Formulary Updates

June 2023

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for April 2023. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in April 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
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Section II. Highmark Medicare Part D Formularies

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

HIGHMARK

Important Drug Safety Updates

Brimonidine Tartrate Ophthalmic Solution by Apotex Corp.

On March 1, 2023, Apotex Corp. voluntarily recalled for six (6) lots of Brimonidine Tartrate Ophthalmic Solution, 0.15%. This recall is being initiated out of an abundance of caution due to cracks that have developed in some of the units' caps of Brimonidine tartrate ophthalmic solution bottles.

Brimonidine Tartrate Ophthalmic Solution is an alpha-adrenergic receptor agonist indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Dabigatran Etexilate Capsules, USP 75mg and 150mg

On March 22, 2023, Ascend Laboratories LLC. voluntarily recalled Dabigatran Etexilate Capsules. USP 75 mg and 150 mg to the consumer/user level due to the presence of a nitrosamine. N-nitroso-dabigatran, above the established Acceptable Daily Intake (ADI) level.

Nitrosamines are common in water and foods, including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of nitrosamines. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time.

Atovaquone Oral Suspension, USP 750mg/5ml by Camber Pharmaceuticals

On March 13, 2023**,** Camber Pharmaceuticals, Inc. is voluntarily recalling Atovaquone Oral Suspension, USP 750mg/5mL to the Consumer/User level, due to the potential Bacillus cereus contamination in the product.

In the population most at risk, immunocompromised population, there is a reasonable probability that microbial contamination of Atovaquone Oral Suspension can result in disseminated, life-threatening infections such as endocarditis and necrotizing soft tissue infections. To date, Camber has not received any reports of adverse events related to this recall.

Akorn Operating Company LLC, Various Human Drug Products

On April 26, 2023, Gurnee, IL, Akorn Operating Company LLC has filed Chapter 7 bankruptcy on February 23, 2023. In connection with that filing, the company has ceased and shut down all operations and terminated all its employees of all domestic US Sites. The Akorn Trustee is initiating a voluntary recall of various within-expiry human and animal products as a result of the closures and discontinuation of the Quality activities of these marketed products. The discontinuation of the Quality program means the company will not be able to support or guarantee that the products will meet all intended specifications through the labeled shelf life of the product. Further distribution or use of any remaining product on the market should cease immediately.

The discontinuation of the Quality program would result in the company's inability to assure that products meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess which render the products adulterated. While specific risks to patients, from use of these adulterated products, cannot always be identified or assessed, it is also not possible to rule out patient risks resulting from the use of such products. Akorn has not received any reports of adverse events related to this recall.

FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use | FDA

On April 13, 2023, as part of ongoing efforts to address the opioid crisis, the FDA is updating the prescribing information of opioid medications. The updates include information stating that the risk of overdose increases with an increase in dose; Immediate-release (IR) products should not be used for an extended period unless pain is severe enough to require that and alternative treatments remain inadequate, and many acute pain conditions require no more than a few days of treatment; Extended release (ER) products should be used for severe and persistent pain that requires an extended treatment period and for which other treatments are inadequate. A new warning for opioid-induced hyperalgesia is added for both IR and ER products. Patients should take their opioid medications exactly as prescribed and should talk their healthcare provider before making any changes to their regimen.

FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions

On May 11, 2023, the FDA is requiring updates to the boxed warning and other information to ensure the prescribing information is made consistent across prescription stimulants. The current prescription information for some prescription stimulants do not provide up to date warnings about misuse and abuse. The FDA will add information that patients should not share their prescription stimulants, and the boxed warning information will describe the risks of misuse, abuse, addiction, and overdose consistently across all medicines in the class.

Highmark Formulary Update – April 2023

SECTION I. Highmark Commercial and Healthcare Reform Formularies

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

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

- Highmark Comprehensive Formulary
- Highmark Healthcare Reform Comprehensive Formulary

Highmark is 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 May 2023, unless otherwise noted.

Brand Name	Generic Name	Comments
Altuviiio	antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl	Hemophilia
Eligard	leuprolide acetate	Advanced prostate cancer
Naloxone nasal spray (4 mg/0.25 mL)*	Naloxone nasal spray (4 mg/0.25 mL)	Opioid overdose reversal
Orenitram Month 1 Titration Pack (168 tabs)**	treprostinil Month 1 Titration Pack (168 tabs)	Pulmonary arterial hypertension
Orenitram Month 2 Titration Pack (336 tabs)**	treprostinil Month 2 Titration Pack (336 tabs)	Pulmonary arterial hypertension
Orenitram Month 3 Titration Pack (252 tabs)**	treprostinil Month 3 Titration Pack (252 tabs)	Pulmonary arterial hypertension

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
**Added for Commercial Comprehensive only

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Airsupra*	albuterol and budesonide	generic albuterol sulfate HFA, Ventolin HFA
Atorvaliq	atorvastatin suspension	atorvastatin calcium, rosuvastatin calcium, simvastatin tablet
Austedo XR	deutetrabenazine	tetrabenazine
Brenzavvy*	bexagliflozin	Farxiga, Jardiance, Invokana
Filspari	sparsentan	irbesartan, lisinopril tablet, valsartan tablet
Jaypirca	pirtobrutinib	Prescriber discretion
Jesduvroq*	daprodustat	Epogen, Procrit, Aranesp
Orserdu	elacestrant	anastrozole tablet
Skyclarys	omaveloxolone	Prescriber discretion
Tezspire pen injector	tezepelumab-ekko pen injector	Dupixent

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.

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

Brand Name	Generic Name
Altuviiio	antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl
Austedo XR	deutetrabenazine
Filspari	sparsentan
Jaypirca	pirtobrutinib
Jesduvroq	daprodustat
Orenitram Month 1 Titration Pack (168 tabs)	treprostinil Month 1 Titration Pack (168 tabs)
Orenitram Month 2 Titration Pack (336 tabs)	treprostinil Month 2 Titration Pack (336 tabs)
Orenitram Month 3 Titration Pack (252 tabs)	treprostinil Month 3 Titration Pack (252 tabs)
Orserdu	elacestrant
Skyclarys	omaveloxolone
Tezspire pen injector	tezepelumab-ekko pen injector

Table 4. Products to Be Removed or Shifted to Higher Tier – Effective July 2023

Brand name	Generic Name	Preferred Alternatives
All Commercial & Healthcare Reform Comprehensive products		
Amitiza 24 mcg capsules	lubiprostone	lubiprostone
Amitiza 8 mcg capsule	lubiprostone	lubiprostone

Brand name	Generic Name	Preferred Alternatives
Ciloxan 0.3% ointment	ciprofloxacin hcl	ciprofloxacin 0.3% eye drop
Daliresp 250 mcg tablet	roflumilast	roflumilast
Daliresp 500 mcg tablet	roflumilast	roflumilast
Gilenya 0.5 mg capsule	fingolimod hcl	fingolimod
Latanoprost 0.005% eye drop	latanoprost/pf	latanoprost
Primaquine 26.3 mg tablet	primaquine phosphate	primaquine generic
Timolol 0.5%-latanoprost 0.005%	timolol maleate/latanoprost/pf	latanoprost, timolol maleate drops
Tobradex eye ointment	tobramycin/dexamethasone	tobramycin-dexameth ophth susp
Tobradex st 0.3-0.05% eye drop	tobramycin/dexamethasone	tobramycin-dexameth ophth susp
Tobrex 0.3% eye ointment	tobramycin	tobramycin 0.3% eye drop

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 May 2023, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Altuviiio	antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl	4	Hemophilia
Naloxone nasal spray (4 mg/0.25 mL)*	Naloxone nasal spray (4 mg/0.25 mL)	2	Opioid overdose reversal
Orenitram Month 1 Titration Pack (168 tabs)	treprostinil Month 1 Titration Pack (168 tabs)	4	Pulmonary arterial hypertension
Orenitram Month 2 Titration Pack (336 tabs)	treprostinil Month 2 Titration Pack (336 tabs)	4	Pulmonary arterial hypertension
Orenitram Month 3 Titration Pack (252 tabs)	treprostinil Month 3 Titration Pack (252 tabs)	4	Pulmonary arterial hypertension

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were not added to the formulary			
Airsupra*	albuterol and budesonide	NF	generic albuterol sulfate HFA, Ventolin HFA
Atorvaliq	atorvastatin suspension	NF	atorvastatin calcium, rosuvastatin calcium, simvastatin tablet
Austedo XR	deutetrabenazine	NF	tetrabenazine
Brenzavvy*	bexagliflozin	NF	Farxiga, Jardiance, Invokana
Filspari	sparsentan	NF	irbesartan, lisinopril tablet, valsartan tablet
Jaypirca	pirtobrutinib	NF	Prescriber discretion
Jesduvroq*	daprodustat	NF	Epogen, Procrit, Aranesp
Orserdu	elacestrant	NF	anastrozole tablet, exemastane
Skyclarys	omaveloxolone	NF	Prescriber discretion
Tezspire pen injector	tezepelumab-ekko pen injector	NF	Dupixent

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.

