# Formulary Updates



#### Published July 2024

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

Please reference the guide below to navigate this communication:

#### Section I. Highmark Commercial and Healthcare Reform Formularies

- A. Changes to the Highmark Comprehensive Formulary and the Highmark Healthcare Reform Comprehensive Formulary
- 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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#### Section II. Highmark Medicare Part D Formularies

- A. Changes to the Highmark Medicare Part D 5-Tier Open 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 Availity<sup>®</sup> or our website). Click the **Pharmacy Program/Formularies** link from the menu on the left.



This information is issued on behalf of Highmark Blue Shield and its affiliated Blue companies, which are independent licensees of the Blue Cross Blue Shield Association. Highmark Inc. d/b/a Highmark Blue Shield and certain of its affiliated Blue companies serve Blue Shield members in 21 counties in central Pennsylvania and 13 counties in northeastern New York. As a partner in joint operating agreements, Highmark Blue Shield also provides services in conjunction with a separate health plan in southeastern Pennsylvania. Highmark Inc. or certain of its affiliated Blue companies also serve Blue Cross Blue Shield members in 29 counties in western Pennsylvania, 13 counties in northeastern Pennsylvania, the state of West Virginia plus Washington County, Ohio, the state of Delaware and 8 counties in western New York. All references to Highmark in this document are references to Highmark Inc. d/b/a Highmark Blue Shield 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

None at this time

#### Highmark Formulary Update – June 2024

#### **SECTION I. Highmark Commercial and Healthcare Reform Formularies**

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

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

- Highmark Comprehensive Formulary
- Highmark Healthcare Reform Comprehensive Formulary

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

#### Table 1. Products Added

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

Brand Name	Generic Name	Comments
Edurant PED*	rilpivirine	HIV-1
Rezenopy* naloxone hydrochloride nasal spray		Opioid Overdose
Rinvoq LQ		Polyarticular juvenile idiopathic arthritis; psoriatic arthritis

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

\*Effective date to be determined.

#### Table 2. Products Not Added\*\*

Brand Name	Generic Name	Preferred Alternatives
Duvyzat	givinostat	Prescriber discretion
Entresto Sprinkle*	sacubitril and valsartan oral pellets	entresto tablets
Ingrezza Sprinkle	valbenazine	Prescriber discretion
Libervant	diazepam buccal film	diazepam rectal gel
Ogsiveo	nirogacestat	Prescriber discretion
Ojemda tablets	tovorafenib	Prescriber discretion

Ojemda oral suspension	tovorafenib	Prescriber discretion
Opsynvi	macitentan and tadalafil	sildenafil citrate 20 mg, tadalafil,ambrisentan, bosentan
Pivya*	pivmecillinam	Prescriber discretion
Retevmo* tablets	selpercatinib	Prescriber discretion
Rezdiffra	resmetirom	Prescriber discretion
Selarsdi 45 mg/0.5 mL prefilled syringe*	ustekinumab-aekn	Stelara syringe (mL) 45mg/0.5ml; Stelara vial (mL) 45mg/0.5ml
Selarsdi 90 mg/mL prefilled syringe*	ustekinumab-aekn	Stelara syringe (mL) 90 mg/mL
Spevigo subcutaneous	spesolimab-sbzo	Prescriber discretion
Talzenna soft gels	talazoparib	Prescriber discretion
Tryvio*	aprocitentan	spironolactone tablets
Vafseo*	vadadustat	Aranesp, Procrit, Epogen
Vijoice granules	alpelisib	Prescriber discretion
Voydeya	danicopan	Prescriber discretion
Winrevair	sotatercept-csrk	sildenafil citrate 20 mg, tadalafil ambrisentan, bosentan
Xolremdi	mavorixafor	Prescriber discretion
Xromi*	hydroxyurea	hydroxyurea capsule

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.

#### 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 <u>Provider Resource Center</u> 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
Dihydroergotamine Mesylate Injection	dihydroergotamine mesylate injection
Duvyzat	givinostat

Entresto Sprinkle	sacubitril and valsartan oral pellets
Ingrezza Sprinkle	valbenazine
Migranal Nasal Spray	dihydroergotamine 4 mg/mL spray
Ogsiveo	nirogacestat
Ojemda tablets	tovorafenib
Ojemda oral suspension	tovorafenib
Opsynvi	macitentan and tadalafil
Retevmo tablets	selpercatinib
Rezdiffra	resmetirom
Rinvoq LQ	upadacitinib
Selarsdi 45 mg/0.5 mL prefilled syringe	ustekinumab-aekn
Selarsdi 90 mg/mL prefilled syringe	ustekinumab-aekn
Spevigo subcutaneous	spesolimab-sbzo
Talzenna soft gels	talazoparib
Trudhesa	dihydroergotamine mesylate
Tryvio	aprocitentan
Vafseo	vadadustat
Vijoice granules	alpelisib
Voydeya	danicopan
Winrevair	sotatercept-csrk
Xolremdi	mavorixafor
Xromi	hydroxyurea

#### **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 <u>here</u>.

#### Table 1. Formulary Updates

All formulary changes effective July 2024, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives	
	Items listed below	were a	dded to the formulary	
Rezenopy*	naloxone hydrochloride nasal spray	2	Opioid Overdose	
Edurant PED*	rilpivirine	3	HIV-1	
Slynd*	drospirenone	3	Pregnancy prevention	
Rinvoq LQ	upadacitinib	4	Polyarticular juvenile idiopathic arthritis; psoriatic arthritis	
	Items listed below were not added to the formulary			
Duvyzat	givinostat	NF	Prescriber discretion	

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Entresto Sprinkle*	sacubitril and valsartan oral pellets	NF	Entresto tablets
Ingrezza Sprinkle	valbenazine	NF	Prescriber discretion
Libervant	diazepam buccal film	NF	diazepam rectal gel
Ogsiveo	nirogacestat	NF	Prescriber discretion
Ojemda tablets	tovorafenib	NF	Prescriber discretion
Ojemda oral suspension	tovorafenib	NF	Prescriber discretion
Opsynvi	macitentan and tadalafil	NF	sildenafil citrate 20 mg, tadalafil, ambrisentan, bosentan
Pivya*	pivmecillinam	NF	Prescriber discretion
Retevmo tablets*	selpercatinib	NF	Prescriber discretion
Rezdiffra	resmetirom	NF	Prescriber discretion
Selarsdi 45 mg/0.5 mL prefilled syringe*	ustekinumab-aekn	NF	Stelara syringe (mL) 45mg/0.5mL; Stelara vial (mL) 45mg/0.5mL
Selarsdi 90 mg/mL prefilled syringe*	ustekinumab-aekn	NF	Stelara syringe (mL) 90 mg/mL
Spevigo subc utaneous	spesolimab-sbzo	NF	Prescriber discretion
Talzenna soft gels	talazoparib	NF	Prescriber discretion
Tryvio*	aprocitentan	NF	spironolactone tablets
Vafseo*	vadadustat	NF	Aranesp, Procrit, Epogen
Vijoice granules	alpelisib	NF	Prescriber discretion
Voydeya	danicopan	NF	Prescriber discretion
Winrevair	sotatercept-csrk	NF	sildenafil citrate 20 mg, tadalafil, ambrisentan, bosentan
Xolremdi	mavorixafor	NF	Prescriber discretion
Xromi	hydroxyurea	NF	hydroxyurea capsule

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, organized by therapeutic class, is available <u>here</u>.

