

# Formulary Updates



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Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for August 2024. 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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- A. Changes to the Highmark Comprehensive Formulary and the Highmark Healthcare Reform Comprehensive Formulary
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As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (accessible via [Availity®](#) or our website). Click the **Pharmacy Program/Formularies** link from the menu on the left.



The following entities, which serve the noted regions, are independent licensees of the Blue Cross Blue Shield Association: Western and Northeastern PA: Highmark Inc. d/b/a Highmark Blue Cross Blue Shield, Highmark Choice Company, Highmark Health Insurance Company, Highmark Coverage Advantage Inc., Highmark Benefits Group Inc., First Priority Health, First Priority Life or Highmark Senior Health Company. Central and Southeastern PA: Highmark Inc. d/b/a Highmark Blue Shield, Highmark Benefits Group Inc., Highmark Health Insurance Company, Highmark Choice Company or Highmark Senior Health Company. Delaware: Highmark BCBSD Inc. d/b/a Highmark Blue Cross Blue Shield. West Virginia: Highmark West Virginia Inc. d/b/a Highmark Blue Cross Blue Shield, Highmark Health Insurance Company or Highmark Senior Solutions Company. Western NY: Highmark Western and Northeastern New York Inc. d/b/a Highmark Blue Cross Blue Shield. Northeastern NY: Highmark Western and Northeastern New York Inc. d/b/a Highmark Blue Shield.

All references to "Highmark" in this document are references to the Highmark company that is providing the member's health benefits or health benefit administration and/or to one or more of its affiliated Blue companies.

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

## Important Drug Safety Updates

### [Glenmark Pharmaceuticals, Inc. Potassium Chloride Extended Release 750mg Capsules](#)

On June 24, 2024, Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ, is voluntarily recalling 114 batches of Potassium Chloride Extended-Release Capsules, USP (750 mg) 10 mEq K, to the consumer level. The product is being recalled because of failed dissolution.

The failed dissolution of potassium chloride extended-release capsules may cause high potassium levels, also known as hyperkalemia, which can result in irregular heartbeat that can lead to cardiac arrest. For patients who require chronic use of potassium chloride extended-release oral capsules — especially in those patients with underlying comorbidities or conditions that cause altered excretory mechanisms for potassium such as hypertension, heart failure, or renal dysfunction — there is a reasonable probability of developing hyperkalemia that may lead to a range of severity of adverse events from being asymptomatic to more severe potential life threatening adverse events of hyperkalemia such as cardiac arrhythmias, severe muscle weakness, and death. To date, the firm has not received any reports of hyperkalemia or serious adverse events from spontaneous sources related to this recall.

### [American Health Packaging Potassium Chloride Extended Release 750mg Capsules](#)

On June 25, 2024, American Health Packaging on behalf of BluePoint Laboratories is voluntarily recalling 21 batches of Potassium Chloride Extended-Release Capsules, USP (750 mg) 10 mEq K, to the consumer level. The product is being recalled because of failed dissolution.

The failed dissolution of potassium chloride extended-release capsules may cause high potassium levels, also known as hyperkalemia, which can result in irregular heartbeat that can lead to cardiac arrest. For patients who require chronic use of potassium chloride extended-release oral capsules, especially in those patients with underlying comorbidities or conditions that cause altered excretory mechanisms for potassium such as hypertension, heart failure, or renal dysfunction, there is a reasonable probability of developing hyperkalemia that may lead to a range of severity of adverse events from being asymptomatic to more severe potential life threatening adverse events of hyperkalemia such as cardiac arrhythmias, severe muscle weakness, and death. To date, the firm has not received any reports of hyperkalemia or serious adverse events from spontaneous sources related to this recall.

### [Par Pharmaceutical Clonazepam Orally Disintegrating Tablets 0.25 mg tablets](#)

On July 16, 2024, Endo USA, Inc., is voluntarily recalling one lot of Clonazepam Orally Disintegrating Tablets, USP (C-IV) 0.25 mg tablets, which may also appear as Clonazepam Orally Disintegrating Tablets, USP (C-IV) 0.125 tablets 60-count pack to the consumer level. The product lot is being recalled due to mislabeling where an incorrect strength appears on the cartons of some packs to show the product strength as 0.125 mg and not 0.25 mg due to an error at a third-party packager. The blister strips inside the product pack reflect the correct strength of 0.25 mg.

Children and adults who are inadvertently prescribed a two-fold overdose of clonazepam would be at risk for the adverse effects of significant sedation, dizziness, ataxia, and confusion. There is reasonable probability for significant, possibly life-threatening, respiratory depression especially for patients with concomitant pulmonary disease, patients who have prescribed dosing near maximal dosing, and patients also taking other medications that could cause additional respiratory depression. To date, Endo has not received any reports of adverse events associated with this product lot recall.

### [B. Braun 0.9% Sodium Chloride for Injection USP 1000 mL in E3 Containers](#)

On Aug. 8, 2024, B. Braun Medical Inc. (B. Braun), is voluntarily recalling two lots of 0.9% Sodium Chloride for Injection USP 1000 mL in E3 containers within the United States to the consumer level. The voluntary recall has been initiated due to the potential for particulate matter and fluid leakage of the respective containers.

There is a reasonable probability of embolic phenomena such as stroke or ischemia/infarct to other organs and possible infection if these particulates are not sterile that could lead to permanent damage or impairment of body function which could be life-threatening. The affected batches were inadvertently released to the market prior to the completion of the required acceptance activities for embedded particulate matter which may result in leakage. To date, there have been no customer complaints received and there have been no reports of serious injury or death associated with this issue.

## Highmark Formulary Update – August 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 August 2024, unless otherwise noted.

Brand Name	Generic Name	Comments
Capvaxive	pneumococcal 21-valent conjugate vaccine	Streptococcus pneumoniae
Mresvia	Respiratory Syncytial Virus Vaccine	Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older

Coverage may be contingent upon plan benefits.

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

Brand Name	Generic Name	Preferred Alternatives
Augtyro 160 mg	reprotrectinib	Xalkori, Vitrakvi
Chewtadzy 10 mg, 20 MG	tadalafil	sildenafil citrate, tadalafil tablet
Chewtadzy 5 mg	tadalafil	sildenafil citrate, finasteride 5 mg tablet, tamsulosin hcl
Iqirvo	elafibranor	ursodiol tablet, ursodiol 300 mg capsules
Nypozi	filgrastim-txid	Nivestym, Zarxio
Ohtuvayre	ensifentrine	Serevent Diskus, Striverdi Respimat, tiotropium bromide
Ondansetron ODT 16 mg	ondansetron	ondansetron ODT 8 mg; ondansetron HCl 8 mg

Brand Name	Generic Name	Preferred Alternatives
Onyda XR	clonidine hydrochloride	clonidine ER tablets 0.1 mg, guanfacine ER
Pyzchiva 45 mg/0.5 mL	ustekinumab-ttwe	Stelara syringe (mL) 45mg/0.5ml; Stelara vial (ml) 45mg/0.5mL
Pyzchiva 90mg/mL	ustekinumab-ttwe	Stelara syringe (mL) 90 mg/mL
Scemblix 100 mg	asciminib	Iclusig
Sofdra	sofipironium	Prescriber discretion
Torpenz	everolimus	everolimus tablet
Triglide	fenofibrate	fenofibrate 160 mg tablet
Vigafyde	vigabatrin	Vigpoder, vigabatrin powder for solution
Zoryve cream 0.15%	roflumilast	tacrolimus ointment, fluticasone 0.05% cream

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 Provider Resource Center and access the **Pharmacy Program/Formularies** link for details on the formularies and formulary options that apply to Highmark Delaware Healthcare Reform members. Once on the page, click on **Healthcare Reform**, which is under the “Line of Business” header.