Table 2. Products to Be Removed or Shifted to Higher Tier – Effective July 2023

Brand Name	Generic Name	Preferred Alternatives
All Healthcare Reform Essential Products		
Amitiza 24 mcg capsules	lubiprostone	lubiprostone
Amitiza 8 mcg capsule	lubiprostone	lubiprostone
Aubagio 14 mg tablet	teriflunomide	teriflunomide
Aubagio 7 mg tablet	teriflunomide	teriflunomide
Cetrotide 0.25 mg vial	cetrorelix acetate	cetrorelix acetate
Daliresp 250 mcg tablet	roflumilast	roflumilast
Daliresp 500 mcg tablet	roflumilast	roflumilast
Dexilant dr 30 mg capsule	dexlansoprazole	dexlansoprazole dr
Dexilant dr 60 mg capsule	dexlansoprazole	dexlansoprazole dr
Gilenya 0.5 mg capsule	fingolimod hcl	fingolimod
Hetlioz 20 mg capsule	tasimelteon	tasimelteon
Keveyis 50 mg tablet	dichlorphenamide	dichlorphenamide
Latuda 120 mg tablet	lurasidone hcl	lurasidone hcl
Latuda 20 mg tablet	lurasidone hcl	lurasidone hcl
Latuda 40 mg tablet	lurasidone hcl	lurasidone hcl
Latuda 60 mg tablet	lurasidone hcl	lurasidone hcl
Latuda 80 mg tablet	lurasidone hcl	lurasidone hcl
Livalo 1 mg tablet	pitavastatin calcium	pitavastatin (anticipated generic)
Livalo 2 mg tablet	pitavastatin calcium	pitavastatin (anticipated generic)
Livalo 4 mg tablet	pitavastatin calcium	pitavastatin (anticipated generic)
Mirvaso 0.33% gel	brimonidine tartrate	brimonidine tartrate
Mirvaso 0.33% gel pump	brimonidine tartrate	brimonidine tartrate
Primaquine 26.3 mg tablet	primaquine phosphate	primaquine generic

Restasis 0.05% eye emulsion	cyclosporine	cyclosporine
Zioptan 0.0015% eye drop	tafluprost/pf	tafluprost

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 May 2023, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Altuviiio	antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl	4	Hemophilia
Naloxone nasal spray (4 mg/0.25 mL)*	Naloxone nasal spray (4 mg/0.25 mL)	3	Opioid overdose reversal
Eligard	leuprolide acetate	4	Advanced prostate cancer
Orenitram Month 1 Titration Pack (168 tabs)	treprostinil Month 1 Titration Pack (168 tabs)	4	Pulmonary arterial hypertension
Orenitram Month 2 Titration Pack (336 tabs)	treprostinil Month 2 Titration Pack (336 tabs)	4	Pulmonary arterial hypertension
Orenitram Month 3 Titration Pack (252 tabs)	treprostinil Month 3 Titration Pack (252 tabs)	4	Pulmonary arterial hypertension
Items listed below were not added to the formulary			
Airsupra*	albuterol and budesonide	NF	generic albuterol sulfate HFA, Ventolin HFA
Atorvaliq	atorvastatin suspension	NF	atorvastatin calcium, rosuvastatin calcium, simvastatin tablet
Austedo XR	deutetrabenazine	NF	tetrabenazine
Brenzavvy*	bexagliflozin	NF	Farxiga, Jardiance, Invokana
Filspari	sparsentan	NF	irbesartan, lisinopril tablet, valsartan tablet
Jaypirca	pirtobrutinib	NF	Prescriber discretion
Jesduvroq*	daprodustat	NF	Retacrit, Aranesp
Orserdu	elacestrant	NF	anastrozole tablet, exemastane
Skyclarys	omaveloxolone	NF	Prescriber discretion

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Tezspire pen injector	tezepelumab-ekko pen injector	NF	Dupixent

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.

Table 2. Products to Be Removed or Shifted to Higher Tier – Effective July 2023

Brand Name	Generic Name	Preferred Alternatives
All Core Products		
Amitiza 24 mcg capsules	lubiprostone	lubiprostone
Amitiza 8 mcg capsule	lubiprostone	lubiprostone
Aubagio 14 mg tablet	teriflunomide	teriflunomide
Aubagio 7 mg tablet	teriflunomide	teriflunomide
Daliresp 250 mcg tablet	roflumilast	roflumilast
Daliresp 500 mcg tablet	roflumilast	roflumilast
Delestrogen 50 mg/5 ml vial	estradiol valerate	estradiol valerate
Gilenya 0.5 mg capsule	fingolimod hcl	fingolimod
Keveyis 50 mg tablet	dichlorphenamide	dichlorphenamide
Primaquine 26.3 mg tablet	primaquine phosphate	primaquine generic
Timolol 0.5%-latanopros 0.005%	timolol maleate/latanoprost/pf	latanoprost, timolol maleate drops

D. Changes to the Highmark National Select Formulary

The National Select Formulary is an incentive formulary with a non-formulary drug list to manage products in therapeutic categories for which preferred alternatives are available. The National Select Formulary is available for select Commercial self-funded (ASO) plans. A list of drugs included on the National Select Formulary, listed by therapeutic class, is available here.

Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (Preferred)			
Altuviiio	antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl	2	Hemophilia
Austedo XR	deutetrabenazine	2	Chorea associated with Huntington's disease and tardive dyskinesia
Orserdu	elacestrant	2	Advanced breast cancer
Tezspire pen injector	tezepelumab-ekko pen injector	2	Severe asthma
Items listed below were added to the formulary (Non-Preferred)			

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Airsupra*	albuterol and budesonide	3	generic albuterol sulfate HFA
Atorvaliq*	atorvastatin suspension	3	atorvastatin calcium, rosuvastatin calcium, simvastatin tablet
Brenzavvy*	bexagliflozin	3	Farxiga, Jardiance
Jesduvroq*	daprodustat	3	Prescriber discretion
Naloxone nasal spray (4 mg/0.25 mL)*	Naloxone nasal spray (4 mg/0.25 mL)	3	naloxone, Kloxxado
Orenitram Month 1 Titration Pack (168 tabs)*	treprostinil Month 1 Titration Pack (168 tabs)	3	Prescriber discretion
Orenitram Month 2 Titration Pack (336 tabs)*	treprostinil Month 2 Titration Pack (336 tabs)	3	Prescriber discretion
Orenitram Month 3 Titration Pack (252 tabs)*	treprostinil Month 3 Titration Pack (252 tabs)	3	Prescriber discretion
Skyclarys*	omaveloxolone	3	Prescriber discretion
Items listed below were not added to the formulary			
Filspari	sparsentan	NF	irbesartan, lisinopril tablet, valsartan tablet
Jaypirca	pirtobrutinib	NF	Calquence

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
Altuviiio	antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl
Austedo XR	deutetrabenazine
Filspari	sparsentan
Jaypirca	pirtobrutinib
Jesduvroq	daprodustat
Orenitram Month 1 Titration Pack (168 tabs)	treprostinil Month 1 Titration Pack (168 tabs)
Orenitram Month 2 Titration Pack (336 tabs)	treprostinil Month 2 Titration Pack (336 tabs)
Orenitram Month 3 Titration Pack (252 tabs)	treprostinil Month 3 Titration Pack (252 tabs)
Orserdu	elacestrant
Skyclarys	omaveloxolone
Tezspire pen injector	tezepelumab-ekko pen injector