Table 1. Formulary UpdatesAll formulary changes effective July 2024 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives		
	Items listed below were added to the formulary				
Edurant PED*	rilpivirine	3	HIV-1		
Rezenopy*	naloxone hydrochloride nasal spray	3	Opioid Overdose		
Ingrezza Sprinkle	valbenazine	4	Tardive Dyskinesia and Chorea associated with Huntington's disease		
Rinvoq LQ	upadacitinib	4	Polyarticular juvenile idiopathic arthritis; psoriatic arthritis		
Slynd*	drospirenone	4	Pregnancy prevention		
-	Items listed below w	ere not	added to the formulary		
Duvyzat	givinostat	NF	Prescriber discretion		
Entresto Sprinkle *	sacubitril and valsartan oral pellets	NF	Entresto tablets		
Libervant	diazepam buccal film	NF	diazepam rectal gel		
Ogsiveo	nirogacestat	NF	Prescriber discretion		
Ojemda tablets	tovorafenib	NF	Prescriber discretion		
Ojemda oral suspension	tovorafenib	NF	Prescriber discretion		
Opsynvi	macitentan and tadalafil	NF	sildenafil citrate 20 mg, tadalafil, ambrisentan		
Pivya *	pivmecillinam	NF	Prescriber discretion		
Retevmo tablets*	selpercatinib	NF	Prescriber discretion		
Rezdiffra	resmetirom	NF	Prescriber discretion		
Selarsdi 45 mg/0.5 mL prefilled syringe*	ustekinumab-aekn	NF	Stelara syringe (mL) 45mg/0.5mL; Stelara vial (mL) 45mg/0.5mL		
Selarsdi 90 mg/mL prefilled syringe*	ustekinumab-aekn	NF	Stelara syringe (mL) 90 mg/mL		
Spevigo subc utaneous	spesolimab-sbzo	NF	Prescriber discretion		
Talzenna soft gels	talazoparib	NF	Prescriber discretion		
Tryvio *	aprocitentan	NF	spironolactone tablets		
Vafseo*	vadadustat	NF	Aranesp, Retacrit		
Vijoice granules	alpelisib	NF	Prescriber discretion		
Voydeya	danicopan	NF	Prescriber discretion		
Winrevair	sotatercept-csrk	NF	sildenafil citrate 20 mg, tadalafil, ambrisentan		

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Xolremdi	mavorixafor	NF	Prescriber discretion
Xromi*	hydroxyurea	NF	hydroxyurea capsule

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, organized by therapeutic class, is available **here**.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives		
	Items listed below were added to the formulary (Preferred)				
Rezdiffra	resmetirom	2	NASH		
Talzenna soft gels 0.1 mg, 0.25 mg, 0.35 mg 0.5 mg, 0.75 mg, 1 mg	talazoparib	2	breast cancer		
Opsynvi	macitentan and tadalafil	2	Pulmonary arterial hypertension (PAH)		
Winrevair	sotatercept-csrk	2	Pulmonary arterial hypertension (PAH)		
Ojemda tablets	tovorafenib	2	BRAF-mutated pediatric low-grade glioma (LGG)		
Ojemda oral suspension	tovorafenib	2	BRAF-mutated pediatric low-grade glioma (LGG)		
I	tems listed below were ad	ded to	the formulary (Non-Preferred)		
Libervant*	diazepam buccal film	3	diazepam rectal gel		
Voydeya*	danicopan	3	Prescriber discretion		
Ingrezza Sprinkle	valbenazine	3	Prescriber discretion		
Ogsiveo	nirogacestat	3	Prescriber discretion		
Retevmo tablets*	selpercatinib	3	Prescriber discretion		
Rinvoq LQ*	upadacitinib	3	Prescriber discretion		
Duvyzat*	givinostat	3	Prescriber discretion		
Edurant PED*	rilpivirine	3	Prescriber discretion		

#### Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Entresto Sprinkle*	sacubitril and valsartan oral pellets	3	Entresto tablets
Pivya*	pivmecillinam	3	Prescriber discretion
Rezenopy*	naloxone hydrochloride nasal spray	3	Prescriber discretion
Selarsdi 45 mg/0.5 mL prefilled syringe*	ustekinumab-aekn	3	Stelara Syringe (MI) 45mg/0.5ml; Stelara Vial (MI) 45mg/0.5ml
Selarsdi 90 mg/mL prefilled syringe*	ustekinumab-aekn	3	Stelara Syringe (MI) 90 Mg/MI
Spevigo subc utaneous	spesolimab-sbzo	3	Prescriber discretion
Tryvio*	aprocitentan	3	spironolactone tablets
Vafseo*	vadadustat	3	Procrit, Retacrit
Vijoice granules*	alpelisib	3	Prescriber discretion
Xromi*	hydroxyurea	3	hydroxyurea capsule
	Items listed below were not added to the formulary		
None at this time.			

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
Dihydroergotamine Mesylate Injection	dihydroergotamine mesylate injection
Duvyzat	givinostat
Entresto Sprinkle	sacubitril and valsartan oral pellets
Ingrezza Sprinkle	valbenazine
Migranal Nasal Spray	dihydroergotamine 4 mg/mL spray
Ogsiveo	nirogacestat
Ojemda tablets	tovorafenib
Ojemda oral suspension	tovorafenib
Opsynvi	macitentan and tadalafil
Retevmo tablets	selpercatinib
Rezdiffra	resmetirom
Rinvoq LQ	upadacitinib
Selarsdi 45 mg/0.5 mL prefilled syringe	ustekinumab-aekn
Selarsdi 90 mg/mL prefilled syringe	ustekinumab-aekn
Spevigo subcutaneous	spesolimab-sbzo
Talzenna soft gels	talazoparib
Trudhesa	dihydroergotamine mesylate

Tryvio	aprocitentan
Vafseo	vadadustat
Vijoice granules	alpelisib
Voydeya	danicopan
Winrevair	sotatercept-csrk
Xolremdi	mavorixafor
Xromi	hydroxyurea

## E. Updates to the Pharmacy Utilization Management Programs

## 1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Acute Migraine Therapies – Commercial and Healthcare Reform	6/24/2024	Policy revised for Migranal (dihydroergotamine) and Trudhesa (dihydroergotamine) to require step through plan-preferred generic zolmitriptan nasal spray.
Acute Migraine Therapies – Commercial and Healthcare Reform	TBD	Policy revised to update Migranal (dihydroergotamine) and Trudhesa (dihydroergotamine) to misc. specialty oral benefits, and dihydroergotamine injection to misc. specialty injectable benefits.
Adenosine Triphosphate- Citrate Lyase (ACL) Inhibitors – Commercial and Healthcare Reform	6/24/2024	Policy revised to update existing criteria based on expanded indications for Nexletol (bempedoic acid) and Nexlizet (bempedoic acid/ezetimibe), including prescriber attestation that member will be using Nexletol or Nexlizet in combination with other LDL-C lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible for both the Heterozygous Familial Hypercholesterolemia and Primary Hyperlipidemia indications, and that there is either clinical documentation of established ASCVD or that member has a high risk for CVD for the Hyperlipidemia indication. Removed requirement of using with a maximally tolerated statin. Reauthorization criteria revised to include prescriber attestation that member will continue using Nexletol or Nexlizet in combination with other LDL-C lowering therapies, or alone when concomitant LDL-C lowering therapies, or solve the solve possible for HeFH or primary hyperlipidemia.
ALK-Targeting Kinase Inhibitors – Commercial and Healthcare Reform	6/24/2024	Policy revised for Alecensa (alectinib) to include the member either has a diagnosis of metastatic non-small cell lung cancer (NSCLC), or NSCLC following tumor resection that is either node

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		positive or with tumors $\geq$ 4 cm with the prescriber attesting that Alecensa is being used for adjuvant treatment.
Anti-Obesity – Commercial and Healthcare Reform	6/6/2024	Policy revised for all targets updating documentation requirements to attestation. For initial authorization of Contrave (bupropion/naltrexone), Qsymia (phentermine and topiramate extended-release), and Xenical (orlistat), require prescriber attestation that the member will use the requested therapy in combination with a lifestyle modification program that encourages a reduced-calorie diet and increased physical activity.
Anti-Obesity – Commercial and Healthcare Reform	5/22/2024	Policy revised for anti-obesity medications to change weight related comorbidities to the following: cardiovascular disease, coronary artery disease, hypertension, dyslipidemia, sleep apnea, osteoarthritis, type II diabetes, polycystic ovarian syndrome, non-alcoholic steatohepatitis/non- alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease.
BCR-ABL Kinase Inhibitors – Commercial and Healthcare Reform	6/24/2024	Policy revised for Iclusig (ponatinib) to require age and diagnosis based on expanded FDA-approved indication for newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia.
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Commercial and Healthcare Reform	7/2/2024	Policy revised to add Ojemda (tovorafenib) to require that member is 6 months of age or older and diagnosis is based on FDA-approved indication.
CGRP Inhibitors – Commercial and Healthcare Reform	6/24/2024	Policy revised to add plan-preferred language to step through one agent from two different prophylactic migraine medication classes. Removed Onabotulinum toxin A (Botox) as an option to step through.
CGRP Inhibitors and Reyvow (lasmiditan) – Commercial National Select Formulary	6/24/2024	Policy revised to remove Onabotulinum toxin A (Botox) as an option to step through.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	6/24/2024	Policy revised for Actemra (tocilizumab) in rheumatoid arthritis and polyarticular juvenile idiopathic arthritis to allow exception for adalimumab step if the member has heart failure or a previously treated lymphoproliferative disorder. For systemic sclerosis-associated