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

Brand Name	Generic Name
Augtyro	repotrectinib
Iqirvo	elafibranor
Nypozi	filgrastim-txid
Ohtuvayre	ensifentrine
Onyda XR	Clonidine Hydrochloride
Pyzchiva 45 mg/0.5 mL, 90mg/mL	ustekinumab-ttwe
Scemblix 100 mg	asciminib
Sofdra	sofipironium
Torpenz	everolimus
Vigafyde	vigabatrin
Zoryve cream 0.15%	roflumilast

### **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 2024, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
<b>Items listed below were added to the formulary</b>			
Capvaxive	pneumococcal 21-valent conjugate vaccine	\$0	Streptococcus pneumoniae
Mresvia	Respiratory Syncytial Virus Vaccine	\$0	Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older
<b>Items listed below were not added to the formulary</b>			
Augtyro 160 mg	reprotrectinib	NF	Xalkori, Vitrakvi
Chewtadzy 10 mg, 20 MG	tadalafil	NF	sildenafil citrate, tadalafil tablet
Chewtadzy 5 mg	tadalafil	NF	sildenafil citrate, finasteride 5 mg tablet, tamsulosin hcl
Iqirvo	elafibranor	NF	ursodiol tablet, ursodiol 300 mg capsules
Nypozi	filgrastim-txid	NF	Nivestym, Zarxio
Ohtuvayre	ensifentrine	NF	Serevent Diskus, Striverdi Respimat, tiotropium bromide
Ondansetron ODT 16 mg	ondansetron	NF	ondansetron ODT 8 mg; ondansetron HCl 8 mg
Onyda XR	Clonidine Hydrochloride	NF	clonidine ER tablets 0.1 mg, guanfacine ER
Pyzchiva 45 mg/0.5 mL	ustekinumab-ttwe	NF	Stelara syringe (ml) 45mg/0.5ml; Stelara vial (ml) 45mg/0.5ml
Pyzchiva 90mg/mL	ustekinumab-ttwe	NF	Stelara syringe (mL) 90 mg/mL
Scemblix 100 mg	asciminib	NF	Iclusig
Sofdra	sofipironium	NF	Prescriber discretion
Torpenz	everolimus	NF	everolimus tablet
Triglide	fenofibrate	NF	fenofibrate 160 mg tablet
Vigafyde	vigabatrin	NF	Vigpoder, vigabatrin powder for solution
Zoryve cream 0.15%	roflumilast	NF	tacrolimus ointment, fluticasone 0.05% cream

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 2024 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
<b>Items listed below were added to the formulary</b>			
Capvaxive	pneumococcal 21-valent conjugate vaccine	3	Streptococcus pneumoniae
Mresvia	Respiratory Syncytial Virus Vaccine	3	Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older
<b>Items listed below were not added to the formulary</b>			
Augtyro 160 mg	repotrectinib	NF	Xalkori, Vitrakvi
Chewtadzy 10 mg, 20 MG	tadalafil	NF	sildenafil citrate, tadalafil tablet
Chewtadzy 5 mg	tadalafil	NF	sildenafil citrate, finasteride 5 mg tablet, tamsulosin HCl
Iqirvo	elafibranor	NF	ursodiol tablet, ursodiol 300 mg capsules
Nypozi	filgrastim-txid	NF	Nivestym,
Ohtuvayre	ensifentrine	NF	Serevent Diskus, Striverdi Respimat, tiotropium bromide
Ondansetron ODT 16 mg	ondansetron	NF	ondansetron ODT 8 mg; ondansetron HCl 8 mg
Onyda XR	Clonidine Hydrochloride	NF	clonidine ER tablets 0.1 mg, guanfacine ER
Pyzchiva 45 mg/0.5 mL	ustekinumab-ttwe	NF	Stelara syringe (mL) 45mg/0.5mL; Stelara vial (mL) 45mg/0.5mL
Pyzchiva 90mg/mL	ustekinumab-ttwe	NF	Stelara syringe (mL) 90 mg/mL
Scemblix 100 mg	asciminib	NF	Iclusig
Sofdra	sofipironium	NF	Drysol
Torpenz	everolimus	NF	everolimus tablet
Triglide	fenofibrate	NF	fenofibrate 160 mg tablet
Vigafyde	vigabatrin	NF	Vigpoder, vigabatrin powder for solution
Zoryve cream 0.15%	roflumilast	NF	tacrolimus ointment, fluticasone 0.05% cream

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
<b>Items listed below were added to the formulary (Preferred)</b>			
Capvaxive	pneumococcal 21-valent conjugate vaccine	2	Streptococcus pneumoniae
Mresvia	Respiratory Syncytial Virus Vaccine	2	Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older
Scemblix 100 mg	asciminib	2	Treatment of: Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), and Ph+ CML in CP with the T315I mutation
<b>Items listed below were added to the formulary (Non-Preferred)</b>			
Ondansetron ODT 16 mg	ondansetron	1	ondansetron ODT 8 mg; ondansetron HCL 4 mg/5 mL; ondansetron HCL 8 mg
Chewtadzy 10 mg, 20 MG	tadalafil	3	sildenafil citrate
Chewtadzy 5 mg	tadalafil	3	sildenafil citrate, finasteride 5 mg tablet, tamsulosin HCl
Iqirvo	elafibranor	3	ursodiol tablet, ursodiol 300 mg capsules
Nypozi	filgrastim-txid	3	Nivestym, Zarxio
Ohtuvayre	ensifentrine	3	Serevent Diskus, Striverdi Respimat, tiotropium bromide
Onyda XR	Clonidine Hydrochloride	3	Clonidine ER tablets 0.1 mg, guanfacine ER
Sofdra	sofipironium	3	Prescriber discretion
Triglide	fenofibrate	3	fenofibrate 160 mg tablet
Vigafyde	vigabatrin	3	Prescriber discretion
Scemblix 100 mg	asciminib	2	Iclusig
Torpenz	everolimus	3	everolimus tablet
<b>Items listed below were not added to the formulary</b>			
Augtyro	repotrectinib	NF	Xalkori, Vitrakvi
Ondansetron ODT 16 mg	ondansetron	NF	Generic ondansetron ODT

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
Augtyro	repotrectinib
Iqirvo	elafibranor
Nypozi	filgrastim-txid
Ohtuvayre	ensifentrine
Onyda XR	clonidine hydrochloride
Pyzchiva 45 mg/0.5 mL	ustekinumab-ttwe
Pyzchiva 90mg/mL	ustekinumab-ttwe
Scemblix 100 mg	asciminib
Sofdra	sofpironium
Torpenz	everolimus
Vigafyde	vigabatrin
Zoryve cream 0.15%	roflumilast

**E. Updates to the Pharmacy Utilization Management Programs**

**1. Prior Authorization Program**

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Adbry (tralokinumab-ldrm) – Commercial and Healthcare Reform	8/23/2024	Policy revised for Adbry (tralokinumab-ldrm) to update quantity limit table to allow 300 mg autoinjector (FDA-approved dosing) for adult patients
Anti-Obesity – Administrative Services Only (ASO) Commercial	TBD	New policy created mirroring policy J-0184.
Anti-Obesity – Commercial and Healthcare Reform	TBD	Policy revised for Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide) for initiation to require attestation rather than documentation of baseline height, weight, and body mass index. For Zepbound (tirzepatide) for continuation and maintenance, doses allowed for approval expanded to 7.5 mg and 12.5 mg.
Anti-Obesity – Fully Insured Commercial and Healthcare Reform	TBD	New policy created for Contrave (bupropion and naltrexone), Qsymia (phentermine and topiramate extended-release), Saxenda (liraglutide), Wegovy (semaglutide), Xenical (orlistat), and Zepbound (tirzepatide). For all agents for initiation, requiring

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		<p>baseline height, weight, and BMI; and documentation of healthy dietary changes and increased physical activity for at least 6 months prior to initiation and while using therapy. For all agents for maintenance, requiring baseline and current height, weight and BMI; and documentation of healthy dietary changes and increased physical activity. For initiation and maintenance of Contrave, Qsymia, and Xenical in adults, requiring age of 18 years or older, use for chronic weight management, and baseline BMI <math>\geq 35 \text{ kg/m}^2</math>. Additionally for reauthorization, requiring at least 5% weight loss from baseline. For initiation and maintenance of Contrave and Qsymia in adolescents or adults who initiated therapy as adolescents, requiring age of 12 years or older, use for chronic weight management, and baseline BMI <math>\geq 95</math>th percentile standardized for age and sex. Additionally for reauthorization, requiring BMI reduction of <math>\geq 3</math> percentile points from baseline. For Saxenda, Wegovy, and Zepbound for initiation and maintenance in adults, requiring age of 18 years or older, use for chronic weight management, baseline BMI <math>\geq 40 \text{ kg/m}^2</math>, at least two weight related comorbidities (asthma, cardiovascular disease, chronic obstructive pulmonary disease, dyslipidemia, hypertension, non-alcoholic steatohepatitis/non-alcoholic fatty liver disease, obstructive sleep apnea, osteoarthritis of the lower extremities, peripheral vascular disease, polycystic ovarian syndrome, or prediabetes), documentation of an in-person appointment with the provider, attestation that the member does not have type 2 diabetes, that the agent will not be used with any other GLP-1 RA containing agent, and if the request is for Saxenda or Wegovy, intolerance/contraindication to plan-preferred Zepbound. Additionally for maintenance, weight loss of <math>\geq 7.5\%</math> from baseline and maintenance dosing. For Saxenda and Wegovy for initiation and maintenance in adolescents or adults who initiated as adolescents, requiring age of 12 years or older, use for chronic weight management, baseline BMI <math>\geq 36 \text{ kg/m}^2</math> or BMI that is <math>\geq 120\%</math> of the 95% percentile for age and sex, documentation of an in-person appointment</p>