Table 3. Products to Be Removed or Shifted to Higher Tier – Effective July 2023

Brand Name	Generic Name	Preferred Alternatives
All National Select Products		
Alvesco 160 mcg inh	ciclesonide	Arnuity Ellipta, Asmanex hfa
Alvesco 80 mcg inh	ciclesonide	Arnuity Ellipta, Asmanex hfa
Aptensio xr 10 mg cap	methylphenidate hcl	methylphenidate er
Aptensio xr 15 mg cap	methylphenidate hcl	methylphenidate er
Aptensio xr 20 mg cap	methylphenidate hcl	methylphenidate er
Aptensio xr 30 mg cap	methylphenidate hcl	methylphenidate er
Aptensio xr 40 mg cap	methylphenidate hcl	methylphenidate er
Aptensio xr 50 mg cap	methylphenidate hcl	methylphenidate er
Aptensio xr 60 mg cap	methylphenidate hcl	methylphenidate er
Flovent 100 mcg diskus	fluticasone propionate	Arnuity Ellipta, Asmanex hfa
Flovent 100 mcg diskus	fluticasone propionate	Arnuity Ellipta, Asmanex hfa
Flovent 50 mcg diskus	fluticasone propionate	Arnuity Ellipta, Asmanex hfa
Flovent hfa 110 mcg inhaler	fluticasone propionate	Arnuity Ellipta, Asmanex hfa
Flovent hfa 220 mcg inhaler	fluticasone propionate	Arnuity Ellipta, Asmanex hfa
Flovent hfa 44 mcg inhaler	fluticasone propionate	Arnuity Ellipta, Asmanex hfa
Gilenya 0.5 mg capsule	fingolimod hcl	fingolimod
Lucentis 0.3 mg/0.05 ml vial	ranibizumab	Byooviz, Cimerli
Lucentis 0.5 mg/0.05 ml syringe	ranibizumab	Byooviz, Cimerli
Lucentis 0.5 mg/0.05 ml vial	ranibizumab	Byooviz, Cimerli
Methylphenidate er 72 mg tab	methylphenidate hcl	methylphenidate er 54 mg tab, methylphenidate er 18 mg tab
Ravicti 1.1 gram/ml liquid	glycerol phenylbutyrate	sodium phenylbutyrate, Pheburane
Relexxii er 72 mg tablet	methylphenidate hcl	methylphenidate er 54 mg tab, methylphenidate er 18 mg tab
Xyrem 500 mg/ml oral solution	sodium oxybate	sodium oxybate

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Adalimumab BIOSIMILARS –	TBD	Policy revised for adalimumab biosimilars to allow approval for all of Humira's (adalimumab) FDA-

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Commercial and Healthcare Reform		approved indications, including pediatric ulcerative colitis, uveitis, and hidradenitis suppurativa.
Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors – Commercial and Healthcare Reform	04/12/2023	Policy revised for Nexletol (bempedoic acid) and Nexlizet (bempedoic acid/ezetimibe) to remove LDLRAP1 gene mutation and add that the requested drug is prescribed by or in consultation with one of the following: cardiologist, lipid specialist, or endocrinologist, from the initial authorization criteria for heterozygous familial hypercholesterolemia (HeFH). Reauthorization criteria revised to require a 10% or greater reduction in low-density lipoprotein cholesterol (LDL-C) level from baseline. Authorization duration revised to an initial authorization duration of 6 months and reauthorization duration of 12 months.
Anti-EGFR and HER2 Kinase Inhibitors – Commercial and Healthcare Reform	04/12/2023	Policy revised for Tukysa (tucatinib) to require age and diagnosis based on FDA-approved indication.
Aubagio (teriflunomide) – Commercial and Healthcare Reform	07/01/2023	Policy revised to reflect availability of generic Aubagio (teriflunomide). In addition to age and FDA approved diagnosis, if the request is for brand Aubagio, the member must have experienced therapeutic failure or intolerance to generic teriflunomide. For reauthorization, in addition to therapeutic response, if the request is for brand Aubagio, the member must have experienced therapeutic failure or intolerance to generic teriflunomide.
Austedo/Austedo XR (deutetrabenazine) – Commercial and Healthcare Reform	05/30/2023	Policy revised to include Austedo XR (deutetrabenazine); a new extended-release formulation of Austedo (deutetrabenazine). Criteria for coverage of Austedo XR for both chorea associated with Huntington's disease as well as tardive dyskinesia (TD) requires age and FDA-approved indication. For TD diagnosis, prescriber must attest that the member continues to experience symptoms of TD despite dose reduction/tapering/discontinuation of the offending medication(s), or that dose reduction/tapering/discontinuation of the offending medication(s) would not be appropriate. Quantity Level Limits section removed.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
BTK Inhibitors – Commercial and Healthcare Reform	04/12/2023	Policy revised to add Jaypirca (pirtobrutinib) to the policy. Jaypirca requires a diagnosis of mantle cell lymphoma (MCL); the MCL must be classified as relapsed/refractory (RR); the member must have received at least two previous lines of systemic therapy; one of the previous lines of therapy was a BTK inhibitor. Criteria for Jaypirca quantity limit overrides, for concomitant use of a moderate CYP3A4 inducer, were also added. Policy revised for Brukinsa (zanubrutinib) requiring age and diagnosis based on FDA-approved indication.
CDK Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised for Kisqali (ribociclib) removing prescribers' attestation that the member is not a candidate for therapy with Ibrance (palbociclib) and Verzenio (abemaciclib). Added prescriber attestation that the member is not a candidate for therapy to Kisqali and Verzenio to Ibrance's criteria.
CDK Inhibitors – Commercial and Healthcare Reform	04/12/2023	Policy revised for Verzenio (abemaciclib) to remove Ki-67 score from endocrine therapy indication and removed requirement that the members are postmenopausal females, and males from aromatase inhibitor indication due to Verzenio's expanded indication.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	04/12/2023	Policy revised to add Amjevita (adalimumab-atto) labeler [55513] as a preferred product at parity to Humira for all of Humira's FDA approved indications. Policy revised for Kevzara (sarilumab) to require age and diagnosis based on FDA approved indication.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	01/01/2024	Policy terminated and Comm/HCR lines of business moved into J-1049
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	05/01/2023	Policy revised for Olumiant (baricitinib) in rheumatoid arthritis to require the requested dose is for 1 mg or 2 mg. In alopecia areata, if the request is for Olumiant (baricitinib) 4 mg, the member has had inadequate response to 2 mg, or has nearly complete or complete scalp hair loss. For reauthorization, if the request is for Olumiant (baricitinib) 4 mg, the member has alopecia areata and one of the following: continues to have nearly complete or complete scalp hair loss and requires additional therapy, or prescriber attests reducing dose to Olumiant (baricitinib) 2 mg is not clinically appropriate at this time.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	01/01/2024	Policy revised to add Comm/HCR lines align all Comm/HCR lines of business to have Taltz (ixekizumab) as a preferred agent and Cosentyx (secukinumab) as non-preferred.
Chronic Inflammatory Diseases – Commercial National Select Formulary	04/12/2023	Policy revised to add Amjevita (adalimumab-atto) labeler [55513] as a preferred product at parity to Humira for all of Humira's FDA approved indications.
Chronic Inflammatory Diseases – Commercial National Select Formulary	05/01/2023	Policy revised for Olumiant (baricitinib) in rheumatoid arthritis to require the requested dose is for 1 mg or 2 mg. In alopecia areata, if the request is for Olumiant (baricitinib) 4 mg, the member has had inadequate response to 2 mg, or has nearly complete or complete scalp hair loss. For reauthorization, if the request is for Olumiant (baricitinib) 4 mg, the member has alopecia areata and one of the following: continues to have nearly complete or complete scalp hair loss and requires additional therapy, or prescriber attests reducing dose to Olumiant (baricitinib) 2 mg is not clinically appropriate at this time.
Chronic Inflammatory Diseases – Commercial National Select Formulary	04/12/2023	Policy revised for Kevzara (sarilumab) to require age and diagnosis based on FDA approved indication.
Cibinqo (abrocitinib) – Commercial and Healthcare Reform	04/12/2023	Policy revised for Cibinqo (abrocitinib) to allow for FDA-approved expanded age indication of 12 years and older
Clotting Factor Products – Commercial and Healthcare Reform	04/12/2023	Policy revised to add Altuviiio (antihemophilic factor recombinant Fc-VWF-XTEN fusion protein-ehtl) as a plan-preferred agent in the policy.
Filspari (sparsentan) – Commercial and Healthcare Reform	04/13/2023	New policy for Filspari (sparsentan) requiring age; diagnosis based on FDA-approved indication confirmed by biopsy and supported by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g or proteinuria ≥ 1 g/day; trial/failure/contraindication to a maximally tolerated dose of either an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB); and the member will not be using Filspari (sparsentan) in combination with renin-angiotensin system inhibitor or endothelin receptor antagonist. Reauthorization to require a reduction in UPCR or proteinuria from baseline and the member will not be using Filspari (sparsentan) in combination with renin-angiotensin system inhibitor or endothelin