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		interstitial lung disease, criteria added for disease confirmation by high-resolution computed tomography; one of the following: C-reactive protein ≥ 6 mg/mL, Erythrocyte sedimentation rate ≥ 28 mm/h, or Platelet count ≥ 330 x 10 <sup>9</sup> /L; and forced vital capacity > 55% of the predicted value. Off-label indication of polymyalgia rheumtica (PMR) added requiring age, diagnosis, specialist, and use in combination with tapering course of corticosteroids, inadequate response, or intolerance. For Cosentyx (secukinumab) in Enthesitis-Related Arthritis, step through non- biologic DMARD removed. Entyvio (vedolizumab) subcutaneous new indication for Crohn's disease (CD) added requiring age, FDA-approved indication, specialist, trial/failure to 2 step 1 preferred biologics for Crohn's disease or the member has received at least 2 doses of Entyvio (vedolizumab) intravenous at least 6 weeks before initiating SC or undergoing induction therapy. Kevzara (sarilumab) and Orencia (abatacept) criteria revised to allow exception for biologic step therapy if the member has heart failure or a previously treated lymphoproliferative disorder. Kineret (anakinra) criteria for Deficiency of Interleukin-1 Receptor Antagonist (DIRA) revised to remove immunosuppressant step and add genetic testing. Otezla (apremilast) criteria requiring age ≥ 6 to < 18 years, weight ≥ 20 kg, and moderate-to-severe disease, specialist, and trial/failure to systemic therapy or phototherapy or contraindication to all. Rinvoq (upadacitinib) LQ added to existing criteria for Rinvoq in psoriatic arthritis (PsA). If the request is for Rinvoq LQ, the member is 2 to < 18 years; if the request is for Rinvoq tablets, the member is 18 years or older. New criteria created for Rinvoq/Rinvoq LQ (upadacitinib) in polyarticular juvenile idiopathic arthritis (PJIA) requiring age, FDA-approved diagnosis, specialist, trial/failure/contraindication to one non-biologic disease modifying anti- rheumatic drug (DMARD) or member requires initial biologic therapy due to involvement of

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		(adalimumab or Enbrel preferred). Rinvoq (upadacitinib) LQ added as a preferred agent for PJIA and PsA.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	5/24/2024	Policy reinstated and revised to remove Commercial National Select formulary.
Chronic Inflammatory Diseases – Commercial National Select Formulary	5/24/2024	Policy revised to only include Commercial National Select Formulary. Policy revised to add adalimumab-aaty as non-preferred adalimumab product. Entyvio (vedolizumab) subcutaneous updated to allow 2 step 1 or 2 preferred agents for ulcerative colitis (UC), instead of just step 1 agents. Omvoh (mirikizumab-mrkz) SC updated to allow 1 step 1 preferred agent for UC, instead of 2 step 1 agents; or already received induction therapy or undergoing induction therapy. Sotyktu (deucravacitinib) criteria revised to remove triple step through preferred step 1 agents. Zymfentra (infliximab-dyyb) revised to remove step through 2 step 1 preferred agents for UC and Crohn's disease.
Chronic Inflammatory Diseases – Commercial National Select Formulary	6/24/2024	Policy revised for Actemra (tocilizumab) in rheumatoid arthritis and polyarticular juvenile idiopathic arthritis to allow exception for adalimumab step if the member has heart failure or a previously treated lymphoproliferative disorder. For systemic sclerosis-associated interstitial lung disease, criteria added for disease confirmation by high-resolution computed tomography; one of the following: C-reactive protein ≥ 6 mg/mL, Erythrocyte sedimentation rate ≥ 28 mm/h, or Platelet count ≥ 330 x 10 <sup>9</sup> /L; and forced vital capacity > 55% of the predicted value. Off-label indication of polymyalgia rheumtica (PMR) added requiring age, diagnosis, specialist, and use in combination with tapering course of corticosteroids, inadequate response, or intolerance. For Cosentyx (secukinumab) in Enthesitis-Related Arthritis, step through non- biologic DMARD removed. Entyvio (vedolizumab) subcutaneous new indication for Crohn's disease (CD) added requiring age, FDA-approved indication, specialist, trial/failure to 2 step 1 or 2 preferred biologics for Crohn's disease or the member has received at least 2 doses of Entyvio (vedolizumab) intravenous at least 6 weeks before

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		initiating SC or undergoing induction therapy. Kevzara (sarilumab) and Orencia (abatacept) criteria revised to allow exception for biologic step therapy if the member has heart failure or a previously treated lymphoproliferative disorder. Kineret (anakinra) criteria for Deficiency of Interleukin-1 Receptor Antagonist (DIRA) revised to remove immunosuppressant step and add genetic testing. Otezla (apremilast) criteria revised to add pediatric plaque psoriasis criteria requiring age $\geq$ 6 to < 18 years, weight $\geq$ 20 kg, and moderate-to-severe disease, specialist, and trial/failure to systemic therapy or phototherapy or contraindication to all. Rinvoq (upadacitinib) LQ added to existing criteria for Rinvoq in psoriatic arthritis (PsA). If the request is for Rinvoq LQ, the member is 2 to < 18 years; if the request is for Rinvoq tablets, the member is 18 years or older. New criteria created for Rinvoq/Rinvoq LQ (upadacitinib) in polyarticular juvenile idiopathic arthritis (PJIA) requiring age, FDA-approved diagnosis, specialist, trial/failure/contraindication to one non-biologic disease modifying anti- rheumatic drug (DMARD) or member requires initial biologic therapy due to involvement of high- risk joints or high disease activity, and trial/failure to 1 tumor necrosis factor blocker therapy (adalimumab or Enbrel preferred). Rinvoq (upadacitinib) LQ added as a preferred agent for PJIA and PsA.
Conjupri (levamlodipine) – Commercial and Healthcare Reform	6/24/2024	Policy revised for Conjupri (levamlodipine) for reauthorization to require attestation of blood pressure reduction from baseline and if the request is for brand Conjupri, trial/failure of generic levamlodipine. Removed plan-preferred language from initial authorization.
Continuity of Care; Prior Authorization Override Exception – Commercial and Healthcare Reform – West Virginia	TBD	Step therapy Exception (WV) removed from policy and incorporated into new policy, Step Therapy Exceptions – Commercial and Healthcare Reform. This policy will only deal with Continuity of Care/Prior Authorization in WV.
Coverage Outside of Contract Parameters – Commercial and Healthcare Reform	6/24/2024	Obesity-related conditions removed as potential therapy exclusion.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Daybue (trofinetide) – Commercial and Healthcare Reform	6/24/2024	Policy revised for Daybue (trofinetide) to require pathogenic mutation in the MECP2 gene and is being prescribed by or in consultation with a specialist experienced in the treatment of Rett syndrome. Reauthorization revised to require stabilization or improvement in clinical features of Rett syndrome. Initial authorization duration updated to 3 months.
Delaware - Step Therapy Override Exception – Commercial and Healthcare Reform	TBD	Policy archived; step therapy for all four Highmark states (DE, NY, PA, WV) combined into one new policy: J-XXXX Step Therapy Exceptions
Duvyzat (givinostat) – Commercial and Healthcare Reform	TBD	New policy for Duvyzat (givinostat) to require age, diagnosis based on FDA-approved indication supported by a documented pathogenic mutation in the dystrophin gene, that the member is ambulatory, the medication is prescribed by or in consultation with a physician who specializes in treating neuromuscular disorders, and the member will receive concomitant corticosteroid therapy, unless contraindicated or not tolerated. Reauthorization to require attestation of positive clinical response and that the member will continue to receive concomitant corticosteroid therapy, unless contraindicated or not tolerated.
Gattex (teduglutide) – Commercial and Healthcare Reform	6/24/2024	Policy revised for Gattex (teduglutide) for adults requiring prescriber attestation that a colonoscopy of the entire colon, with removal of polyps, was complete within 6 months prior to initiation of therapy. For patients 1 to 17 years old, requiring prescriber attestation that a fecal occult blood test was performed within 6 months prior to initiation of therapy.
HIF PH Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised to include Vafseo (vadadustat) to require FDA approved age and diagnosis and require clinical documentation of hemoglobin <11, prescribed by or in consultation with a nephrologist or hematologist, trial/failure of intravenous iron or intravenous iron is not appropriate, and trial/failure of an erythropoiesis stimulating agent. Reauthorization requiring a clinically meaningful increase in hemoglobin from baseline and hemoglobin ≤ 11.
Immediate Release Fentanyl Citrate –	6/24/2024	Subsys (fentanyl) sublingual spray removed from policy; it is no longer commercially available. Brand Actiq (fentanyl citrate) is no longer