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		with the provider, attestation that the member does not have type 2 diabetes, and that the agent will not be used with any other GLP-1 RA containing agent. Additionally for maintenance, BMI reduction of $\geq 3$ percentile points from baseline, maintenance dosing for all agents, and if over 18 years old, intolerance/contraindication to Zepbound.
BCR-ABL Kinase Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised for Scemblix (asciminib) quantity limit criteria to allow for approval of 8 tablets per day of the 40 mg strength.
Benlysta (belimumab) – Commercial and Healthcare Reform	8/23/2024	Policy revised for Benlysta (belimumab) subcutaneous to update age from 18 years or older to 5 years or older. Quantity limitations table updated to reflect FDA approved dosing regimens.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	8/23/2024	Policy revised to add new indication for Kevzara (sarilumab) to require diagnosis of polyarticular juvenile idiopathic arthritis (pJIA), weight of 63 kg or greater, prescribed by or in consultation with a rheumatologist, therapeutic failure or intolerance to at least one nonbiological DMARD, all nonbiological DMARDS are contraindicated or initial biologic therapy is needed due to involvement of high-risk joints, high disease activity, and/or member is judged by their physician to be at high risk of disabling joint damage and therapeutic failure or intolerance to at least two step 1 or 2 agents for pJIA or prescriber attests member has heart failure or a previously treated lymphoproliferative disorders. Policy revised to add new indication for Skyrizi (risankizumab) subcutaneous (SC) to require diagnosis of moderately to severely active ulcerative colitis, 18 years of age or older, prescribed by or in consultation with a gastroenterologist and if requesting Skyrizi cartridge with on-body injector, the member has received 3 induction doses of Skyrizi IV within 3 months of initiating therapy with Skyrizi SC or is currently undergoing induction therapy with Skyrizi SC.
Chronic Inflammatory Diseases – Commercial National Select Formulary	8/23/2024	Policy revised to add new indication for Kevzara (sarilumab) to require diagnosis of polyarticular juvenile idiopathic arthritis (pJIA), weight of 63 kg

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		<p>or greater, prescribed by or in consultation with a rheumatologist, therapeutic failure or intolerance to at least one nonbiological DMARD, all nonbiological DMARDS are contraindicated or initial biologic therapy is needed due to involvement of high-risk joints, high disease activity, and/or member is judged by their physician to be at high risk of disabling joint damage and therapeutic failure or intolerance to at least two step 1 or 2 agents for pJIA or prescriber attests member has heart failure or a previously treated lymphoproliferative disorders. Policy revised to add new indication for Skyrizi (risankizumab) subcutaneous (SC) to require diagnosis of moderately to severely active ulcerative colitis, 18 years of age or older, prescribed by or in consultation with a gastroenterologist and if requesting Skyrizi cartridge with on-body injector, the member has received 3 induction doses of Skyrizi IV within 3 months of initiating therapy with Skyrizi SC or is currently undergoing induction therapy with Skyrizi SC.</p>
Corlanor (ivabradine) – Commercial and Healthcare Reform	8/23/2024	<p>Policy revised for Corlanor (ivabradine) to add generic ivabradine as a target and to require concurrent use of one beta-blocker with efficacy in heart failure or trial/failure/contraindication to all beta-blockers with efficacy in heart failure. Reauthorization revised for Corlanor (ivabradine) oral solution to require FDA-approved age. For brand Corlanor, require trial/failure of generic.</p>
CSF1R Tyrosine Kinase Inhibitors – Commercial and Healthcare Reform	8/23/2204	<p>Policy revised for Turalio (pexidartinib) to update authorization duration to 12 months.</p>
Emflaza (deflazacort) – Commercial and Healthcare Reform	8/23/2024	<p>Policy revised for Emflaza (deflazacort) suspension to require step through generic tablet and suspension, and for generic suspension, require step through generic tablet.</p>
Endari (L-glutamine) – Commercial and Healthcare Reform	TBD	<p>Policy revised to require therapeutic failure or intolerance to generic prescription L-glutamine in initial and reauthorization.</p>
Entresto Sprinkles (sacubitril/valsartan) – Commercial and Healthcare Reform	TBD	<p>Policy created for Entresto sprinkles (sacubitril/valsartan) requiring pediatric age, weight &lt; 40 kg or weight between 40 kg and 50 kg with trial/failure of Entresto (sacubitril/valsartan)</p>

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		tablets or inability to swallow tablets, and FDA-approved diagnosis. Reauthorization requiring pediatric age, weight < 40 kg or weight between 40 kg and 50 kg with trial/failure of Entresto (sacubitril/valsartan) tablets or inability to swallow tablets, and positive response to therapy.
Fertility – Commercial and Healthcare Reform – New York	8/23/2024	Policy revised for all fertility agents to remove age and fertility duration requirements.
Fibrates – Commercial and Healthcare Reform	TBD	Policy revised to add Triglide (fenofibrate) as a target requiring FDA-approved diagnosis and trial/failure/contraindication to a plan-preferred fibrate medication.
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) for Diabetes – Commercial and Healthcare Reform	8/23/2024	Policy revised to add liraglutide as a target.
KRAS G12C Inhibitors – Commercial and Healthcare Reform	8/23/2024	Policy revised for Krazati (adagrasib) to require age and diagnosis based on FDA-approved expanded indication for colorectal cancer. For non-small cell lung cancer, policy revised to require that Krazati (adagrasib) is being used as a single agent based on updated indication.
Kuvan and Javygtor (sapropterin dihydrochloride) – Commercial and Healthcare Reform	8/23/2024	Policy revised to remove criteria that the member is not concomitantly utilizing Palynziq (pegvaliase-pqpz) injection from initial and reauthorization criteria. Added statement in limitations of coverage that the member is not using Kuvan or Javygtor (sapropterin dihydrochloride) in combination with Palynziq injection.
Lacosamide products – Healthcare Reform	8/23/2024	Policy revised for Motpoly XR (lacosamide) to allow for expanded indication for adjunctive therapy for the treatment of primary generalized tonic-clonic seizures, weighs at least 50 kg, and tried and filed generic lacosamide tablets. Reauthorization that Motpoly XR is being used as adjunctive therapy for tonic-clonic seizures and member has experienced a reduction in seizure frequency from baseline.
Market Watch Programs – Delaware	TBD	Policy for high cost/low value medications revised to add Baclofen 15 mg tablet to require trial/failure of baclofen 5 mg, 10 mg, or 20 mg and tizanidine. Policy revised to add ondansetron 16 mg orally disintegrating tablet (ODT) requiring

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		trial/failure to ondansetron 8 mg tablet, ondansetron 8 mg ODT, and ondansetron 4 mg/5 mL oral solution.
Market Watch Programs – New York, Pennsylvania, and West Virginia	TBD	Policy for high cost/low value medications revised to add Baclofen 15 mg tablet to require trial/failure of baclofen 5 mg, 10 mg, or 20 mg and tizanidine. Policy revised to add ondansetron 16 mg orally disintegrating tablet (ODT) requiring trial/failure to ondansetron 8 mg tablet, ondansetron 8 mg ODT, and ondansetron 4 mg/5 mL oral solution.
Mechanistic Target of Rapamycin Kinase (mTOR) Inhibitors – Commercial and Healthcare Reform	8/23/2024	Policy revised to add Torpenz (everolimus) to require age and diagnosis based on FDA-approved indications for breast cancer, renal angiomyolipoma and tuberous sclerosis complex (TSC), and TSC with subependymal giant cell astrocytoma and trial/failure to generic everolimus tablets.
Miebo (perfluorohexyloctane) – Commercial and Healthcare Reform	8/23/2024	Policy revised for Miebo (perfluorohexyloctane) to remove brand Restasis (cyclosporine) as a step therapy qualifier, and only require generic cyclosporine (generic Restasis)
Mucosal Agents – Commercial and Healthcare Reform	7/26/2024	Policy revised to add back Aquoral (oxidized glycerol triesters) since product is again available on the market.
Northera (droxidopa) – Commercial and Healthcare Reform	8/23/2024	Policy revised for Northera (droxidopa) to require age per FDA-approved diagnosis.
NTRK and ROS1 Inhibitors – Commercial and Healthcare Reform	8/23/2024	Policy revised for Augtyro (repotrectinib) to require age and diagnosis based on expanded FDA-approved indication for solid tumors.
Ohtuvayre (ensifentine) – Commercial and Healthcare Reform	8/23/2024	New policy for Ohtuvayre (ensifentine) requiring the member to be 18 years of age and older, the member has a diagnosis of COPD, the member has a post-bronchodilator FEV1 ≤ 80% predicted, the member meets one of the following: a modified Medical Research Council dyspnea scale score of ≥ 2, a COPD assessment Test score of ≥ 10, Gold group B, or Gold group E, and the member has inadequate symptom control despite regular treatment for at least 3 months with at least two (2) plan-preferred maintenance COPD controllers (e.g. LABA/LAMA, LAMA/LABA/ICS), unless intolerant of, or has contraindications to these agents. When a benefit, reauthorization of Ohtuvayre may be approved