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		receptor antagonist. Initial authorization duration of 9 months and reauthorization duration of 12 months.
Fingolimod – Commercial and Healthcare Reform	04/12/2023	Policy revised to add criteria for new strength of Gilenya (fingolimod) 0.25 mg. Requires diagnosis based on FDA-approved indication, age between 10-17, and weight ≤ 40 kg. Reauthorization for Gilenya 0.25 mg requires a therapeutic response to therapy, and verification of age and weight.
Hereditary Angioedema – Commercial and Healthcare Reform	04/12/2023	Policy revised for Takhzyro (lanadelumab-flyo) to update age to 2 years and older based on updated FDA expanded indication
Jesduvroq (daprodustat) – Commercial and Healthcare Reform	TBD	New policy created for Jesduvroq (daprodustat) requiring age, diagnosis of FDA-approved indication, duration of dialysis for at least 4 months, documentation of hemoglobin (Hb) less than 11 g/dL, specialist prescriber, therapeutic failure/contraindication/intolerance or inappropriateness of one (1) intravenous iron therapy, and therapeutic failure/intolerance/contraindication to one (1) erythropoiesis-stimulating agent. Reauthorization requiring prescriber attestation of clinically meaningful increase in Hb from baseline and member's Hb level less than or equal to 11 g/dL. Initial authorization duration of 6 months and reauthorization duration of 12 months.
Livmarli (maralixibat) – Commercial and Healthcare Reform	04/12/2023	Policy revised for Livmarli (maralixibat) to lower age to 3 months of age or older based on FDA-approved indication.
Lotronex (alosetron) – Commercial and Healthcare Reform	04/12/2023	Policy revised for Lotronex (alosetron) to specify that irritable bowel syndrome with diarrhea is classified as severe and chronic disease.
Market Watch Programs – Delaware	TBD	Policy revised to target all strengths of Relexxii (methylphenidate hydrochloride ER) to require trial/failure to amphetamine/dextroamphetamine ER, dexmethylphenidate HCl ER, dextroamphetamine ER, and methylphenidate ER.
Market Watch Programs – NY, PA, and WV	TBD	Policy revised to target all strengths of Relexxii (methylphenidate hydrochloride ER) to require trial/failure to amphetamine/dextroamphetamine ER, dexmethylphenidate HCl ER, dextroamphetamine ER, and methylphenidate ER.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Oral Isotretinoin Therapy – Commercial and Healthcare Reform	04/12/2023	Policy revised for oral isotretinoin products to add sulfacetamide (lotion) as an option with other topical antibiotics. Also added Accutane as an option for patients to try and fail.
Orserdu (elacestrant) – Commercial and Healthcare Reform	04/13/2023	New policy created for Orserdu (elacestrant) requiring the member to be a postmenopausal female or a male that is 18 years of age or older with appropriate diagnosis per FDA-approved indication, a tumor status of ER-positive, HER2-negative, with an ESR1 gene mutation, and to have experienced disease progression on or after an endocrine-based regimen.
Palforzia (peanut (Arachis hypogaea) allergen powder-dnfp) – Commercial and Healthcare Reform	04/12/2023	Policy revised for Palforzia (peanut (Arachis hypogaea) allergen powder-dnfp) to allow prescribing/consultation from an immunologist specialist and clarify the member does not have eosinophilic esophagitis or eosinophilic gastrointestinal disease. Reauthorization criteria updated to require positive clinical response to therapy and attestation the member will continue a peanut-avoidant diet.
Ponvory (ponesimod) – Commercial and Healthcare Reform	04/12/2023	Policy revised to change step to generic dimethyl fumarate or fingolimod.
Pulmonary Hypertension – Commercial and Healthcare Reform	04/12/2023	Policy revised for Revatio (sildenafil) to remove requirement of documentation of New York Heart Association or World Health Organization Functional Class II or III symptoms from baseline and to add an exception to right heart catheterization when all of the following are met: the member is 17 years of age or younger, the risk of right heart catheterization outweighs the benefit, and the prescriber attests alternative studies were completed such as contrast-enhanced computed tomography (CT) scan, magnetic resonance imaging (MRI), or other specified testing ruling out other causes of PH (e.g., for congenital metabolic diseases, gastroesophageal reflux disease). Quantity limit approval criteria added for quantities over 20 mg three times per day based on maximum FDA-approved dosing per age and weight.
Relistor (methylnaltrexone bromide) – Commercial and Healthcare Reform	04/12/2023	Policy revised for Relistor (methylnaltrexone bromide) to update step for Amitiza (lubiprostone) to generic lubiprostone. Diagnosis criteria updated to match FDA-approved indication. Initial

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		authorization criteria updated to specify therapeutic failure, contraindication, or intolerance to scheduled dosing of one (1) laxative
Skyclarys (omaveloxolone) – Commercial and Healthcare Reform	05/30/2023	New policy created for Skyclarys (omaveloxolone) to require age, diagnosis based on FDA-approved indication confirmed by genetic testing, and prescribed by or in consultation with a neurologist or a provider who specializes in Friedreich's ataxia. Reauthorization criteria requires positive clinical response to therapy.
Symproic (naldemedine) – Commercial and Healthcare Reform	04/12/2023	Policy revised for Symproic (naldemedine) for initial authorization criteria to specify therapeutic failure, contraindication, or intolerance to scheduled dosing of one (1) laxative and to update the plan-preferred product Amitiza to generic lubiprostone.
Tezspire (tezepelumab-ekko) – Commercial and Healthcare Reform	04/13/2023	New policy created for Tezspire (tezepelumab-ekko) FDA indication, a history of at least 2 or more asthma exacerbations requiring oral or injectable corticosteroid treatment or at least 1 asthma exacerbation that required hospitalization in the past 12 months, and inadequate symptom control despite regular treatment with medium or high-dose inhaled corticosteroids (ICS) and at least 1 additional asthma controller, with or without oral corticosteroids (OCS). The member must also meet one (1) of the following criteria: pre-bronchodilator forced expiratory volume in 1 second (FEV1) below 80% in adults, pre-bronchodilator FEV1 below 90% in adolescents, or FEV1 reversibility of at least 12% and 200 mL after albuterol (salbutamol) administration. For reauthorization, members must meet one (1) of the following criteria: decreased rescue medication or OCS use, decrease in frequency of severe asthma exacerbations, increase in pulmonary function from baseline (e.g., FEV1), or reduction in reported asthma-related symptoms.
Urea Cycle Disorder Medications – Commercial and Healthcare Reform	TBD	Policy revised to clarify that Olpruva (sodium phenylbutyrate) will be used as adjunct to dietary management.
Viberzi (eluxadoline) – Commercial National Select	04/12/2023	Policy terminating to combine with J-0439 Viberzi (eluxadoline) – Commercial and Healthcare Reform.

*For Commercial and Healthcare Reform policies, an exception to some or all the criteria above may be

granted for select members and/or circumstances based on state and/or federal regulations.
**All effective dates are tentative and subject to delay pending internal review or approval.