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Commercial and Healthcare Reform		commercially available; only generic fentanyl citrate oral transmucosal lozenge is available. Fentanyl citrate buccal tablet is a single source product and was added to the policy.
Ingrezza/Ingrezza Sprinkle – Commercial and Healthcare Reform	6/24/2024	Policy revised to add Ingrezza Sprinkle (valbenazine). Criteria remains the same as that for Ingrezza (valbenazine). Member must be 18 years of age or older, have an FDA-approved diagnosis. If the diagnosis is tardive dyskinesia (TD), the prescriber attests that the member continues to experience symptoms of TD despite dose reduction, tapering, or discontinuation of the offending medication, or the prescriber attests that these changes would not be appropriate for the member.
Interferon Beta – Commercial and Healthcare Reform	6/24/2024	Policy revised to remove Extavia (interferon beta- 1b) as product is no longer commercially available.
Interleukin (IL)-5 Antagonists – Commercial and Healthcare Reform	6/24/2024	Policy revised for Fasenra pen (benralizumab) to reflect new updated indication of add-on maintenance treatment of patients 6 years of age and older with severe asthma, and with an eosinophilic phenotype. Criteria updated to require prebronchodilator FEV1 below 90% in children.
Interleukin-1β blockers – Commercial and Healthcare Reform	6/24/2024	Policy revised for Arcalyst (rilonacept) to require prescriber specialist for all indications; for Deficiency of Interleukin-1 Receptor Antagonist (DIRA) genetic testing confirmed a mutation in the <i>IL1RN</i> gene; for recurrent pericarditis updated to a single step through standard therapies. Policy revised for Ilaris (canakinumab) to require prescriber specialist for all indications; for gout flares, requiring concomitant urate lowering therapy.
Dichlorphenamide Products – Commercial and Healthcare Reform	6/24/2024	Policy revised to include Ormalvi (dichlorphenamide), a new generic dichlorphenamide. Criteria for initial authorization as well as reauthorization remains the same for Keveyis, Ormalvi, and dichlorphenamide. If the request is for Keveyis or Ormalvi, the member has experienced therapeutic failure or intolerance to generic dichlorphenamide.
Market Watch Programs – Delaware	6/24/2024	Policy revised to add Tolectin 600 (tolmetin) as a targeted drug with therapeutic alternatives of ibuprofen, meloxicam tablets, or naproxen.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Market Watch Programs – New York, Pennsylvania, and West Virginia	6/24/2024	Policy revised to add Tolectin 600 (tolmetin) as a targeted drug with therapeutic alternatives of ibuprofen, meloxicam tablets, or naproxen.
Mucosal Agents – Commercial and Healthcare Reform	6/24/2024	Policy revised to remove Episil (bioadhesive film spray), NeutraSal (supersaturated calcium phosphate rinse), and Xerostomia Relief (oxygenated glycerol triesters) as products are no longer available on the market.
New York Plan-Preferred Step Therapy Exception – Commercial and Healthcare Reform	TBD	Policy archived; step therapy for all four Highmark states (DE, NY, PA, WV) combined into one new policy: Step Therapy Exceptions
Ophthalmic Cyclosporines for Dry Eye Disease – Commercial and Healthcare Reform	7/1/2024	Policy revised to add Restasis (cyclosporine) as a target requiring diagnosis of dry eye disease, age of ≥ 18 years, and if request is for multidose, trial/failure of plan-preferred generic cyclosporine emulsion. If request is for Restasis (cyclosporine) single dose, trial/failure of generic cyclosporine emulsion. Reauthorization requiring positive clinical response to therapy.
PARP Inhibitors – Commercial and Healthcare Reform	6/24/2024	Policy revised to add Talzenna (talazoparib) soft gels requiring the same criteria as Talzenna (talazoparib) capsules for breast cancer and prostate cancer
Pennsylvania Step Therapy Exception – Commercial and Healthcare Reform	TBD	Policy archived; step therapy for all four Highmark states (DE, NY, PA, WV) combined into one new policy: Step Therapy Exceptions
Pulmonary Hypertension – Commercial and Healthcare Reform	6/24/2024	Policy revised to add Opsynvi (macitentan and tadalafil) and Winrevair (sotatercept-csrk) to require diagnosis based on FDA-approved indication supported by results of a right heart catheterization substantiating all of the following: mean pulmonary arterial pressure greater than 20 mmHg at rest, pulmonary wedge pressure 15 mmHg or less, and pulmonary vascular resistance 3 Wood units or greater and the drug is prescribed by or in consultation with a cardiovascular or pulmonary specialist. For Opsynvi (macitentan and tadalafil), the member has documented NYHA or WHO Functional Class II or III symptoms from baseline, and has experienced therapeutic failure, contraindication or intolerance to at least one agent from the following drug classes: generic

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		endothelin-1 receptor antagonists (ERA), generic phosphodiesterase (PDE5) Inhibitors, or soluble guanylate cyclase (sGC) stimulators. For Winrevair (sotatercept-csrk), the member has a diagnosis of WHO group PAH, the member has documented NYHA or WHO Functional Class III or IV symptoms from baseline, and the member meets one of the following: the member is currently receiving at least two agents from two different classes of medications: generic ERA, generic PDE5 inhibitor, sGC, or generic prostacyclin agent OR if the member is only on one pulmonary arterial hypertension (PAH)- specific agent, the prescriber attests the member is unable to tolerate dual background therapy. The prescriber also must attest the member is on maximally tolerated PAH-specific background therapy, the member will continue background therapy with PAH-specific therapies while being treated with Winrevair (sotatercept-csrk), and the member has unresponsive or progressive disease despite established PAH-specific therapies. Reauthorization to require positive clinical response to therapy.
Relyvrio (sodium phenylbutyrate and taurorsodiol) – Commercial and Healthcare Reform	6/21/2024	Terminating policy as drug was withdrawn from the market.
Rezdiffra (resmetirom) – Commercial and Healthcare Reform	6/24/2024	New policy created for Rezdiffra (resmetirom) to include requirements that the member is 18 years of age or older, the medication is being prescribed by or in consultation with a gastroenterologist or hepatologist, a diagnosis of NASH (ICD-10: K75.81) has been confirmed by either a liver biopsy or non-invasive tests (NITs) performed within the past 6 months, there is stage F2 or F3 fibrosis present, the prescriber attests that the member is utilizing appropriate lifestyle interventions, the prescriber attests that the member is receiving standard of care pharmacologic treatment for comorbid diseases, and the prescriber attests that the member does not have evidence of cirrhosis, hepatic decompensation, or hepatocellular carcinoma (HCC). Reauthorization requires attestation of the

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		following: stabilization of fibrosis as demonstrated by NIT, Rezdiffra is being used in conjunction with appropriate diet and exercise, and the member continues to use standard of care pharmacologic treatment to manage comorbid diseases.
Branded hydroxyurea Products – Commercial and Healthcare Reform	TBD	Policy revised to add Xromi (hydroxyurea) oral solution as a target requiring FDA-approved age and indication, recurrent painful sickle cell crises, inability to swallow tablets, and trial/failure of plan- preferred generic hydroxyurea. Inability to swallow tablets removed as initial authorization criteria for Siklos (hydroxyurea). Reauthorization for Xromi (hydroxyurea) requiring FDA-approved age, and for all targets either reduction in painful sickle cell crises or blood transfusions.
Spevigo (spesolimab- sbzo) Subcutaneous – Commercial and Healthcare Reform	6/24/2024	New policy created for Spevigo (spesolimab-sbzo) subcutaneous requiring age, FDA-approved diagnosis, prescribed by or in consultation with a dermatologist, at least 1 previous generalized pustular psoriasis (GPP) flare that had evidence of fresh pustulation, attestation not currently experiencing a flare, and member requires prevention for future flares. Reauthorization of positive clinical response to therapy. Quantity limit override is allowed (4 x 150 mg syringes) for induction therapy. Authorization duration of 12 months.
Step Therapy Exceptions – Commercial and Healthcare Reform	TBD	Policy created to encompass step therapy exception criteria for Delaware, New York, Pennsylvania and West Virginia based on current legislation. This policy will replace the individual policies, J-0241, J-1092, J-1331, and J-0513.
Sucraid (sacrosidase) – Commercial and Healthcare Reform	6/24/2024	Policy revised for Sucraid (sacrosidase) to remove description of negative lactose breath test and added description defining sucrose breath hydrogen test and 13 carbon sucrose breath tests results.
Tryvio (aprocitentan) – Commercial and Healthcare Reform	TBD	Policy created for Tryvio (aprocitentan) requiring FDA approved age and diagnosis, attestation of adherence to current antihypertensive medications, and trial/failure/contraindication to maximally tolerated doses of all of the following: thiazide diuretic, angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, calcium channel blocker, and mineralocorticoid receptor