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		when one (1) of the following criteria is met: The prescriber attests that the member has experienced a reduction in symptoms of COPD, the prescriber attests that the member has experienced an improvement in exercise tolerance, the prescriber attests that the member has experienced delayed disease progression, or the prescriber attests that the member has experienced a reduction in the number of exacerbations.
Ophthalmic Cyclosporines for Dry Eye Disease – Commercial and Healthcare Reform	8/23/2024	Policy revised for brand Restasis (cyclosporine) reauthorization to require trial/failure to generic cyclosporine ophthalmic emulsion. Criteria for Cequa (cyclosporine) and Vevye (cyclosporine) revised to remove brand Restasis (cyclosporine) as a step qualifier, and only require generic cyclosporine (generic Restasis).
Oxervate (cenegermin-bkbj) – Commercial and Healthcare Reform	8/23/2024	Policy revised for Oxervate (cenegermin-bkbj) reauthorization authorization duration to clarify that an additional 8 week authorization may be granted for one eye, not to exceed 8 weeks total per eye in a member's lifetime.
Palynziq (pegvaliase-pqpz) – Commercial and Healthcare Reform	8/23/2024	Policy revised to remove criteria that the member has a prescription for an auto-injectable epinephrine agent.
Primary Axillary Hyperhidrosis – Commercial and Healthcare Reform	8/23/2024	Policy revised to add Sofdra (sofipironium) to require age, FDA-approved diagnosis, the Hyperhidrosis Disease Severity Scale (HDSS) score of 3 or 4, and trial/failure/contraindication to one topical aluminum chloride 20% product. Reauthorization of HDSS score of 2 or lower. Initial authorization duration of 6 months and reauthorization duration of 12 months.
Primary Biliary Cholangitis – Commercial and Healthcare Reform	8/23/2024	Policy revised to add Iqirvo (elafibranor) to require diagnosis and age based on FDA-approved indication, therapeutic failure to ursodiol therapy defined as alkaline phosphatase (ALP) levels $\geq 1.67 \times$ upper limit of normal (ULN) or bilirubin levels $> 1-2 \times$ ULN or experienced contraindication or intolerance to ursodiol monotherapy and used in combination with ursodiol unless ursodiol is contraindicated or not tolerated. Reauthorization criteria to require member experience positive clinical response defined by ALP level $< 1.67 \times$ ULN or total

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		bilirubin level < ULN, member requires additional therapy and used in combination with ursodiol unless ursodiol is contraindication or not tolerated. Limitation of coverage includes, lqirvo should not be used in decompensated cirrhosis.
RET Kinase Inhibitors – Commercial and Healthcare Reform	8/23/2024	Policy revised for Retevmo (selpercatinib) to require a RET gene fusion as detected by an FDA-approved test for solid tumors and updated age for medullary thyroid cancer, thyroid cancer, and solid tumors based on expanded indications.
Ustekinumab Biosimilars – Commercial and Healthcare Reform	TBD	Policy revised to add Pyzchiva (ustekinumab-ttwe) requiring age and diagnosis based on FDA-approved indication; prescriber specialist; therapeutic failure/intolerance to Stelara; the member achieved clinical response or remission with intravenous induction dosing for Crohn's disease and ulcerative colitis; 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. For Crohn's disease, if the member is a non-responder or partial responder to one syringe every 8 weeks, one prefilled syringe every 4 weeks may be approved.
Vigabatrin – Commercial and Healthcare Reform	TBD	Policy revised to add Vigafyde (vigabatrin) to require diagnosis and age based on FDA-approved indication, used as monotherapy and therapeutic failure or intolerance to generic vigabatrin packet for oral solution. Reauthorization requiring diagnosis and age based on FDA-approved indication, used as monotherapy and therapeutic failure or intolerance to generic vigabatrin packet for oral solution and reduction in seizure frequency from baseline.
Voquezna (vonoprazan) Products – Commercial and Healthcare Reform	8/23/2024	Policy revised for Voquezna (vonoprazan) to require age, FDA-approved indication, and trial and failure through omeprazole and pantoprazole



<b>Policy Name*</b>	<b>Policy Effective Date**</b>	<b>Updates and/or Approval Criteria</b>
		if the request is for non-erosive gastroesophageal reflux disease.
Vtama (tapinarof) and Zoryve (roflumilast) – Commercial and Healthcare Reform	8/23/2024	Policy revised to add Zoryve (roflumilast) 0.15% cream requiring FDA-approved diagnosis of atopic dermatitis, age 6 years or older, therapeutic failure, contraindication or intolerance to two generic formulary topical corticosteroid or facial or anogenital involvement and therapeutic failure, contraindication or intolerance to generic topical tacrolimus or topical pimecrolimus.
Wakix (pitolisant) – Commercial and Healthcare Reform	8/23/2204	Policy revised to edit age to 6 years of age and older. Added age edit of ≥ 18 years of age and has diagnosis of narcolepsy with cataplexy. For < 18 years of age, removed "without cataplexy".

\*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

<b>Policy Name*</b>	<b>Policy Effective Date**</b>	<b>Updates and Automatic Approval Criteria</b>
Bevespi (glycopyrrolate/formoterol) – Commercial and Healthcare Reform	TBD	Policy revised to include Healthcare Reform (HCR).
Brand lacosamide products – Commercial	8/23/2024	Policy revised for Motpoly XR (lacosamide) to allow for expanded indication for adjunctive therapy for the treatment of primary generalized tonic-clonic seizures, weighs at least 50 kg, and tried and filed generic lacosamide tablets. Reauthorization that Motpoly XR is being used as adjunctive therapy for tonic-clonic seizures and member has experienced a reduction in seizure frequency from baseline.
Brand Reliever Inhalers – Commercial and Healthcare Reform	8/23/2024	Policy updated to require that the member has a diagnosis of asthma.
Buprenorphine (non-opioid dependence use) – Commercial, Healthcare Reform	8/23/2024	Policy revised for brand Butrans (buprenorphine) transdermal patch and Belbuca (buprenorphine) buccal film to ask for diagnosis based on FDA-approved indication.
Chemotherapy Induced or Post Operative Nausea and Vomiting –	8/23/2024	Policy revised to add ondansetron orally disintegrating tablet (ODT) 16 mg to require age, FDA-approved diagnosis for 16 mg or greater