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Acute Migraine Therapies – Commercial and Healthcare Reform	TBD	Policy revised for Cambia (diclofenac potassium) to step through generic if request is for brand and to step through diclofenac potassium 50 mg tablets or have the inability to swallow tablets. Initial criteria revised for Frova (frovatriptan), Maxalt MLT (rizatriptan), Relpax (eletriptan), Migranal (dihydroergotamine), Zomig Nasal Spray (zolmitriptan), and Treximet (sumatriptan/naproxen) to step through respective generics if the request is for brand. Reauthorization criteria revised to require therapeutic failure or intolerance to the generic equivalent product for brand products.
Additional Quantities of Reliever Inhalers – Commercial and Healthcare Reform	TBD	Policy revised to add Airsupra (budesonide and albuterol) as a targeted medication to require that the member is adherent to maximally tolerated controller medication, the member has been counselled on proper inhaler technique, and the member requires chronic maintenance of reliever inhaler therapy.
Beta Blocker Management – Commercial and Healthcare Reform	04/12/2023	Policy revised to remove Dutoprol (metoprolol succinate; hydrochlorothiazide extended release).
Beta Blocker Management – Commercial National Select	04/12/2023	Policy revised to remove Dutoprol (metoprolol succinate; hydrochlorothiazide extended release).
Brand Reliever Inhalers – Commercial and Healthcare Reform	TBD	New policy created for Brand Reliever Inhalers; Airsupra (budesonide and albuterol) to require 18 years and older, a diagnosis of bronchoconstriction and trial/failure of generic albuterol. Reauthorization criteria requires positive clinical response to therapy.
Direct Oral Anticoagulants (DOACs) – Commercial and Healthcare Reform	04/12/2023	Policy revised for Pradaxa (dabigatran etexilate) oral pellets to add the member has experienced therapeutic failure, contraindication, or intolerance to Xarelto oral suspension.
Doxycycline Products – Commercial and Healthcare Reform	07/01/2023	Oracea (doxycycline 40 mg) was added as a targeted product and may be approved when all of the following criteria are met: The member is 8 years of age or older, the member has a diagnosis

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		or rosacea with inflammatory lesions (papules and pustules), the member has experienced therapeutic failure, contraindication or intolerance to at least one (1) of the following topical agents: metronidazole cream, metronidazole lotion, metronidazole topical gel or generic azelaic acid. and the member has experienced therapeutic failure, contraindication, or intolerance to plan preferred doxycycline. For Commercial and HCR Plans, an authorization duration of 12 months was added for Oracea (doxycycline 40 mg).
Ibsrela (tenapanor) – Commercial and Healthcare Reform	04/12/2023	Policy revised for Ibsrela (tenapanor) to update step for Amitiza (lubiprostone) to generic lubiprostone.
Latuda (lurasidone) – Commercial	04/12/2023	Policy revised to reflect availability of generic Latuda (lurasidone). For both the bipolar indication as well as the schizophrenia indication, if the request is for brand Latuda, the member must have experienced therapeutic failure or intolerance to generic lurasidone. For reauthorization, in addition to the member experiencing a positive clinical response to therapy, if the request is for brand Latuda, the member must have experienced therapeutic failure or intolerance to generic lurasidone.
Latuda (lurasidone) – Healthcare Reform	04/12/2023	Policy revised to reflect availability of generic Latuda (lurasidone). For both the bipolar indication as well as the schizophrenia indication, if the request is for brand Latuda, the member must have experienced therapeutic failure or intolerance to generic lurasidone. For reauthorization, in addition to the member experiencing a positive clinical response to therapy, if the request is for brand Latuda, the member must have experienced therapeutic failure or intolerance to generic lurasidone.
Lidoderm (lidocaine patch) and ZTLido (lidocaine 1.8% topical system) – Commercial and Healthcare Reform	04/12/2023	Policy revised to add a criterion to the existing reauthorization criterion. In addition to the prescriber attesting that the member has experienced a positive clinical response to therapy, if the request is for Ztlido or brand Lidoderm (lidocaine) 5%, the member must have experienced therapeutic failure or intolerance to plan-preferred generic lidocaine 5% patch.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Lubiprostone – Commercial and Healthcare Reform	03/09/2023	Policy for lubiprostone authorized generic terminated.
Lyrica/Lyrica CR (pregabalin/pregabalin ER) – Commercial and Healthcare Reform	07/01/2023	Policy revised to include reauthorization criteria for brand Lyrica (pregabalin) and Lyrica CR (pregabalin extended-release) to require therapeutic failure or intolerance to generic pregabalin or pregabalin extended-release, respectively. Policy revised to remove brand Lyrica (pregabalin) from automatic approval criteria.
Mesalamine Ulcerative Colitis Treatments – Commercial and Healthcare Reform	TBD	Policy revised for non-preferred mesalamine products to target generic Asacol HD (mesalamine) delayed-release tablet and generic Pentasa (mesalamine) controlled-release capsule requiring trial/failure to one of the following generic products: mesalamine 0.375 g extended-release capsule (generic Apriso), mesalamine 400 mg DR capsules (generic Delzicol), mesalamine 1.2 g DR tablets (generic Lialda), or generic mesalamine 4 g/60 mL enema (non-kit). For brand and generic Rowasa (mesalamine) enema kit, trial/failure to generic mesalamine enema (non-kit) is required. If the request is for brand Apriso, Canasa, Delzicol, Asacol HD, Pentasa 500 mg, or Lialda, the member has tried/failed respective AB-generic product.
Motegrity (prucalopride) – Commercial and Healthcare Reform	04/12/2023	Policy revised for Motegrity (prucalopride) to update step for Amitiza (lubiprostone) to generic lubiprostone.
Naprosyn (naproxen) Oral Suspension, meloxicam suspension, and ketoprofen 25 mg – Commercial National Select Formulary	TBD	Policy revised for meloxicam suspension and Naprosyn (naproxen) suspension: member must have an inability to swallow tablets and capsules and also have experienced a therapeutic failure or intolerance to generic ibuprofen suspension. If reauthorization is requested for meloxicam suspension, or Naprosyn (naproxen) suspension, the prescriber must attest that the member has experienced a positive clinical response to therapy as well as the member still has an inability to swallow tablets and capsules. Remove NSAID oral suspensions from automatic approval criteria.
Non-preferred Atypical Antipsychotic Medications	04/12/2023	Policy revised to reflect availability of generic Latuda (lurasidone). For both the bipolar indication as well as the schizophrenia indication, if the request is for brand Latuda, the member must have experienced therapeutic failure or intolerance to generic lurasidone.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Non-Preferred Bupropion Products – Commercial and Healthcare Reform	TBD	Policy revised to require therapeutic failure or intolerance to a plan-preferred, generic antidepressant, other than a bupropion product. In addition, if the request is for brand Wellbutrin XL, the member must have experienced therapeutic failure or intolerance to generic, extended-release bupropion HCl. If the request is for brand Wellbutrin SR, the member must have experienced therapeutic failure or intolerance to generic, sustained-release bupropion HCl. If the request is for Auvelity, Aplenzin, Forfivo XL, or Bupropion XL 450 mg, the member has experienced therapeutic failure or intolerance to plan-preferred, generic sustained-release or extended-release bupropion HCl. Policy revised for reauthorization: for Auvelity (bupropion/dextromethorphan), Aplenzin (bupropion), Forfivo XL (bupropion), and Bupropion XL 450 mg (bupropion), the prescriber must attest that the member has experienced positive clinical response to therapy. For brand Wellbutrin SR (bupropion) and brand Wellbutrin XL (bupropion), the prescriber must attest that the member has experienced positive clinical response to therapy. In addition, the member must have experienced therapeutic failure or intolerance to generic bupropion SR (for Wellbutrin SR) or generic bupropion XL (for Wellbutrin XL).
Non-Preferred Liquid Dosage Form Drugs – Commercial and Healthcare Reform	5/15/2023	Policy revised to add Atorvaliq (atorvastatin) and Flolipid (simvastatin) oral suspension. Automatic approval criteria removed.
Non-Preferred NSAIDs – Commercial and Healthcare Reform	TBD	Policy revised for Indocin (indomethacin) suspension, meloxicam suspension, and Naprosyn (naproxen) suspension: member must be unable to swallow tablets and capsules and also have experienced a therapeutic failure or intolerance to plan-preferred, generic ibuprofen suspension. If reauthorization is requested for Indocin suspension, meloxicam suspension, or Naprosyn (naproxen) suspension, the prescriber must attest that the member has experienced a positive clinical response to therapy as well as the member has an inability to swallow tablets and capsules. Remove NSAID oral suspensions from automatic approval criteria.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Non-Preferred Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised to add Brenzavvy (bexagliflozin) to require diagnosis of type 2 diabetes mellitus; trial/failure/contraindication to a metformin-containing product or will be using Brenzavvy (bexagliflozin) in combination with a metformin-containing product; and trial/failure/contraindication to products containing canagliflozin (Invokana, Invokamet, Invokamet XR), dapagliflozin (Farxiga, Xigduo XR), and empagliflozin (Jardiance, Synjardy, Synjardy XR). Reauthorization criteria to require attestation that the member requires continued therapy with Brenzavvy (bexagliflozin).
Proton Pump Inhibitors (PPIs) – Healthcare Reform	04/12/2023	Policy terminated (combined with J-0334)
Relexxii (methylphenidate hydrochloride) – Commercial and Healthcare Reform	07/01/2023	Policy revised for Relexxii (methylphenidate hydrochloride ER) to target all strengths of Relexxii.
Seysara (sarecycline) – Commercial and Healthcare Reform	04/12/2023	Policy revised to require therapeutic failure, intolerance, or contraindication to at least (1) generic topical agent indicated for the treatment of acne and therapeutic failure, intolerance, or contraindication to at least two (2) generic plan preferred oral antibiotics indicated for the treatment of acne.
Trulance (plecanatide) – Commercial and Healthcare Reform	04/12/2023	Policy revised for Trulance (plecanatide) to update step for Amitiza (lubiprostone) to generic lubiprostone.
Xhance (fluticasone propionate) – Commercial and Healthcare Reform	04/12/2023	Policy revised to reflect updated indication of Xhance (fluticasone propionate) for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in patients 18 years of age or older. Authorization criteria updated to the member has a diagnosis of CRSwNP.
Zelnorm (tegaserod) – Commercial and Healthcare Reform	04/12/2023	Policy revised for Zelnorm (tegaserod) to update step for Amitiza (lubiprostone) to generic lubiprostone.
Acute Migraine Therapies – Commercial and Healthcare Reform	TBD	Policy revised for Cambia (diclofenac potassium) to step through generic if request is for brand and to step through diclofenac potassium 50 mg tablets or have the inability to swallow tablets. Initial criteria revised for Frova (frovatriptan), Maxalt MLT (rizatriptan), Relpax (eletriptan), Migranal (dihydroergotamine), Zomig Nasal Spray