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		antagonist. Reauthorization requiring a reduction in blood pressure from baseline.
Ustekinumab Biosimilars – Commercial and Healthcare Reform	TBD	Policy revised to add Selarsdi (ustekinumab-aekn) to ustekinumab biosimilar criteria requiring age and diagnosis based on FDA-approved indication; prescriber specialist; therapeutic failure/intolerance to Stelara (ustekinumab); trial/failure of one non-steroidal anti-inflammatory drug, local glucocorticoid injection, and/or non- biologic disease-modifying antirheumatic drug for psoriatic arthritis (PsA), depending on type of PsA; or trial/failure/contraindication to phototherapy OR systemic therapy for plaque psoriasis. Reauthorization to require attestation of disease stability or beneficial response to therapy. Quantity limitation criteria to allow for induction and maintenance dosing per FDA-label. Criteria for Wezlana (ustekinumab-auub) revised to add prescriber specialist and for inflammatory bowel disease, attestation that the member has received a single ustekinumab intravenous induction dose or will undergo induction therapy before starting Wezlana (ustekinumab-auub) subcutaneous.
Voydeya (danicopan) – Commercial and Healthcare Reform	6/24/2024	Policy for Voydeya (danicopan) created to require member is $\geq 18$ years of age, drug prescribed by or in consultation with a hematologist who specializes in paroxysmal nocturnal hemoglobinuria (PNH), the member has a diagnosis of PNH with clinically significant extravascular hemolysis (EVH) (either hemoglobin [Hb] $\leq 9.5$ gm/dL or absolute reticulocyte count [ARC] $\geq 120 \times 10^{9}$ /L), the prescriber attests that the member is currently receiving Ultomiris (ravulizumab) or Soliris (eculizumab) for the treatment of PNH, the prescriber attests that the member has been receiving Ultomiris or Soliris for the treatment of PNH for $\geq 6$ months. Initial authorization is given for a period of 6 months. Reauthorization, for a 12-month period requires positive clinical response to therapy evidenced by one of the following: increased or stabilized hemoglobin (Hb) levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, or increased reticulocyte levels.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Xadago (safinamide) – Commercial and Healthcare Reform	6/24/2024	Policy revised for Xadago (safinamide) to update authorization duration to 12 months.
Xdemvy (lotilaner) – Commercial and Healthcare Reform	6/24/2024	Policy revised for Xdemvy (lotilaner) to add reauthorization criteria requiring diagnosis based on FDA-approved indication supported by microscopic examination of pulled eyelashes or identification of collarettes via slit-lamp evaluation. Criteria for initial and reauthorization to require that the member is experiencing at least one blepharitis symptom associated with Demodex infestation. Additional reauthorization criteria to require that the member has not received a treatment course of Xdemvy within the previous 180 days and prescriber attests that the member requires retreatment with Xdemvy.
Xolremdi (mavorixafor) – Commercial and Healthcare Reform	7/2/2024	Policy created for Xolremdi (mavorixafor) requiring FDA-approved age and diagnosis, documentation of a genotype confirmed variant of CXCR and an absolute neutrophil count ≤ 400 cells/µL. Reauthorization requiring attestation of reduction of incidence of infections.

\*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
Doxycycline Products – Commercial and Healthcare Reform	6/24/2024	Policy updated to include if the request is for brand Oracea, the member has experienced therapeutic failure or intolerance to generic doxycycline monohydrate IR-DR 40 mg.
Insomnia Medications – Commercial and Healthcare Reform	6/24/2024	Policy revised to remove brand Intermezzo (zolpidem tartrate) as it is no longer on market. Policy revised to clarify preferred product of zolpidem tartrate tablets.
Benzodiazepines for Emergency Use – Commercial and Healthcare Reform	6/24/2024	Policy revised to include Libervant (diazepam). Coverage of Libervant requires that the member is between the ages of 2 and 5 years, the member has a diagnosis of seizure clusters or acute repetitive seizures, and the member is

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		currently receiving antiepileptic maintenance therapy.
Intraocular Pressure Reducing Agents – Commercial and Healthcare Reform	TBD	Policy revised to add Azopt (brinzolamide) requiring FDA-approved diagnosis, trial/failure to generic dorzolamide eye drops, and if the request is for brand Azopt, trial/failure to generic brinzolamide eye drops. Combigan (brimonidine tartrate/timolol maleate) added requiring FDA- approved diagnosis, trial/failure to generic timolol maleate ophthalmic solution (non-dropperette), 0.5% dosed twice a day and brimonidine tartrate ophthalmic solution, 0.2% dosed three times per day, available separately and taken together; if the request is for brand Combigan, the member has experienced therapeutic failure or intolerance to generic brimonidine tartrate/timolol maleate.
Lidocaine Patches and Topical System – Commercial and Healthcare Reform	6/24/2024	Policy revised to add Lidocan IV (lidocaine patch 5%), Lidocan V (lidocaine patch 5%), and Tridacaine (lidocaine patch 5%) as targeted medications. Criteria for post-herpetic neuralgia (PHN) to require diagnosis and the member has experienced therapeutic failure, contraindication or intolerance to one plan-preferred agents (tricyclic antidepressant, gabapentin, or pregabalin). Criteria for neuropathic pain associated with cancer to require diagnosis and that the member meets one of the following: the member is using the product as adjuvant therapy with an antidepressant, the member is using the product as adjuvant with an opioid, or the member is using the product as adjuvant with an opioid, or the member is using the product as adjuvant therapy in patients who are unable to swallow. Reauthorization to require that the prescriber attests that the member has experienced a positive clinical response to therapy.
Non-preferred Atypical Antipsychotic Medications – Healthcare Reform Essential Formulary	6/24/2024	Policy revised for Fanapt (iloperidone) to add manic or mixed episodes with Bipolar I Disorder or Bipolar II Disorder criteria requiring age $\geq$ 18 years, diagnosis, and therapeutic failure, intolerance or contraindication to two plan- preferred generic products — risperidone, olanzapine and quetiapine.
Non-Preferred Dipeptidyl Peptidase IV	6/24/2024	Policy revised to add sitagliptin, an authorized generic of Zituvio (sitagliptin), as a target

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
(DPP-IV) Inhibitors – Commercial and Healthcare Reform		requiring diagnosis, use in combination with a metformin containing product or trial/failure/contraindication to metformin, and trial/failure to both a plan-preferred linagliptin and sitagliptin product. Reauthorization requiring need for continued therapy.
Non-Preferred Erectile Dysfunction Therapy – Commercial and Healthcare Reform	6/24/2024	Policy revised to include criteria that member must be 18 years of age or older.
Non-Preferred Methylphenidate ER Products for ADHD – Commercial and Healthcare Reform	6/24/2024	Policy revised to include criteria for Metadate CD (methylphenidate HCI extended release). The member must have an FDA-approved diagnosis, be between 6 and 15 years of age, and either experienced therapeutic failure, contraindication, or intolerance to at least two of the following generic, plan-preferred products: amphetamine/dextroamphetamine extended- release, methylphenidate HCI extended-release, dexmethylphenidate HCI extended-release, or dextroamphetamine extended-release and have an inability to swallow tablets or capsules. Reauthorization criteria requiring prescriber attestation that the member has experienced positive clinical response to therapy and the member still cannot swallow tablets or capsules. Authorization duration of 12 months.
Non-Preferred NSAIDs – Commercial and Healthcare Reform	6/24/2024	Policy revised to add Tolectin 600 (tolmetin) requiring FDA-approved diagnosis and trial/failure to three plan-preferred, generic products, or contraindication to all.
Rayos (prednisone) – Commercial and Healthcare Reform	6/24/2024	Policy revised to require in addition to therapeutic failure or intolerance to plan-preferred, generic, immediate-release prednisone that the member has also experienced therapeutic failure or intolerance to one of the following plan-preferred, generic corticosteroids: 1. prednisolone, 2. methylprednisolone, or 3. hydrocortisone.
Xhance (fluticasone propionate) – Commercial and Healthcare Reform	TBD	Policy revised to include a new FDA-approved diagnosis: Treatment of chronic rhinosinusitis without nasal polyps (CRSsNP) in patients 18 years of age and older. Criteria added for this diagnosis and revised for previous diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP). For both diagnoses, the member must be 18 years of age, have a diagnosis of

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		CRSsNP or CRSwNP, and have experienced therapeutic failure, contraindication, or intolerance to two corticosteroid nasal sprays, one of which is plan-preferred, generic mometasone furoate.
Zerviate (cetirizine ophthalmic solution) 0.24% – Commercial and Healthcare Reform	6/24/2024	Policy revised to include that the member has experienced therapeutic failure, contraindication or intolerance to both plan-preferred, generic products: olopatadine ophthalmic drops and azelastine ophthalmic drops. Reauthorization criteria includes that the prescriber attests that the member has experienced positive clinical response to therapy and that the member requires additional therapy. Initial authorization duration is for 14 days, whereas reauthorization duration is for 6 months.
Non-Preferred Ophthalmic Antihistamines – Commercial and Healthcare Reform	TBD	Policy revised to add Bepreve (bepotastine besilate ophthalmic solution) requiring age, FDA- approved diagnosis, and trial/failure/contraindication to olopatadine ophthalmic drops and azelastine ophthalmic drops. If the request is for brand Bepreve, the member has tried/failed generic bepotastine besilate. Step therapy for Zerviate (cetirizine ophthalmic solution) was updated to add azelastine ophthalmic drops. Reauthorization added to require positive clinical response and attestation that additional therapy is needed.