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Commercial and Healthcare Reform		strength, and trial/failure to ondansetron ODT 8 mg taken as 2 tablets together to equal a single dose of 16 mg. For chemotherapy induced nausea and vomiting prophylaxis, trial/failure to generic granisetron; for post operative nausea or vomiting prophylaxis, trial/failure to one other agent FDA-approved for the same condition and for reauthorization, attestation the member is undergoing a new operation.
Colony-Stimulating Factors – Commercial and Healthcare Reform	8/23/2024	Policy revised for all colony-stimulating factor agents to update criteria to match FDA-approved indication.
Colony-Stimulating Factors – Commercial and Healthcare Reform	TBD	Policy revised for Nypozi (filgrastim-txid) to require diagnosis based on FDA-approved indication, and trial/failure to Nivestym (filgrastim-aafi) and Zarxio (filgrastim-sndz) except when Nypozi (filgrastim-txid) is being used for Hematopoietic Acute Radiation Syndrome. Nypozi (filgrastim-txid) is to not be used in combination with other colony-stimulating factor agents. Reauthorization criteria for Nypozi (filgrastim-txid) requires diagnosis based on FDA-approved indication and colony-stimulating factor agents to not be used in combination with each other.
Erectile Dysfunction Limits – Commercial, Healthcare Reform and Medicare	TBD	Policy revised to add Chewtadzy (tadalafil) QL 5 mg: 30 tablets for 30 days, and 90 tablets for 90 days 10 mg, 20 mg: 6 tablets for 34 days and 18 tablets for 35-90 days
Intraocular Pressure Reduction Agents – Commercial and Healthcare Reform	TBD	Policy revised to add Alphagan (brimonidine) requiring FDA-approved diagnosis and trial/failure to generic brimonidine 0.2% ophthalmic solution. Added Cosopt/Cosopt PF (dorzolamide/timolol) requiring FDA-approved diagnosis, trial/failure to individual components used separately, and if request is for brand, failure of generic (non-preservative free). Added Timoptic in Ocludose (timolol maleate) and Istalol (timolol maleate) requiring FDA-approved diagnosis, and trial/failure to generic timolol maleate (non-dropperette).
Lidocaine Patches and Topical System – Commercial and Healthcare Reform	8/23/2024	Policy revised to add Tridacaine II (lidocaine patch 5%) and Tridacaine III (lidocaine patch 5%) as targets.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Non-Preferred Benign Prostatic Hyperplasia (BPH) Therapy – Commercial and Healthcare Reform	TBD	Policy revised to add Chewtadzy (tadalafil) to require FDA-approved indication of benign prostatic hyperplasia (BPH) and require trial/failure of 1 plan-preferred generic alpha-1 blockers (alfuzosin, doxazosin, tamsulosin, terazosin) and 1 trial/failure of plan-preferred generic 5-alpha reductase inhibitors (dutasteride, finasteride), and trial/fail of generic tadalafil OR unable to swallow tablet.
Non-Preferred Dipeptidyl Peptidase IV (DPP-IV) Inhibitors – Commercial and Healthcare Reform	8/23/2024	Policy revised to add Zituvimet (sitagliptin/metformin) as a target.
Non-Preferred Erectile Dysfunction Therapy – Commercial and Healthcare Reform	TBD	Policy revised to add Chewtadzy (tadalafil) to require 18 years of age or older, FDA-approved indication of erectile dysfunction (ED), and trial/failure of generic tadalafil and sildenafil OR unable to swallow tablet.
Non-Preferred Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) – Commercial and Healthcare Reform	8/23/2024	Policy revised to remove Victoza (liraglutide) as a qualifier.
Non-Preferred Ophthalmic NSAIDs – Commercial and Healthcare Reform	TBD	Policy revised to add Bromsite (bromfenac ophthalmic solution) and Prolensa (bromfenac ophthalmic solution) to require diagnosis based on FDA-approved indication and therapeutic failure or intolerance to generic diclofenac sodium 0.1% or ketorolac tromethamine 0.5%. For brand Bromsite and Prolensa (bromfenac ophthalmic solution), requiring therapeutic failure or intolerance to generic bromfenac ophthalmic solution 0.075% or 0.07%, respectively.
Non-Stimulant Treatment of ADHD – Commercial and Healthcare Reform	TBD	Policy revised to add Onyda XR (clonidine extended release) suspension requiring FDA-approved age and diagnosis; trial/failure/contraindication to a stimulant, or history of substance abuse, or concern for drug diversion; and inability to swallow tablets or capsules. For Qelbree (viloxazine), criteria updated requiring inability to swallow tablets and capsules whole.
Pulmicort (budesonide) nebulizer suspension – Commercial and Healthcare Reform	TBD	Policy revised for Pulmicort (budesonide) nebulizer suspension to remove the Commercial National Select formulary

\*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
Adbry (tralokinumab-ldrm)	4 mL per 21 days	12 mL per 63 days
Capvaxive (pneumococcal 21-valent conjugate vaccine)	0.5 mL per 365 days	0.5 mL per 365 days
Chewtadzy (tadalafil) 10 mg, 20 MG	6 tablets per 30 days	18 tablets per 90 days
Mresvia (Respiratory Syncytial Virus Vaccine)	1 dose per 185 days	1 dose per 185 days
Pyzchiva (ustekinumab-ttwe) 45 mg/0.5 mL	1 syringe (0.5 mL) per 84 days	1 syringe (0.5 mL) per 84 days
Pyzchiva (ustekinumab-ttwe) 90mg/mL	1 syringe (1 mL) per 84 days	1 syringe (1 mL) per 84 days
Sofdra (sofipironium)	1 bottle (40.2 mL) per 30 days	3 bottles (120.6 mL) per 90 days

\*Effective date to be determined.

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

Drug Name	Retail Edit Limit	Mail Edit Limit
Zoryve (roflumilast) cream 0.15%	1 tube (60 grams) per dispensing event	3 tubes (180 grams) per dispensing event

\*Effective date to be determined.

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

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

Drug Name	Daily Limit
Augtyro (repotrectinib) 160 mg	2 capsules per day
Augtyro (repotrectinib) 40 mg	6 capsules per day
Austedo XR (deutetrabenazine) 6 mg, 12 mg, 24 mg, 18 mg, 30 mg, 36 mg, 42 mg, 48 mg	1 tablet per day
Chewtadzy (tadalafil) 5 mg	1 tablet per day
Ingrezza Sprinkle (valbenazine)	1 capsule per day
Iqirvo (elafibranor)	1 tablet per day
Ohtuvayre (ensifentrine)	2 unit-dose ampules per day
Onyda XR (clonidine hydrochloride)	4 mL (4 mg) per day
Retevmo (selpercatinib)	40 mg tablets: 3 tablets per day
Scemblix (asciminib) 100 mg	4 tablets per day
Torpenz (everolimus)	1 tablet per day
Triglide (fenofibrate)	1 tablet per day
Voydeya (danicopan) 100 MG	6 tablets per day
Voydeya (danicopan) 50mg	9 tablets per day

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

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

## SECTION II. Highmark Medicare Part D Formularies

### **A. Changes to the Highmark Medicare Part D 5-Tier Incentive Formulary**

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

[Incentive Formulary](#)  
[Compass Formulary](#)

**Table 1. Preferred Products**

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

Brand Name	Generic Name	Comments
Mresvia	Respiratory Syncytial Virus Vaccine	Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older

**Table 2. Non-Preferred Products**

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

Brand Name	Generic Name	Preferred Alternatives
Chewtadzy 5 mg	tadalafil	finasteride 5 mg tablet, tamsulosin
ondansetron ODT 16 mg	ondansetron	ondansetron tablet ODT 8mg; ondansetron HCl solution; ondansetron HCl tablet 8 mg
Onyda XR	clonidine hydrochloride	clonidine ER tablets; atomoxetine
Triglide	fenofibrate	fenofibrate 160 mg tablet

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

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

- [Performance Formulary](#)
- [Venture Formulary](#)
- [Fundamental Formulary](#)

**Table 1. Preferred Products**

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

Brand Name	Generic Name	Comments
Mresvia	Respiratory Syncytial Virus Vaccine	Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older

**Table 2. Non-Preferred Products**

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

Brand Name	Generic Name	Preferred Alternatives
ondansetron ODT 16 mg*	ondansetron	ondansetron tablet ODT 8mg; ondansetron HCl solution; ondansetron HCl tablet 8 mg

\*Only pertaining to Venture formulary

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

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

Brand Name	Generic Name	Preferred Alternatives
Ahzantive	aflibercept-mrbb	Avastin, Eylea
Bkemv	eculizumab-aeab	Prescriber Discretion
Chewtadzy 5 mg	tadalafil	finasteride 5 mg tablet, tamsulosin
Iqirvo	elafibranor	urodiol tablet
Kisunla	donanemab-azbt	Prescriber Discretion
Nypozi	filgrastim-txid	Nivestym, Zarxio
Ohtuvayre	ensifentrine	Serevent Diskus, Striverdi Respimat, tiotropium bromide
ondansetron ODT 16 mg**	ondansetron	ondansetron tablet ODT 8mg; ondansetron HCl solution; ondansetron HCl tablet 8 mg
Onyda XR	clonidine hydrochloride	clonidine ER tablets; atomoxetine
Opuviz	aflibercept-yszy	Avastin, Eylea
Piasky	crovalimab-akkz	Prescriber Discretion
Pyzchiva 45 mg/0.5 mL, 90mg/mL, 130 mg/26 mL	ustekinumab-ttwe	Stelara
Rytelo	Imetelstat	Procrit, Retacrit
Sofdra	sofipironium	Prescriber Discretion
Tepylute	thiotepa	Thiotepa
Torpenz	everolimus	everolimus (antineoplastic) tablet
Triglide	fenofibrate	fenofibrate 160 mg tablet
Vigafyde	vigabatrin	vigabatrin tablets, vigabatrin powder for solution

Yesafili	aflibercept-jbvf	Avastin, Eylea
Zoryve cream 0.15%	roflumilast	tacrolimus ointment, fluticasone 0.05% cream

\*Physicians may request coverage of these products using the [Prescription Drug Medication Request Form](#).