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		(zolmitriptan), and Treximet (sumatriptan/naproxen) to step through respective generics if the request is for brand. Reauthorization criteria revised to require therapeutic failure or intolerance to the generic equivalent product for brand products.

*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
Airsupra (albuterol and budesonide)*	2 inhalers per 25 days	2 inhalers per 25 days
Atorvaliq (atorvastatin suspension)	4 bottles (600 mL) per 30 days	12 bottles (1,800 mL) per 90 days
Orenitram (treprostinil) Month 1 Titration Pack (168 tabs)	1 titration pack (168 tabs) per 720 days	1 titration pack (168 tabs) per 720 days
Orenitram (treprostinil) Month 2 Titration Pack (336 tabs)	1 titration pack (336 tabs) per 720 days	1 titration pack (336 tabs) per 720 days
Orenitram (treprostinil) Month 3 Titration Pack (252 tabs)	1 titration pack (252 tabs) per 720 days	1 titration pack (252 tabs) per 720 days
Revatio (sildenafil) suspension	2 bottles (224 mL) per 30 days	6 bottles (672 mL) per 90 days
Rowasa (mesalamine) rectal enema kit*	4 kits (28 enemas) per 28 days	6 kits (42 enemas) per 42 days
Takhzyro (lanadelumab-flyo) 150 mg/1mL	2 mL (2 syringes) per 28 days	6 mL (6 syringes) per 84 days
Tezspire (tezepelumab-ekko) pen injector	1 pen per 28 days	3 pens per 84 days

*Effective date to be determined.

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

No changes at this time.

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

Drug Name	Daily Limit
Apriso (mesalamine) extended-release capsules*	4 capsules (1,500 mg) per day
Asacol HD (mesalamine) delayed-release tablets*	168 tablets per 28 days
Austedo XR (deutetrabenazine)	6 mg tablets: 7 tablets/day; 12 mg tablets: 3 tablets per day; 24 mg tablets: 2 tablets per day
Brenzavvy (bexagliflozin)*	1 tablet per day
Canasa (mesalamine) rectal suppository*	28 suppositories per 28 days
Delzicol (mesalamine) delayed-release capsules*	6 capsules (2,400 mg) per day
Erleada 240 mg tablet	1 tablet per day
Filspari (sparsentan)	1 tablet per day
Jaypirca (pirtobrutinib)	100 mg: 2 tablets per day; 50 mg: 1 tablet per day
Jesduvroq (daprodustat)*	1 mg, 2 mg, 4 mg tablets: 1 tablet per day 6 mg tablets: 2 tablets per day 8 mg tablets: 3 tablets per day
Lialda (mesalamine) delayed-release tablets*	4 tablets (4,800 mg) per day
Lumakras (sotorasib) 320 mg	3 tablets per day
Orserdu (elacestrant)	86 mg tablets: 3 tablets per day 345 mg tablets: 1 tablet per day
Pentasa (mesalamine) 250 mg extended-release capsules*	448 capsules per 28 days
Pentasa (mesalamine) 500 mg extended-release capsules*	224 capsules per 28 days
Sfrowasa (mesalamine) rectal enema (non-kit)*	28 enemas per 28 days
Skyclarys (omaveloxolone)	3 capsules (150 mg) 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 nasal spray (4 mg/0.25 mL)	Naloxone nasal spray (4 mg/0.25 mL)	Opioid overdose reversal

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

Brand Name	Generic Name	Preferred Alternatives
Airsupra	albuterol and budesonide	Provider discretion
Atorvaliq	atorvastatin suspension	Provider discretion
Brenzavvy	bexagliflozin	Provider discretion

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

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

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

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

Brand Name	Generic Name	Comments
Naloxone nasal spray (4 mg/0.25 mL)	Naloxone nasal spray (4 mg/0.25 mL)	Opioid overdose reversal

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

No changes at this time.

Table 3. Products Not Added*
Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Preferred Alternatives

Airsupra	albuterol and budesonide	albuterol sulfate hfa
Atorvaliq	atorvastatin suspension	atorvastatin, rosuvastatin, simvastatin tablet
Austedo XR	deutetrabenazine	Provider discretion
Brenzavvy	bexagliflozin	Invokana, Jardiance
Dapzura RT	daptomycin	Provider discretion
Orenitram Month 1 Titration Pack (168 tabs)	treprostinil Month 1 Titration Pack (168 tabs)	Orenitram
Orenitram Month 2 Titration Pack (336 tabs)	treprostinil Month 2 Titration Pack (336 tabs)	Orenitram
Orenitram Month 3 Titration Pack (252 tabs)	treprostinil Month 3 Titration Pack (252 tabs)	Orenitram
Tezspire pen injector	tezepelumab-ekko pen injector	Provider discretion

*Physicians may request coverage of these products using the Prescription Drug Medication Request Form.

C. Additions to the Specialty Tier

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

Brand Name	Generic Name
Austedo XR*	deutetrabenazine
Dapzura RT*	daptomycin
Filspari	sparsentan
Jaypirca	pirtobrutinib
Lamzede	velmanase alfa-tycy
Orenitram Month 1 Titration Pack (168 tabs)*	treprostinil Month 1 Titration Pack (168 tabs)
Orenitram Month 2 Titration Pack (336 tabs)*	treprostinil Month 2 Titration Pack (336 tabs)
Orenitram Month 3 Titration Pack (252 tabs)*	treprostinil Month 3 Titration Pack (252 tabs)
Orserdu	elacestrant
Rykindo	risperidone
Skyclarys	omaveloxolone
Syfovre	pegcetacoplan
Tezspire pen injector*	tezepelumab-ekko pen injector

*Incentive Formulary Only

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Adalimumab BIOSIMILARS – Medicare	TBD	Policy revised for adalimumab biosimilars to allow approval for all of Humira's (adalimumab) FDA-approved indications, including pediatric