\*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
Duvyzat (givinostat)	420 ml per 28 days	1260 ml per 28 days

Drug Name	Retail Edit Limit	Mail Edit Limit
Ojemda (tovorafenib) 100 mg tablets	24 tablets per 28 days	72 tablets per 84 days
Ojemda (tovorafenib) 25 mg/mL oral suspension	96 mL per 28 days	288 mL per 84 days
Rinvoq LQ (upadacitinib)	360 mL (2 bottles) per 30 days	1,080 mL (6 bottles) per 90 days
Selarsdi (ustekinumab-aekn) 45 mg/0.5 mL prefilled syringe*	1 syringe per 84 days	1 syringe per 84 days
Selarsdi (ustekinumab-aekn) 90 mg/mL prefilled syringe*	1 syringe per 84 days	1 syringe per 84 days
Spevigo (spesolimab-sbzo) subcutaneous	2 syringes (2 mL) per 28 days	6 syringes (6 mL) per 84 days
Winrevair (sotatercept-csrk)	2 kits per 21 days	6 kits per 63 days
Xromi (hydroxyurea)*	One bottle per 26 days	Three bottles per 78 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
Libervant (diazepam buccal film)	4 films/dispensing
	event

\*Effective date to be determined.

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

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

Drug Name	Daily Limit
Edurant PED (rilpivirine)*	6 tablets per day
Entresto Sprinkle (sacubitril and valsartan oral pellets)*	8 capsules per day
Ogsiveo (nirogacestat) 100 mg, 150 mg	2 tablets per day
Opsynvi (macitentan and tadalafil)	1 tablet per day
Retevmo (selpercatinib) tablets*	Two tablets per day
Rezdiffra (resmetirom)	1 tablet/day
Talzenna (talazoparib) soft gels 0.1 mg, 0.35 mg	1 capsule per day
0.5 mg, 0.75 mg, 1 mg	
Talzenna (talazoparib) soft gels 0.25 mg	3 capsules per day
Tryvio (aprocitentan)*	One tablet per day
Vafseo (vadadustat) 150 mg, 450 mg*	One tablet per day
Vafseo (vadadustat) 300 mg*	Two tablets per day
Vijoice (alpelisib) granules	1 oral granule packet
	per day
Xolremdi (mavorixafor)	4 capsules per day

\*Effective date to be determined.

\*\*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
	naloxone hydrochloride nasal spray	Opioid Overdose

#### Table 2. Non-Preferred Products

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

Brand Name	Generic Name	Preferred Alternatives
Pivya	pivmecillinam	Prescriber discretion
Xromi	hydroxyurea	hydroxyurea tablets

#### 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:

- <u>Performance Formulary</u>
- Venture Formulary
- Fundamental Formulary

#### Table 1. Preferred Products

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

No changes at this time.

#### Table 2. Non-Preferred Products

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

Brand Name	Generic Name	Preferred Alternatives
Pivya	pivmecillinam	Prescriber discretion

#### Table 3. Products Not Added\*

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

Brand Name	Generic Name	Preferred Alternatives
Entresto Sprinkle	sacubitril and valsartan oral pellets	Entresto tablets
Hercessi	trastuzumab-strf	Kanjinti, Trazimera
Ingrezza Sprinkle	valbenazine	Prescriber discretion
Opsynvi	macitentan and tadalafil	sildenafil, tadalafil, ambrisentan, bosentan, riociguat
Rezenopy	naloxone hydrochloride nasal spray	Prescriber discretion
Risvan	risperidone ISM	risperidone microspheres
Selarsdi 45 mg/0.5 mL prefilled syringe	ustekinumab-aekn	Stelara
Selarsdi 90 mg/mL prefilled syringe	ustekinumab-aekn	Stelara
Spevigo subcutaneous	spesolimab-sbzo	Prescriber discretion
Tryvio	aprocitentan	spironolactone tablets, eplerenone tablets
Voydeya	danicopan	Prescriber discretion
Winrevair	sotatercept-csrk	sildenafil, tadalafil, ambrisentan, bosentan
Xromi	hydroxyurea	hydroxyurea tablets

\*Physicians may request coverage of these products using the <u>Prescription Drug Medication Request Form</u>.

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

Brand Name	Generic Name
Anktiva	nogapendekin alfa inbakicept-pmln
Duvyzat	givinostat
Edurant PED	rilpivirine
Entresto Sprinkle	sacubitril and valsartan oral pellets
Hercessi	trastuzumab-strf
Ingrezza Sprinkle	valbenazine

Libervant	diazepam buccal film
Ogsiveo	nirogacestat
Ojemda tablets	tovorafenib
Ojemda oral suspension	tovorafenib
Opsynvi	macitentan and tadalafil
Retevmo	selpercatinib
Rezdiffra	resmetirom
Rinvoq LQ	upadacitinib
Risvan	risperidone ISM
Selsarsdi	ustekinumab-aekn
Spevigo	spesolimab-sbzo
Talzenna soft gels 0.1 mg, 0.25 mg, 0.35 mg	talazoparib
0.5 mg, 0.75 mg, 1 mg	
Tevimbra	tislelizumab-jsgr
Tryvio	aprocitentan
Vijoice	alpelisib
Voydeya	danicopan
Winrevair	sotatercept-csrk
Xolremdi	mavorixafor
Zevtera	ceftobiprole medocaril sodium

## 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	6/24/2024	Policy revised to remove age requirement and update existing criteria based on expanded indications for Nexletol (bempedoic acid) and Nexlizet (bempedoic acid/ezetimibe), including prescriber attestation that member will be using Nexletol or Nexlizet in combination with other LDL-C lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible for both the Heterozygous Familial Hypercholesterolemia and Primary Hyperlipidemia indications, and that there is either clinical documentation of established ASCVD or that member has a high risk for CVD for the Hyperlipidemia indication. Removed