\*\* Only pertaining to Performance and Fundamental formularies.

### **C. Additions to the Specialty Tier**

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

<b>Brand Name</b>	<b>Generic Name</b>
Augtyro	repotrectinib
Imdelltra	tarlatamab-dlle
Scemblix	asciminib
Yimmugo	immune globulin intravenous, human-dira

### **D. Updates to the Pharmacy Utilization Management Programs**

#### **1. Prior Authorization Program**

<b>Policy Name</b>	<b>Policy Effective Date*</b>	<b>Updates and/or Approval Criteria</b>
Adbry (tralokinumab-ldrm) – Medicare	8/23/2024	Policy revised for Adbry (tralokinumab-ldrm) to update quantity limit table to allow 300 mg autoinjector (FDA-approved dosing) for adult patients
Administrative Prior Authorizations for Medicare Part D Plans – Medicare	8/23/2024	Policy revised to add Myhibbin (mycophenolate mofetil) as a target for BvD immunosuppressant review, remove Rystiggo (rozanolixzumab) as a target for BvD infusion pump review, and add Ohtuvayre (ensifentrine) as a target for BvD nebulizer review.
Administrative Prior Authorizations for Medicare Part D Plans – Medicare	TBD	Chewtadzy (tadalafil) as a target for DvsNonD review to confirm medically accepted indication unrelated to Medicare excluded indication of erectile dysfunction.
Amitiza (lubiprostone) – Medicare	TBD	New policy for brand Amitiza (lubiprostone) to require diagnosis based on FDA-approved indication and trial/failure/contraindication to generic lubiprostone and Linzess (linaclotide) for chronic idiopathic constipation and irritable bowel syndrome with constipation.
Amyloid beta-Directed Antibodies for	TBD	Policy revised to add Kisunla (donanemab-azbt) to require FDA-approved diagnosis of Alzheimer's disease (mild cognitive impairment



Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Alzheimer's Disease – Medicare		[MCI] or mild dementia), all other possible causes of cognitive impairment or dementia have been ruled out, confirmed presence of amyloid beta pathology via positron emission tomography (PET) imaging, a baseline brain magnetic resonance imaging (MRI) prior to treatment, and member meets criteria in the National Coverage Determination (NCD) 200.3. For reauthorization, the member had MCI or mild dementia at treatment initiation, continues to meet the criteria in NCD 200.3, has obtained or will obtain a brain MRI prior to the 2nd, 3rd, 4th, and 7th infusions, has experienced a reduction from baseline in amyloid beta plaques via PET imaging, has demonstrated positive clinical response as evidenced by slowed decline in cognition, and the prescriber attests that the member requires continued therapy to achieve minimal levels of amyloid plaques on amyloid PET imaging.
Benlysta (belimumab) – Medicare	8/23/2024	Policy revised for Benlysta (belimumab) to remove age requirements. Quantity limitations table updated to reflect FDA-approved dosing regimens.
Carbinoxamine Products – Medicare	TBD	Policy revised to add Karbinal ER (carbinoxamine maleate) extended-release oral suspension requiring diagnosis based on FDA-approved indication. The member has experienced therapeutic failure, contraindication, or intolerance to two (2) different antihistamines.
Chronic Inflammatory Diseases – Medicare	8/1/2024	Policy revised to move Cosentyx (secukinumab) to a preferred agent.
Chronic Inflammatory Diseases – Medicare	8/23/2024	Policy revised to add new indication for Kevzara (sarilumab) to require diagnosis of polyarticular juvenile idiopathic arthritis (pJIA), weight of 63 kg or greater, therapeutic failure or intolerance to at least one nonbiological DMARD, all nonbiological DMARDS are contraindicated or initial biologic therapy is needed due to involvement of high-risk joints, high disease activity, and/or member is judged by their physician to be at high risk of disabling joint damage and therapeutic failure or intolerance to at least two preferred pJIA products. Policy revised to add new indication for Skyrizi (risankizumab) to require diagnosis of moderately to severely active ulcerative colitis, 18

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		years of age or older, and if requesting Skyrizi cartridge with on-body injector, - clinical response/remission achieved after 3 induction doses of Skyrizi IV within 3 months before initiating Skyrizi SC. Policy revised to remove the requirement of therapeutic failure or intolerance to at least one (1) non biological DMARD, or all are contraindicated from Cosentyx for enthesitis-related arthritis.
Corlanor (ivabradine) – Medicare	TBD	Policy revised for Corlanor (ivabradine) to require FDA-approved age for pediatric patients and concurrent use of one beta-blocker with efficacy in heart failure or trial/failure/contraindication to two beta-blockers with efficacy in heart failure.
Corlanor (ivabradine) – Medicare	TBD	Policy revised for Corlanor (ivabradine) to add generic ivabradine as a target and to require concurrent use of or trial/failure/contraindication to one beta-blocker with efficacy in heart failure. For brand Corlanor, require trial/failure of generic.
CSF1R Tyrosine Kinase Inhibitors – Medicare	8/23/2204	Policy revised for Turalio (pexidartinib) to remove age limitation.
Cyramza (ramucirumab) – Medicare	8/23/2024	Policy revised for Cyramza (ramucirumab) to remove age limitation.
Dichlorphenamide Products – Medicare	6/27/2024	Policy revised to temporarily remove step through generic dichlorphenamide as drug does not yet have an RXCUI.
Dichlorphenamide Products – Medicare	TBD	Policy revised to add back in step through generic dichlorphenamide (generic Keveyis)
Disease-Modifying Medications for Generalized Myasthenia Gravis – Medicare	8/23/2024	Policy revised to move Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) and its generalized myasthenia gravis (gMG) criteria from this policy to J-XXXX Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) – Medicare. Policy revised to remove BvD infusion pump review from Rystiggo (rozanolixizumab-noli) criteria.
Duobrii (halobetasol propionate/tazarotene) – Medicare	8/23/2024	Policy revised to remove age requirement.
Elevidys (delandistrogene moxeparvovec-rokl) – Medicare	8/23/2024	Policy revised to remove age restriction and remove requirement that member be ambulatory.
Emflaza (deflazacort) – Medicare	TBD	Policy revised for Emflaza (deflazacort) suspension to require step through generic tablet,

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		unless unable to swallow tablets, and generic suspension. For generic suspension, require step through generic tablet unless unable to swallow tablets.
Endari (L-glutamine) – Medicare	TBD	Policy revised to require therapeutic failure or intolerance to generic prescription L-glutamine in initial and reauthorization.
Entresto Sprinkles (sacubitril/valsartan) – Medicare	8/23/2024	Policy created for Entresto sprinkles (sacubitril/valsartan) requiring pediatric age, weight < 40 kg or weight between 40 kg and 50 kg with trial/failure of Entresto (sacubitril/valsartan) tablets or inability to swallow tablets, and FDA-approved diagnosis. Reauthorization requiring pediatric age, weight < 40 kg or weight between 40 kg and 50 kg with trial/failure of Entresto (sacubitril/valsartan) tablets or inability to swallow tablets, and positive response to therapy.
Epkinly (epcoritamab-bysp) – Medicare	8/23/2024	Policy revised for Epkinly (epcoritamab-bysp) to require diagnosis based on expanded FDA-approved indication for follicular lymphoma and that the member has received at least two lines of prior systemic therapy per FDA-approved indication for diffuse large B-cell lymphoma.
Gimoti (metoclopramide) nasal spray – Medicare	8/23/2024	Policy revised to remove age requirement.
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) – Medicare	8/23/2024	Policy revised to add liraglutide as a non-preferred agent and target.
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) – Medicare	TBD	Policy revised to change Bydureon BCise (exenatide extended release) to preferred and Victoza (liraglutide) to non-preferred.
Hepatitis C Oral Agents – Medicare	TBD	Policy updated for if the request is for a regimen containing Sovaldi (sofosbuvir), Viekira Pak (ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir), brand Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), or Harvoni AG (ledipasvir/sofosbuvir) and the requested regimen that is listed as an alternative regimen, the member has a contraindication to or is otherwise not a candidate for all recommended regimens containing, Epclusa AG (sofosbuvir/velpatasvir) and Mavyret (glecaprevir/pibrentasvir).