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		ulcerative colitis, uveitis, and hidradenitis suppurativa.
Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors – Medicare	TBD	Policy revised for Nexletol (bempedoic acid) and Nexlizet (bempedoic acid/ezetimibe) to remove LDLRAP1 gene mutation from the initial authorization criteria for heterozygous familial hypercholesterolemia (HeFH). Authorization duration revised to an initial authorization duration of 6 months and reauthorization duration of 12 months.
Administrative Prior Authorizations for Medicare Part D Plans – Medicare	04/12/2023	Policy revised to add Heplisav-B (Hepatitis B Vaccine, Recombinant) to BvD Hepatitis B vaccine criteria and to add Jynneos to new BvD Smallpox and Monkeypox Vaccine section.
Anti-EGFR and HER2 Kinase Inhibitors – Medicare	04/12/2023	Policy revised for Tukysa (tucatinib) to require diagnosis based on FDA-approved indication.
Aubagio (teriflunomide) – Medicare	TBD	Policy revised to require therapeutic failure or intolerance to generic teriflunomide if the request is for brand Aubagio (teriflunomide).
Austedo/Austedo XR (deutetrabenazine) – Medicare	TBD	Policy revised to add new extended-release product, Austedo XR (deutetrabenazine) to the policy. As with Austedo (deutetrabenazine), the member must have an FDA-approved diagnosis, and in addition, for a diagnosis of chorea associated with Huntington's disease, for members with comorbid depression, the prescriber must attest that the member is receiving adequate treatment for depression; the prescriber must also attest that the member is not actively suicidal.
BTK Inhibitors – Medicare	04/12/2023	Policy revised to remove age criteria for Brukinsa (zanubrutinib) and Zydelig (idelalisib). Policy revised to add Jaypirca (pirtobrutinib) to the policy. Jaypirca requires a diagnosis of mantle cell lymphoma (MCL); the MCL must be classified as relapsed/refractory (RR); the member must have received at least two previous lines of systemic therapy; one of the previous lines of therapy was a BTK inhibitor. Policy revised for Brukinsa (zanubrutinib) requiring diagnosis based on FDA-approved indication; and to remove requirement for age.
CDK Inhibitors – Medicare	04/12/2023	Policy revised for Kisqali (ribociclib) removing prescribers' attestation that the member is not a

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		candidate for therapy with Ibrance (palbociclib) and Verzenio (abemaciclib). Added prescriber attestation that the member is not a candidate for therapy to Kisqali and Verzenio to Ibrance's criteria.
CDK Inhibitors – Medicare	04/12/2023	Policy revised for Verzenio (abemaciclib) to remove Ki-67 score from endocrine therapy indication and removed requirement that the members are postmenopausal females, and males from aromatase inhibitor indication due to Verzenio's expanded indication.
Chronic Inflammatory Diseases – Medicare	04/12/2023	Policy revised for Kevzara (sarilumab) to require age and diagnosis based on FDA approved indication. Policy revised to add Amjevita (adalimumab-atto) to allow approval for all of Humira's (adalimumab) FDA approved indications. If the request is for Amjevita, the member has experienced therapeutic failure or intolerance to Humira (adalimumab).
Demser (metyrosine) – Medicare	TBD	New policy created for Demser (metyrosine) requiring the member to have a diagnosis of pheochromocytoma defined by elevated metanephrines in plasma or urine or tumor evidence from CT scan or MRI with FDA-approved indication, the member has experienced therapeutic failure, contraindication, or intolerance to one (1) selective alpha-blocker, and if the request is for brand Demser, the member has trial and failure of generic metyrosine.
Enjaymo (sutimlimab-jome) – Medicare	04/12/2023	Policy revised for Enjaymo (sutimlimab-jome) reauthorization to additionally allow attestation of reduced need for red blood cell (RBC) transfusions and other cold agglutinin disease (CAD) related symptoms, or reduced signs/symptoms of hemolysis.
Filspari (sparsentan) – Medicare	04/13/2023	New policy for Filspari (sparsentan) requiring diagnosis based on FDA-approved indication confirmed by biopsy and supported by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g or proteinuria ≥ 1 g/day; and trial/failure/contraindication to either an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB). Reauthorization to require a reduction in UPCR or proteinuria from baseline. Limitations of

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		Coverage to state that concomitant use of Filspari with renin-angiotensin system inhibitors or endothelin receptor antagonists will not be authorized.
Fingolimod – Medicare	04/12/2023	Policy revised to reflect availability of Gilenya (fingolimod) 0.25 mg. Gilenya 0.25 mg as well as Gilenya 0.5 mg will require an FDA-indicated diagnosis. Requirement for therapeutic failure or intolerance to generic fingolimod was removed since a generic fingolimod in a 0.25 mg dosage is not available.
Fleqsuvy (baclofen) – Medicare	04/12/2023	Policy revised to add Lyvispah (baclofen).
FLT3 Kinase Inhibitors – Medicare	04/12/2023	Policy revised for Rydapt (midostaurin) to remove age requirement from approval criteria.
Gamifant (emapalumab-lzsg) – Medicare	04/12/2023	Policy revised for Gamifant (emapalumab-lzsg) to require intolerance to conventional hemophagocytic lymphohistiocytosis (HLH) therapy, or contraindication to all; the member is a suitable candidate for stem cell transplantation (SCT), and attestation the member will discontinue Gamifant (emapalumab-lzsg) upon initiation of SCT and not readminister after SCT.
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) – Medicare	04/12/2023	Policy revised to add Rybelsus (semaglutide) as a step therapy option for Bydureon Bcise (exenatide extended-release) and Byetta (exenatide).
Gocovri and Osmolex ER (amantadine ER) – Medicare	04/12/2023	Policy revised to remove age requirement for Osmolex ER (amantadine extended release) for diagnosis of drug-induced extrapyramidal reactions.
Hereditary Angioedema – Medicare	04/12/2023	Policy revised for all hereditary angioedema products to remove age requirements.
High Risk Medications in the Elderly – Medicare	04/12/2023	Removal of cyclobenzaprine products from criteria.
Lamzede (velmanase alfa-tycv) – Medicare	04/13/2023	New policy for Lamzede (velmanase alfa-tycv) requiring FDA-approved indication.
Latuda (lurasidone) – Medicare	TBD	Policy revised to reflect availability of generic Latuda (lurasidone). For both the bipolar indication as well as the schizophrenia indication, if the request is for brand Latuda, the member must have experienced therapeutic failure or intolerance to generic lurasidone. Automatic approval criteria removed from policy.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Lyvispah (baclofen) – Medicare	04/12/2023	Policy terminated and criteria moved into policy J-1192.
Motegrity (prucalopride) – Medicare	04/12/2023	Policy revised for Motegrity (prucalopride) to update step for Amitiza (lubiprostone) to generic lubiprostone.
Nityr and Orfadin (nitisinone) – Medicare	TBD	New policy for Nityr (nitisinone) and Orfadin (nitisinone) requiring diagnosis confirmed by biochemical or genetic testing and the member has a diet restricted in tyrosine and phenylalanine and the member has experienced therapeutic failure or intolerance to generic nitisinone capsules. For Orfadin oral suspension the member has an inability to swallow. Authorization duration of 12 months.
Non-Preferred Statin Oral Suspensions – Medicare	04/13/2023	New policy for Atorvaliq (atorvastatin) requiring diagnosis based on FDA-approved indication and inability to swallow tablets.
Non-Preferred Statin Oral Suspensions – Medicare	TBD	Policy revised to add Flolipid (simvastatin) requiring diagnosis based on FDA-approved indication and inability to swallow tablets.
Noxafil (posaconazole) – Medicare	TBD	New policy created for Noxafil (posaconazole) to require diagnoses based on FDA approved indications. If the request is for brand Noxafil (posaconazole) delayed-release (DR) tablets, the member has tried/failed generic posaconazole DR tablets. For Noxafil (posaconazole) DR tablets in invasive aspergillosis infection treatment, the member has experienced therapeutic failure, contraindication, or intolerance to voriconazole. Age between 2 to 17 years required for Noxafil (posaconzole) PowderMix DR oral suspension
Orserdu (elacestrant) – Medicare	04/13/2023	New policy created for Orserdu (elacestrant) requiring the member to be a postmenopausal female or a male with appropriate diagnosis per FDA-approved indication, a tumor status of ER-positive, HER2-negative, with an ESR1 gene mutation, and to have experienced disease progression on or after an endocrine-based regimen.
PCSK9 Inhibitors – Medicare	04/12/2023	Policy revised for Leqvio (inclisiran), Praluent (alirocumab), and Repatha (evolocumab) to remove age requirement for all indications.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Programmed Death Receptor Therapies – Medicare	04/12/2023	Policy revised for Jemperli (dostarlimab-gxly) to require diagnosis based on FDA-approved indication. Policy revised for Keytruda (pembrolizumab) to require diagnosis based on FDA-approved indication.
Pulmonary Hypertension – Medicare	04/12/2023	Policy revised for Revatio (sildenafil) to add an exception to right heart catheterization when all of the following are met: the member is 17 years of age or younger, the risk of right heart catheterization outweighs the benefit, and the prescriber attests alternative studies were completed such as contrast-enhanced computed tomography (CT) scan, magnetic resonance imaging (MRI), or other specified testing ruling out other causes of PH (e.g., for congenital metabolic diseases, gastroesophageal reflux disease).
Pyrukynd (mitapivat) – Medicare	04/12/2023	Removed limitations of coverage regarding avoiding use in moderate to severe hepatic impairment as not filed.
Seysara (sarecycline) – Medicare	TBD	New policy created for Seysara (sarecycline) to require diagnosis of inflammatory lesions of non-nodular moderate to severe acne; therapeutic failure, intolerance, or contraindication to at least one (1) generic topical agent indicated for the treatment of acne; and therapeutic failure, intolerance, or contraindication to at least one (1) generic oral antibiotic indicated for the treatment of acne.
Sirturo (bedaquiline) – Medicare	TBD	New policy created for Sirturo (bedaquiline). The approval criteria include for the member to have a diagnosis of one of the following: extensively drug resistant tuberculosis, treatment-intolerant tuberculosis, or nonresponsive multidrug-resistant tuberculosis. The criteria also require the member to have experienced therapeutic failure, contraindication, or intolerance to one of the following: isoniazid or rifampin, rifabutin, or rifapentine. The member also must be using Sirturo in combination with at least 3 other drugs for tuberculosis.
Skyclarys (omaveloxolone) – Medicare	05/05/2023	New policy created for Skyclarys (omaveloxolone) to require age and diagnosis based on FDA-approved indication, confirmed by genetic testing.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Syfovre (pegcetacoplan) – Medicare	04/14/2023	New policy created for Syfovre (pegcetacoplan) to require a diagnosis of geographic atrophy secondary to age-related macular degeneration.
Symproic (naldemedine) and Relistor (methylnaltrexone bromide) – Medicare	04/12/2023	Policy revised for Relistor (methylnaltrexone bromide) and Symproic (naldemedine) to remove age criteria from initial authorization.
Trodelvy (sacituzumab govitecan-hziy) – Medicare	04/12/2023	Policy revised for Trodelvy (sacituzumab govitecan-hziy) to remove age requirement and to require diagnosis based on FDA-approved expanded indication.
Urea Cycle Disorder Medications – Medicare	TBD	Policy revised to clarify that Olpruva (sodium phenylbutyrate) will be used as adjunct to dietary management.
Zinplava (bezlotoxumab) – Medicare	04/12/2023	Policy revised for Zinplava (bezlotoxumab) to require that the member is diagnosed with clinically severe Clostridium difficile or Clostridium difficile ribotype 027/078/244 upon presentation.