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		requirement of using with a maximally tolerated statin. Reauthorization criteria revised to include prescriber attestation that member will continue using Nexletol or Nexlizet in combination with other LDL-C lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible for HeFH or primary hyperlipidemia.
Administrative Prior Authorizations for Medicare Part D Plans – Medicare	5/29/2024	Policy revised adding Wegovy (semaglutide) D vs NonD criteria to deny as Part D excluded if used for weight loss.
ALK-Targeting Kinase Inhibitors – Medicare	6/24/2024	Policy revised for Alecensa (alectinib) to include the member either has a diagnosis of metastatic non-small cell lung cancer (NSCLC), or NSCLC following tumor resection that is either node positive or with tumors $\geq$ 4 cm with the prescriber attesting that Alecensa is being used for adjuvant treatment. Age $\geq$ 18 years requirement removed for Alecensa, Alunbrig, Lorbrena, Xalkori and Zykadia.
Anktiva (nogapendekin alfa inbakicept-pmln) – Medicare	6/24/2024	New policy for Anktiva (nogapendekin alfa inbakicept-pmln) to require diagnosis based on FDA-approved indication and use with Bacillus Calmette-Guérin (BCG).
Atypical Antipsychotics – Medicare	TBD	Policy revised to include Fanapt (iloperidone) requiring FDA-approved diagnosis and therapeutic failure, intolerance, or contraindication to one of the following generic products: olanzapine, quetiapine, risperidone. Policy revised to include Saphris (asenapine) requiring FDA-approved diagnosis, therapeutic failure, intolerance, or contraindication to one of the following generic products: olanzapine, quetiapine, risperidone, and if request is for brand Saphris, member experienced therapeutic failure or intolerance to generic asenapine sublingual tablets. Policy J-1314 Saphris (asenapine) – Medicare will be terminated when this policy is posted.
BCR-ABL Kinase Inhibitors – Medicare	6/24/2024	Policy revised for Iclusig (ponatinib) to require diagnosis based on expanded FDA-approved indication for newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
BRAF Mutation-Targeting	6/24/2024	Policy revised to add Ojemda (tovorafenib) to
& MEK1/2 Kinase Inhibitors – Medicare		require diagnosis based on FDA approved indication
CGRP Inhibitors – Medicare	TBD	Policy revised to remove Onabotulinum toxin A (Botox) as an option to step through.
Chronic Inflammatory Diseases – Medicare	6/24/2024	Policy revised for Otezla (apremilast) to add pediatric plaque psoriasis criteria requiring age ≥ 6 to < 18 years, weight ≥ 20 kg, moderate-to- severe disease, and trial/failure to systemic therapy or phototherapy or contraindication to all. For Behçet's disease, step through topical triamcinolone removed and step through colchicine changed to any 1 systemic therapy. Unbranded adalimumab-aaty and adalimumab- ryvk added as non-preferred adalimumab products directed to 2 preferred adalimumab products and subject to adalimumab prior authorization criteria. Adalimumab prior authorization criteria. Adalimumab criteria in uveitis revised to update from double step through immunosuppressant or corticosteroid. Policy revised to add Rinvoq (upadacitinib) LQ to existing criteria for Rinvoq in psoriatic arthritis (PsA). If the member is 18 years of age or older, requesting Rinvoq tablets. New criteria created for Rinvoq/Rinvoq LQ (upadacitinib) in polyarticular juvenile idiopathic arthritis (PJIA) requiring FDA-approved diagnosis, trial/failure/contraindication to one non-biologic disease modifying anti-rheumatic drug (DMARD) or member requires initial biologic therapy due to involvement of high-risk joints or high disease activity, and trial/failure to 1 tumor necrosis factor blocker therapy. Rinvoq (upadacitinib) LQ added as a preferred agent for PJIA and PsA. Entyvio (vedolizumab) subcutaneous new indication for Crohn's disease added requiring FDA-approved indication, trial/failure to 2 preferred biologics for Crohn's disease, and the member has received at least 2 doses of Entyvio (vedolizumab) intravenous at least 6 weeks before initiating SC and achieved clinical response or remission.
Combination Prescription Drug Safety – Medicare	TBD	Policy revised for concomitant use of opiate agonists, benzodiazepines, and centrally acting musculoskeletal relaxants to additionally require that the prescriber attests that non-opiate

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		therapies have been considered (e.g., NSAIDs, physical therapy) and the prescriber also attests that non-benzodiazepine therapies have been considered (e.g., SSRIs, SNRIs, buspirone).
Duvyzat (givinostat) – Medicare	TBD	New policy for Duvyzat (givinostat) to require diagnosis based on FDA-approved indication supported by a documented pathogenic mutation in the dystrophin gene.
Ergotamines – Medicare	4/11/2024	Policy revised to add Trudhesa back into criteria due to once again a Medicare eligible product.
Eucrisa (crisaborole) – Medicare	6/24/2024	Policy revised for Eucrisa (crisaborole) to remove age requirement.
Gattex (teduglutide) – Medicare	6/24/2024	Policy revised for Gattex (teduglutide) to remove age criteria and remove specification that parental/intravenous nutrition was used for at least 12 months and at least 3 times a week.
Igalmi (dexmedetomidine) – Medicare	TBD	Igalmi not covered by Medicare D; archive policy.
Immediate Release Fentanyl Citrate – Medicare	6/24/2024	Policy revised to remove brand Actiq (fentanyl citrate) and brand Subsys (fentanyl citrate) as they are no longer available.
Interferon Beta – Medicare	6/24/2024	Policy revised to remove Extavia (interferon beta- 1b) as product is no longer commercially available.
Interleukin (IL)-5 Antagonists – Medicare	6/24/2024	Policy revised for Fasenra pen (benralizumab) to reflect new updated indication of add-on maintenance treatment of patients 6 years of age and older with severe asthma, and with an eosinophilic phenotype. Criteria updated to require prebronchodilator FEV1 below 90% in children.
Benzodiazepines for Emergency Use – Medicare	6/24/2024	Policy revised to include Libervant (diazepam). Coverage of Libervant requires that the member is between the ages of 2 and 5 years, the member has a diagnosis of seizure clusters or acute repetitive seizures, and the member is currently receiving antiepileptic maintenance therapy.
Dichlorphenamide Products – Medicare	6/27/2024	Policy revised to include Ormalvi (dichlorphenamide), a new generic dichlorphenamide. Criteria for initial authorization as well as reauthorization remains the same for Keveyis, Ormalvi, and dichlorphenamide. If the request is for Keveyis or Ormalvi, the member

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		has experienced therapeutic failure or intolerance to generic dichlorphenamide.
Lidocaine Patches – Medicare	6/24/2024	Policy revised to add Lidocan IV (lidocaine patch 5%), Lidocan V (lidocaine patch 5%), and Tridacaine (lidocaine patch 5%) as targeted medications. Criteria for post-herpetic neuralgia (PHN) to require diagnosis and the member has experienced therapeutic failure, contraindication or intolerance to one other agent used to treat PHN or the member is unable to swallow oral medications or the member is unable to take an oral medication due to potential adverse events. Criteria for diabetic peripheral neuropathy (DPN) to require diagnosis and the member has experienced therapeutic failure, contraindication or intolerance to one other agent used to treat DPN or the member is unable to swallow oral medications or the member is unable to take an oral neuropathy to require diagnosis and the member has experienced therapeutic failure, contraindication or intolerance to one other agent used to treat DPN or the member is unable to swallow oral medications or the member is unable to take an oral medication due to potential adverse events.
PARP Inhibitors – Medicare	TBD	Policy revised to add Talzenna (talazoparib) soft gels requiring the same criteria as Talzenna (talazoparib) capsules for breast cancer and prostate cancer
Programmed Death Receptor Therapies – Medicare	TBD	Policy revised to include Tevimbra (tislelizumab- jsgr) to require FDA-approved diagnosis.
Provigil (modafinil) and Nuvigil (armodafinil) – Medicare	6/24/2024	Policy revised to change mean sleep latency to less than or equal to 8 minutes for a multiple sleep latency test for narcolepsy.
Pulmonary Hypertension – Medicare	6/24/2024	Policy revised to add Opsynvi (macitentan and tadalafil) and Winrevair (sotatercept-csrk) to require diagnosis based on FDA-approved indication supported by results of a right heart catheterization substantiating all of the following: mean pulmonary arterial pressure greater than 20 mmHg at rest, pulmonary wedge pressure 15 mmHg or less, and pulmonary vascular resistance 3 Wood units or greater. For Opsynvi (macitentan and tadalafil), the member has experienced therapeutic failure, contraindication or intolerance to at least one agent from the following drug classes: generic endothelin-1 receptor antagonists (ERA), generic phosphodiesterase (PDE5) Inhibitors, or soluble guanylate cyclase (sGC) stimulators. For

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	0/4/2024	Winrevair (sotatercept-csrk), the member is currently receiving background therapy with at least one agent from one class of the following medications: generic ERA, generic PDE5 inhibitor, sGC, generic prostacyclin agent. The member will continue background therapy with pulmonary arterial hypertension-specific therapies while being treated with Winrevair (sotatercept-csrk).
Relyvrio (sodium phenylbutyrate and taurorsodiol) – Medicare	6/1/2024	Terminating policy as drug was withdrawn from the market.
Rezdiffra (resmetirom) – Medicare	6/24/2024	New policy created for Rezdiffra (resmetirom) to include requirements of a diagnosis of NASH that has been confirmed by either a liver biopsy or non-invasive tests (NITs) performed within the past 6 months, there is stage F2 or F3 fibrosis present, the prescriber attests that the member is utilizing appropriate lifestyle interventions, the prescriber attests that the member is receiving standard of care pharmacologic treatment for comorbid diseases, and the prescriber attests that the member does not have evidence of cirrhosis, hepatic decompensation, or hepatocellular carcinoma (HCC). Reauthorization requires attestation of the following: stabilization of fibrosis as demonstrated by NIT, Rezdiffra is being used in conjunction with appropriate diet and exercise, and the member continues to use standard of care pharmacologic treatment to manage comorbid diseases.
Rivfloza (nedosiran) – Medicare	4/25/2024	Policy revised to change reauthorization criteria to a reduction in urinary oxalate levels from baseline.
Saphris (asenapine) – Medicare	TBD	Policy to be terminated with policy J-0307 01/01/2025 posting
Sarclisa (isatuximab-irfc) – Medicare	6/24/2024	Policy revised for Sarclisa (isatuximab) to remove age limitation.
Sarclisa (isatuximab-irfc) – Medicare	TBD	Policy revised for Sarclisa (isatuximab) to require relapsed or refractory disease when used in combination with carfilzomib and dexamethasone.
Spevigo (spesolimab- sbzo) – Medicare	6/24/2024	Policy revised to add Spevigo (spesolimab-sbzo) subcutaneous dosage form requiring FDA- approved diagnosis and attestation the member