<b>Policy Name</b>	<b>Policy Effective Date*</b>	<b>Updates and/or Approval Criteria</b>
Idhifa (enasidenib) – Medicare	8/23/2024	Policy revised for Idhifa (enasidenib) to remove age limitation.
Imdelltra (tarlatamab-dlle) – Medicare	8/23/2024	New policy for Imdelltra (tarlatamab-dlle) requiring diagnosis based on FDA-approved indication and disease has progressed on or after platinum-based chemotherapy (e.g., etoposide and either carboplatin or cisplatin taken together).
KRAS G12C Inhibitors – Medicare	8/23/2024	Policy revised for Krazati (adagrasib) to require diagnosis based on FDA-approved expanded indication for colorectal cancer. For non-small cell lung cancer, policy revised to require that Krazati (adagrasib) is being used as a single agent based on updated indication.
Lidocaine Patches – Medicare	8/23/2024	Policy revised to add Tridacaine II (lidocaine patch 5%) and Tridacaine III (lidocaine patch 5%) as targets.
Mechanistic Target of Rapamycin Kinase (mTOR) Inhibitors – Medicare	8/23/2024	Policy revised to add Torpenz (everolimus) to require diagnosis based on FDA-approved indications for breast cancer, renal angiomyolipoma and tuberous sclerosis complex (TSC), and TSC with subependymal giant cell astrocytoma and trial/failure to generic everolimus tablets.
Motpoly XR (lacosamide) – Medicare	8/23/2024	Policy revised for Motpoly XR (lacosamide) to allow for expanded indication for adjunctive therapy for the treatment of primary generalized tonic-clonic seizures, weighs at least 50 kg, and tried and filed generic lacosamide tablets.
Non-Preferred Benign Prostatic Hyperplasia (BPH) Therapy – Medicare	TBD	Policy revised to add Chewtadzy (tadalafil) to require FDA-approved indication of benign prostatic hyperplasia (BPH) and require trial/failure of 2 of following: dutasteride, doxazosin, tamsulosin, terazosin, dutasteride/tamsulosin, finasteride, silodosin, alfuzosin, AND trial/failure of generic tadalafil OR unable to swallow tablet.
Non-stimulant Treatment of ADHD – Medicare	TBD	Policy revised to add Onyda XR (clonidine extended release) suspension requiring FDA-approved age and diagnosis; trial/failure/contraindication to a stimulant, or history of substance abuse, or concern for drug diversion, or condition that contraindicates stimulants, or significant adverse effect with stimulant use; and inability to swallow tablets or capsules.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
NTRK and ROS1 Inhibitors – Medicare	8/23/2024	Policy revised for Augtyro (repotrectinib) to require diagnosis based on expanded FDA-approved indication for solid tumors.
Ohtuvayre (ensifentine) – Medicare	8/23/2024	New policy for Ohtuvayre (ensifentine) requiring the member has a diagnosis of COPD and the member has inadequate symptom control despite regular treatment for at least 3 months with at least two (2) maintenance COPD controllers (e.g. LABA/LAMA, LAMA/LABA/ICS), unless intolerant of, or has contraindications to these agents. If the member is requesting a nebulizer solution, per policy J-0030, the product has been determined to be eligible for coverage under Part D.
Oral Hypomethylating Agents – Medicare	8/23/2024	Policy revised for Inqovi (decitabine/cedazuridine) and Onureg (azacitidine) to remove age limitation.
Oxervate (cenegermin-bkbj) – Medicare	8/23/2024	Policy revised for Oxervate (cenegermin-bkbj) to remove age requirement and update reauthorization authorization duration to clarify that an additional 8 week authorization will be granted for one eye, not to exceed 8 weeks total per eye in a member's lifetime.
Palynziq (pegvaliase-pqz) – Medicare	8/23/2024	Policy revised to remove criteria that the member has a prescription for an auto-injectable epinephrine agent.
Piasky (crovalimab-akkz) – Medicare	8/23/2024	New policy for Piasky (crovalimab-akkz) to require diagnosis of paroxysmal nocturnal hemoglobinuria (PNH), baseline hemoglobin level < 10.5 g/dL, and one of following: elevated lactate dehydrogenase (LDH) greater than/equal to 1.5 times ULN, history of thromboembolic event, clinical findings of systemic complications. Quantity limitations based on weight-based dosing for induction therapy and maintenance therapy. Reauthorization criteria to require prescriber attestation that the member has achieved hemoglobin stabilization or an increase from baseline, decrease from baseline in the number of transfusions, or reduction in hemolysis or decrease in LDH levels.
Primary Biliary Cholangitis – Medicare	8/23/2024	Policy revised to add Iqirvo (elifibranor) to require diagnosis based on FDA-approved indication, therapeutic failure, contraindication or intolerance to ursodiol monotherapy and used in combination with ursodiol unless ursodiol is

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		contraindicated or not tolerated. Limitation of coverage includes, Iqirvo should not be used in decompensated cirrhosis.
Programmed Death Receptor Therapies – Medicare	8/23/2024	Policy revised for Keytruda (pembrolizumab) and Imfinzi (durvalumab) to require diagnosis based on expanded FDA-approved indications for endometrial cancer.
Provigil (modafinil) & Nuvigil (armodafinil) – Medicare	8/23/2024	Policy revised for Provigil (modafinil) & Nuvigil (armodafinil) to remove documentation for narcolepsy and obstructive sleep apnea/hypopnea syndrome.
Radicava (edaravone) – Medicare	8/23/2024	Policy revised for Radicava (edaravone) to add if the request is for brand Radicava, the member has experienced therapeutic failure or intolerance to generic edaravone.
RET Kinase Inhibitors – Medicare	8/23/2024	Policy revised for Retevmo (selpercatinib) for solid tumors to require a RET gene fusion as detected by an FDA-approved test based on expanded indication.
Rezdiffra (resmetirom) – Medicare	7/26/2024	Policy revised for Rezdiffra (resmetirom) to clarify use is in conjunction with diet and exercise in initial authorization and reauthorization. Removed ask that comorbid conditions are managed.
Rybrevant (amivantamab-vmjw) – Medicare	8/23/2024	Policy revised for Rybrevant (amivantamab-vmjw) to specify that the member will be using as a single agent after disease progression on or after platinum-based chemotherapy.
Sirturo (bedaquiline) – Medicare	TBD	Policy updated to include the member has experienced therapeutic failure, contraindication, or intolerance to all of the following: isoniazid and rifampin, rifabutin, or rifapentine.
Sirturo (bedaquiline) – Medicare	8/23/2024	Policy updated to include the member has a diagnosis of one of the following: the member has extensively drug resistant tuberculosis (TB), nonresponsive multidrug-resistant TB, pre-extensively drug-resistant TB, or treatment-intolerant TB.
Somatuline (lanreotide) Depot – Medicare	8/23/2024	Policy revised to remove reauthorization criteria and add generic lanreotide 120 mg/0.5 mL to require diagnosis based on FDA-approved indication. For acromegaly and gastroenteropancreatic neuroendocrine tumors, if the request is for brand Somatuline Depot 120 mg/0.5 mL, member has experienced therapeutic

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		failure or intolerance to generic lanreotide 120 mg/0.5 mL.
Sunosi (solriamfetol) – Medicare	8/23/2024	Policy revised for Sunosi (solriamfetol) to change mean sleep latency to less than or equal to 8 minutes for a multiple sleep latency test for narcolepsy.
Targretin (bexarotene) – Medicare	8/23/2024	Policy revised for Targretin (bexarotene) oral capsules to remove age limitation.
Targretin (bexarotene) – Medicare	TBD	Policy revised for Targretin (bexarotene) gel to require diagnosis based on FDA-approved indication and trial/failure to at least one other therapy for cutaneous T-cell lymphoma.
Trulance (plecanatide) – Medicare	TBD	New policy for Trulance (plecanatide) to require diagnosis based on FDA-approved indication and trial/failure/contraindication to Linzess (linaclotide) and lubiprostone (females only for irritable bowel syndrome with constipation).
Ustekinumab Biosimilars – Medicare	TBD	Policy revised to add Pyzchiva (ustekinumab-ttwe) to ustekinumab biosimilar criteria requiring age and diagnosis based on FDA-approved indication; therapeutic failure/intolerance to Stelara (ustekinumab); the member achieved clinical response or remission with intravenous induction dosing for Crohn's disease and ulcerative colitis; trial/failure/contraindication to phototherapy OR systemic therapy for plaque psoriasis. Quantity limitation criteria to allow for induction and maintenance dosing per FDA label.
Vectibix (panitumumab) – Medicare	8/23/2024	Policy revised for Vectibix (panitumumab) to remove age limitation.
VEGF and EGFR Kinase Inhibitors – Medicare	8/23/2024	Policy revised for Caprelsa (vandetanib) to remove age limitation.
Vigabatrin – Medicare	TBD	Policy revised to add Vigafyde (vigabatrin) to require diagnosis and age based on FDA-approved indication, used as monotherapy and therapeutic failure or intolerance to generic vigabatrin packet for oral solution.
Voquezna (vonoprazan) Products – Medicare	8/23/2024	Policy revised for Voquezna (vonoprazan) to require FDA-approved indication, and trial and failure through omeprazole and pantoprazole if the request is for non-erosive gastroesophageal reflux disease.
Vtama (tapinarof) and Zoryve (roflumilast) – Medicare	8/23/2024	Policy revised to add Zoryve (roflumilast) 0.15% cream requiring FDA-approved diagnosis of atopic dermatitis, therapeutic failure,

