empagliflozin). Or require diagnosis of type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factor(s) and trial/failure/contraindication to all of the following drug-containing products: canagliflozin (Invokana, Invokamet, or Invokamet XR) and empagliflozin (Jardiance, Synjardy, or Synjardy XR).
Ophthalmic Cyclosporine for Dry Eye Disease – Medicare	TBD	Policy revised to add Vevye (cyclosporine) requiring FDA-approved diagnosis, trial/failure/contraindication to brand or generic Restasis (cyclosporine) and brand Xiidra (lifitegrast). Authorization duration of 12 months.
Zerviate (cetirizine ophthalmic solution) – Medicare	01/01/2025	New policy created for Zerviate (cetirizine ophthalmic solution) requiring FDA-approved diagnosis and therapeutic failure, contraindication, or intolerance to plan-preferred, generic olopatadine ophthalmic drops

3. Quantity Level Limit (QLL) Program

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

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Morphine Equivalent Daily Dose – Medicare	08/18/2023	Policy revised to remove references to Lazanda (fentanyl nasal solution) and Abstral (fentanyl sublingual tablets); products have been discontinued and are no longer commercially available.

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)

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