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		has had a previous flare, not currently experiencing a flare, and requires prevention for future generalized pustular psoriasis (GPP) flares. Quantity limit override is allowed (4 x 150 mg syringes) for induction therapy. Authorization duration of 12 months.
Thrombopoiesis Stimulating Agents – Medicare	6/24/2024	Policy revised to add Alvaiz (eltrombopag) as a targeted medication. Criteria for persistent or chronic ITP requires therapeutic failure, contraindication, or intolerance to corticosteroid or immunoglobulin therapy or splenectomy, and documented platelet count of > $30 \times 10^{9}/L$ to < $50 \times 10^{9}/L$ with significant mucous membrane bleeding or one risk factor for bleeding or a documented platelet count of $\leq 30 \times 10^{9}/L$ . Criteria for treatment of thrombocytopenia in patients with chronic Hepatitis C to require Alvaiz is being used to achieve target platelet counts to initiate or maintain interferon therapy in patients with Hepatitis C and documented platelet count of $< 75 \times 10^{9}/L$ . Treatment of patients with severe aplastic anemia to require diagnosis, therapeutic failure to one immunosuppressive therapy, and a documented platelet count of $< 30 \times 10^{9}/L$ . All indications to require therapeutic failure, contraindication, or intolerance to Promacta.
Trastuzumab Products – Medicare	TBD	Policy revised to add Hercessi (trastuzumab-strf) to require diagnosis based on FDA-approved indication, disease overexpresses HER2 based on FDA-approved companion diagnostic test for trastuzumab, and therapeutic failure or intolerance to Kanjinti (trastuzumab-anns) and Trazimera (trastuzumab-gyyp).
Tryvio (aprocitentan) – Medicare	TBD	Policy created for Tryvio (aprocitentan) requiring FDA approved diagnosis, attestation of adherence to current antihypertensive medications, and trial/failure/contraindication to maximally tolerated doses of all of the following: thiazide diuretic, angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, and mineralocorticoid receptor antagonist. Reauthorization requiring attestation of a reduction in blood pressure from baseline.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Ultomiris (ravulizumab- cwvz) – Medicare	6/24/2024	Policy revised for Ultomiris (ravulizumab-cwvz) to reflect a new FDA-approved indication, the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adults. Criteria for coverage requires that the member has a diagnosis of NMOSD and the disease is anti-aquaporin-4 (AQP4) antibody positive. Reauthorization requires that the member has experienced a decrease in the number of NMOSD relapse(s).
Ustekinumab Biosimilars – Medicare	TBD	Policy revised to add Selarsdi (ustekinumab- aekn) to ustekinumab biosimilar criteria requiring age and diagnosis based on FDA-approved indication; therapeutic failure/intolerance to Stelara (ustekinumab); trial/failure/contraindication to phototherapy OR systemic therapy for plaque psoriasis. Quantity limitation criteria to allow for induction and maintenance dosing per FDA-label.
Vivjoa (oteseconazole) – Medicare	TBD	Policy revised to add criterion to require the member has experienced therapeutic failure, contraindication, or intolerance to a six-month maintenance course of oral fluconazole.
Voydeya (danicopan) – Medicare	6/24/2024	Policy for Voydeya (danicopan) created to require the member has a diagnosis of PNH with clinically significant extravascular hemolysis (EVH) (either hemoglobin [Hb] $\leq$ 9.5 gm/dL or absolute reticulocyte count [ARC] $\geq$ 120 x 10^9/L), the prescriber attests that the member is currently receiving Ultomiris (ravulizumab) or Soliris (eculizumab) for the treatment of PNH, the prescriber attests that the member has been receiving Ultomiris or Soliris for the treatment of PNH for $\geq$ 6 months. Initial authorization is given for a period of 6 months. Reauthorization, for a 12-month period requires positive clinical response to therapy evidenced by one of the following: increased or stabilized hemoglobin (Hb) levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, or increased reticulocyte levels.
Xhance (fluticasone propionate) – Medicare	TBD	New policy created for Xhance (fluticasone propionate) to require diagnosis based on FDA- approved indication and therapeutic failure, contraindication, or intolerance to one (1) nasal corticosteroid.

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Xolremdi (mavorixafor) – Medicare	6/24/2024	Policy created for Xolremdi (mavorixafor) requiring FDA-approved diagnosis. Reauthorization requiring attestation of reduction of incidence of infections.
Zynlonta (loncastuximab tesirine-lpyl) – Medicare	6/24/2024	Policy revised for Zynlonta (loncastuximab tesirine-lpyl) to remove age requirement and to require that the member has received at least two lines of prior systemic therapy per FDA-approved indication.

\*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
Mirabegron ER – Medicare	6/24/2024	New policy for generic mirabegron extended release (ER) tablets requiring diagnosis of overactive bladder and therapeutic failure, contraindication, or intolerance to brand Myrbetriq ER tablets.
Non-Preferred Dipeptidyl Peptidase IV (DPP-IV) Inhibitors – Medicare	6/24/2024	Policy revised to add sitagliptin, an authorized generic of Zituvio (sitagliptin), as a target requiring diagnosis and trial/failure to both a plan-preferred linagliptin and sitagliptin product.
Non-Preferred Ophthalmic Antihistamines – Medicare	TBD	Policy revised to add Bepreve (bepotastine besilate ophthalmic solution) requiring FDA- approved diagnosis, and trial/failure/contraindication to azelastine ophthalmic drops. Step therapy for Zerviate (cetirizine ophthalmic solution) was updated to add azelastine ophthalmic drops and remove generic olopatadine drops.

**3. Quantity Level Limit (QLL) Program** Effective date pending CMS approval, completion of internal review and implementation, unless otherwise noted.

Drug Name	Quantity Limit (31 days)
Abrysvo (respiratory syncytial virus vaccine)	1 dose per 365 days
Anktiva (nogapendekin alfa inbakicept- pmln)	36 vials (14.4 mL) per lifetime (999 days)
Arexvy (respiratory syncytial virus vaccine, adjuvanted)	1 dose per 365 days

Drug Name	Quantity Limit (31 days)
Duvyzat (givinostat)	3 bottles (420 mL) per 35 days
Edurant PED (rilpivirine)	186 tablets per 31 days
Entresto Sprinkle (sacubitril and	8 capsules per day
valsartan oral pellets)	
Ingrezza Sprinkle (valbenazine)	31 Sprinkle capsules/31 days
Libervant (diazepam buccal film)	10 films/30 days
Ogsiveo (nirogacestat) 100 mg, 150 mg	2 tablets per day
Ojemda (tovorafenib) 100 mg tablets	24 tablets per 28 days
Ojemda (tovorafenib) 25 mg/mL oral	96 mL per 28 days
suspension	
Opsynvi (macitentan and tadalafil)	31 tablets per 31 days
Retevmo (selpercatinib)	2 tablets per day
Rezdiffra (resmetirom)	31 tablets per 31 days
Rinvoq LQ (upadacitinib)	372 mL per 31 days (12 mL per day)
Risvan (risperidone ISM)	1 single-dose kit per 28 days
Selarsdi (ustekinumab-aekn) 45 mg/0.5	1 syringe (0.5 mL) per 84 days
mL prefilled syringe	
Selarsdi (ustekinumab-aekn) 90 mg/mL prefilled syringe	1 syringe (1 mL) per 84 days
Spevigo (spesolimab-sbzo)	2 syringes (2 mL) per 28 days
subcutaneous	
Talzenna (talazoparib) soft gels 0.1 mg,	1 capsule per day
0.35 mg, 0.5 mg, 0.75 mg, 1 mg	
Talzenna (talazoparib) soft gels 0.25 mg	3 capsules per day
Tevimbra (tislelizumab-jsgr)	20 mL per 21 days
Tryvio (aprocitentan)	One tablet per day
Tyenne (tocilizumab-aazg) vials	40 mL per 28 days
Vijoice (alpelisib)	1 oral granule packet per day
Voydeya (danicopan)	186 tablets per 31 days
Xolremdi (mavorixafor)	4 capsules per day
Xromi (hydroxyurea)	One bottle per 26 days