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		contraindication or intolerance to one generic formulary topical corticosteroid or facial or anogenital involvement and therapeutic failure, contraindication or intolerance to generic topical tacrolimus or topical pimecrolimus.
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) – Medicare	8/23/2024	New policy for Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) requiring diagnosis based on FDA-approved indication of chronic inflammatory demyelinating polyneuropathy (CIDP) supported by diagnostic criteria, and trial/failure/contraindication to corticosteroids. Reauthorization to require improvement in functional ability or strength from baseline. Moved Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) and its generalized myasthenia gravis (gMG) criteria from J-1179 to this policy.
Wegovy (semaglutide) – Medicare Incentive and Compass	7/31/2024	Policy revised for Wegovy (semaglutide) for initiation and reauthorization to remove required step through a statin.
Wegovy (semaglutide) – Medicare Incentive and Compass	7/1/2024	Policy revised for Wegovy (semaglutide) for all ages for initiation and reauthorization to require therapeutic failure/intolerance/contraindication to a moderate or high intensity statin.

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

## 2. Updates to Step Therapy

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Brand Glaucoma Agents – Medicare	TBD	Policy revised to create new policy for brands Alphagan P (brimonidine tartrate) and Combigan (brimonidine tartrate/timolol maleate) requiring FDA-approved diagnosis and step through one of the following generic classes: Prostaglandin analogs, Ophthalmic beta-blockers, Alpha-adrenergic agonists, Carbonic anhydrase inhibitors, Ophthalmic cholinergic agonists, or combination products of these classes. Authorization duration of 12 months.
Celebrex (celecoxib) Step Therapy – Medicare	TBD	Policy revised to target brand Celebrex (celecoxib) only and to require trial/failure to



Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		generic celecoxib and one other oral generic non-steroidal anti-inflammatory drug.
Colony-Stimulating Factors – Medicare	TBD	Policy revised for Nypozi (filgrastim-txid) to require diagnosis based on FDA-approved indication, and trial/failure to Nivestym (filgrastim-aafi) and Zarxio (filgrastim-sndz) except when Nypozi (filgrastim-txid) is being used for Hematopoietic Acute Radiation Syndrome.
Intravitreal Injections – Medicare	TBD	Policy revised to add Ahzantive (aflibercept-mrbb), Opuviz (aflibercept-yszy), and Yesafili (aflibercept-jbvf) requiring FDA-approved diagnosis and trial/failure to Eylea (aflibercept). If the request is for Neovascular (Wet) Age-Related Macular Degeneration (nAMD), the member has experienced therapeutic failure after an adequate trial, contraindication, or intolerance to Avastin (bevacizumab).
Non-Preferred Dipeptidyl Peptidase IV (DPP-IV) Inhibitors – Medicare	TBD	Policy revised to add Zituvimet (sitagliptin/metformin) as a target.
Non-preferred Inhaler Products – Medicare	TBD	Policy revised to add brand Advair Diskus (fluticasone propionate/salmeterol) to the policy and require a diagnosis of asthma and the member has experienced therapeutic failure or intolerance two of the following products: Advair HFA (fluticasone propionate/salmeterol), brand Breo Ellipta (fluticasone furoate/vilanterol), or Dulera (mometasone furoate/formoterol fumarate) or the patient has a diagnosis of COPD and the member has experienced therapeutic failure or intolerance to brand Breo Ellipta (fluticasone furoate/vilanterol). Fluticasone propionate/salmeterol (AirDuo RespiClick) authorized generic was also added to require the member has a diagnosis of asthma and has experienced therapeutic failure or intolerance to two of the following products: Advair HFA (fluticasone propionate/salmeterol), brand Breo Ellipta (fluticasone furoate/vilanterol), or Dulera (mometasone furoate/formoterol fumarate). Flovent HFA/Diskus (fluticasone propionate) was also updated to require the member has a diagnosis of asthma and the member has experienced therapeutic failure or intolerance to two of the following: Asmanex (mometasone

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		furoate) and Qvar (beclomethasone dipropionate). Fluticasone furoate/vilanterol authorized generic and Symbicort (budesonide/formoterol fumarate) updated to require a diagnosis of asthma and the member has experienced therapeutic failure or intolerance two of the following products: Advair HFA (fluticasone propionate/salmeterol), brand Breo Ellipta (fluticasone furoate/vilanterol), or Dulera (mometasone furoate/formoterol fumarate) or the patient has a diagnosis of COPD and the member has experienced therapeutic failure or intolerance to brand Breo Ellipta (fluticasone furoate/vilanterol).
Non-Preferred Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Medicare	8/1/2024	Policy revised to remove Farxiga (dapagliflozin) and Xigduo XR (dapagliflozin/metformin) as targets and add as qualifiers. For all targets, an optional step through either/both agents added when an FDA-approved indication is shared between target and qualifier.
Non-Preferred Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Medicare	TBD	Policy revised for all targets to require step through all qualifiers with shared FDA-approved indications. Invokana (canagliflozin), Invokamet (canagliflozin/metformin), and Invokamet XR (canagliflozin/metformin) changed from qualifier to target.
Ophthalmic Prostaglandins and Rho Kinase Inhibitors – Medicare	TBD	Criteria for Rhopressa (netarsudil) and Rocklatan (netarsudil/latanoprost) revised to remove the required specific trial/failure to latanoprost and that ophthalmic alternatives must be generic. Xelpros (latanoprost ophthalmic emulsion) and brand Zioptan (tafluprost) added to policy requiring FDA-approved diagnosis, trial/failure to Lumigan (bimatoprost), and trial/failure to one other generic glaucoma drug.

### 3. Quantity Level Limit (QLL) Program

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

Drug Name	Retail Quantity Limit (31 days)
Adbry (tralokinumab-ldrm)	300 mg autoinjector: 4 mL per 28 days
Augtyro (repotrectinib) 160 mg	2 capsules per day
Augtyro (repotrectinib) 40 mg	6 capsules per day

Drug Name	Retail Quantity Limit (31 days)
Austedo XR (deutetrabenazine) 18 mg, 30 mg, 36 mg, 42 mg, 48 mg	1 tablet per day
Austedo XR (deutetrabenazine) 6 mg, 12 mg, 24 mg	1 tablet per day
Chewtadzy (tadalafil) 5 mg	1 tablet per day
Imdelltra (tarlatamab-dlle)	31 tablets per 31 days
Iqirvo (elafibranor)	2 doses per 365 days
Kisunla (donanemab-azbt)	2 unit-dose ampules per day
Mresvia (Respiratory Syncytial Virus Vaccine)	4 mL (4 mg) per day
Ohtuvayre (ensifentrine)	1 syringe (0.5 mL) per 84 days
Onyda XR (Clonidine Hydrochloride)	1 syringe (1 mL) per 56 days
Piasky (crovalimab-akkz)	40 mg tablets: 3 tablets per day
Pyzchiva (ustekinumab-ttwe) 130 mg/26 mL	4 tablets per day
Pyzchiva (ustekinumab-ttwe) 45 mg/0.5 mL	1 bottle (40.2 mL) per 30 days
Pyzchiva (ustekinumab-ttwe) 90mg/mL	1 tablet per day
Retevmo (selpercatinib)	1 tablet per day
Scemblix (asciminib) 100 mg	60 grams per 28 days
Scemblix (asciminib) 40 mg	300 mg autoinjector: 4 mL per 28 days
Skyrizi (risankizumab-rzaa)	2 capsules per day
Sofdra (sofipironium)	6 capsules per day
Torpenz (everolimus)	1 tablet per day
Triglide (fenofibrate)	1 tablet per day
Zoryve (roflumilast) cream 0.15%	1 tablet per day