*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
Authorized Generics of Inhaler Products – Medicare	04/12/2023	Policy revised to add fluticasone propionate/salmeterol HFA - authorized generic to policy and require a diagnosis of asthma and therapeutic failure or intolerance to brand Advair HFA (fluticasone propionate/salmeterol).
Brand Reliever Inhalers – Medicare	TBD	Policy revised to add Airsupra (budesonide and albuterol) to require FDA indication and trial/failure of generic albuterol.
Intravitreal Injections – Medicare	04/12/2023	Policy revised to include updated expanded indication allowing use of Eylea (aflibercept) for retinopathy of prematurity.
Non-Preferred Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Medicare	TBD	Policy revised to add Brenzavvy (bexagliflozin) to require diagnosis of type 2 diabetes mellitus and trial/failure/contraindication to both of the following drug products containing canagliflozin (Invokana, Invokamet, or Invokamet XR) and empagliflozin (Jardiance, Synjardy, or Synjardy XR).

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Roszet (rosuvastatin/ezetimibe) – Medicare	TBD	Policy to be terminated.

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)	Mail Order Quantity Limit (90 days)
Airsupra (albuterol and budesonide)	2 inhalers (18.2 mg) per 25 days	2 inhalers (18.2 mg) per 25 days
Apriso (mesalamine) extended-release capsules	4 capsules (1,500 mg) per day	4 capsules (1,500 mg) per day
Asacol HD (mesalamine) delayed-release tablets	6 tablets (4,800 mg) per day	6 tablets (4,800 mg) per day
Atorvaliq (atorvastatin suspension)	4 bottles (600 mL) per 30 days	12 bottles (1,800 mL) per 90 days
Austedo XR (deutetrabenazine)	6 mg tablets: 7 tablets/day; 12 mg tablets: 3 tablets per day; 24 mg tablets: 2 tablets per day	6 mg tablets: 7 tablets/day; 12 mg tablets: 3 tablets per day; 24 mg tablets: 2 tablets per day
Brenzavvy (bexagliflozin)	1 tablet per day	1 tablet per day
Canasa (mesalamine) rectal suppository	1 suppository (1,000 mg) per day	1 suppository (1,000 mg) per day
Delzicol (mesalamine) delayed-release capsules	6 capsules (2,400 mg) per day	6 capsules (2,400 mg) per day
Erleada 240 mg tablet	1 tablet per day	1 tablet per day
Filspari (sparsentan)	1 tablet per day	1 tablet per day
Jaypirca (pirtobrutinib)	100 mg: 2 tablets per day; 50 mg: 1 tablet per day	100 mg: 2 tablets per day; 50 mg: 1 tablet per day
Lialda (mesalamine) delayed-release tablets	4 tablets (4,800 mg) per day	4 tablets (4,800 mg) per day
Lumakras (sotorasib) 320 mg	3 tablets per day	3 tablets per day
Orenitram (treprostinil) Month 1 Titration Pack (168 tabs)	2 titration packs (336 tabs) per 365 days	2 titration packs (336 tabs) per 365 days
Orenitram (treprostinil) Month 2 Titration Pack (336 tabs)	2 titration packs (672 tabs) per 365 days	2 titration packs (672 tabs) per 365 days
Orenitram (treprostinil) Month 3 Titration Pack (252 tabs)	2 titration packs (504 tabs) per 365 days	2 titration packs (504 tabs) per 365 days
Orserdu (elacestrant)	86 mg tablets: 3 tablets per day	86 mg tablets: 3 tablets per day

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
	345 mg tablets: 1 tablet per day	345 mg tablets: 1 tablet per day
Pentasa (mesalamine) 250 mg extended-release capsules	16 capsules (4,000 mg) per day	16 capsules (4,000 mg) per day
Pentasa (mesalamine) 500 mg extended-release capsules	8 capsules (4,000 mg) per day	8 capsules (4,000 mg) per day
Revatio (sildenafil) suspension	7 bottles (784 mL) per 31 days	21 bottles (2,352 mL) per 90 days
Revatio (sildenafil) tablets	12 tablets per day	12 tablets per day
Rowasa (mesalamine) rectal enema kit	1 enema (4,000 mg) per day OR 4 kits (28 enemas) per 28 days	1 enema (4,000 mg) per day OR 4 kits (28 enemas) per 28 days
Rykindo (risperidone)	2 single-dose kits (4 mL) per 28 days	2 single-dose kits (4 mL) per 28 days
Sfrowasa (mesalamine) rectal enema (non-kit)	1 enema (60 mL) per day	1 enema (60 mL) per day
Skyclarys (omaveloxolone)	3 capsules (150 mg) per day	3 capsules (150 mg) per day
Syfovre (pegcetacoplan)	30 mg or 0.2 mL per 25 days	90 mg or 0.6 mL per 75 days
Takhzyro (lanadelumab-flyo) 150 mg/1mL	2 mL (2 syringes) per 28 days	6 mL (6 syringes) per 84 days
Tezspire (tezepelumab-ekko) pen injector	1 pen per 28 days	3 pens per 84 days
Vytorin (ezetimibe-simvastatin)	1 tablet per day	1 tablet per day

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