

Formulary Updates



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Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for **April 2022**. The formularies and pharmaceutical management procedures are updated every two months, and the following changes reflect the decisions made in April 2022 by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Please reference the guide below to navigate this communication:

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As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (accessible via NaviNet® or our website). Click the **PHARMACY PROGRAM/FORMULARIES** link from the menu on the left.



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Important Drug Safety Updates

[SYMJEPI® \(Epinephrine\) Injection by Adamis Pharmaceuticals Corporation: Recall – Potential Manufacturing Defect](#)

On March 21, 2022, Adamis Pharmaceuticals Corporation recalled the above product due to the potential clogging of the needle preventing the dispensing of epinephrine.

If a person is experiencing an allergic reaction and/or anaphylaxis and is unable to access life-saving epinephrine due to the syringe malfunction, it can lead to life-threatening consequences including death. Although not confirmed to be related to the recall, there have been two different customer complaints on three syringes, regarding difficulty in dispensing the product, to date. However, neither US WorldMeds nor Adamis Pharmaceuticals has received, or is aware of, any adverse events related to this recall.

[Orphenadrine Citrate 100 mg Extended Release Tablets by Sandoz, Inc.: Recall – Presence of a Nitrosamine Impurity](#)

On March 21, 2022, Sandoz Inc. recalled the above product due to the presence of a nitrosamine (N-methyl-N-nitroso-2-[(2-methylphenyl)phenylmethoxy]ethanamine (NMOA or Nitroso-Orphenadrine)) impurity, which has the potential to be above the U.S. Food and Drug Administration (FDA)'s Acceptable Daily Intake (ADI) limit of 26.5 ng/day.

Nitrosamines are substances with carcinogenic potency (substances that could cause cancer) when present above the allowable exposure limits. While the use of product belonging to the recalled lots may represent a risk to patients, to date, Sandoz has not received any reports of adverse events related to the presence of a nitrosamine impurity in the lot.

[Accuretic \(Quinapril HCl/Hydrochlorothiazide\), Quinapril and Hydrochlorothiazide Tablets, and Quinapril HCl/Hydrochlorothiazide Tablets by Pfizer: Recall – N-Nitroso-Quinapril Content](#)

On March 22, 2022, Pfizer recalled the above product due to the presence of a nitrosamine, N-nitroso-quinapril, above the 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.

These products are indicated for the treatment of hypertension. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. The products have a safety profile that has been established over 20 years of marketing authorization and through a robust clinical program. To date, Pfizer is not aware of reports of adverse events that have been assessed to be related to this recall.

[Insulin Glargine \(Insulin glargine-yfqn\) Injection, 100 units/mL \(U-100\) by Mylan Pharmaceuticals Inc., a Viatris Company: Recall – Potential Missing Label](#)

On April 12, 2022, Mylan Pharmaceuticals Inc., a Viatris Company, recalled the above product due to potential for the label to be missing on some vials.

For patients receiving treatment with more than one type of insulin (e.g., both short and long-acting insulin), a missing label on Insulin Glargine vials could lead to a mix-up of products/strengths, which may result in less optimal glycemic control (either high or low blood sugar) which could result in serious complications. To date, no adverse events related to this recall have been received for this product.

[ACCUPRIL® \(Quinapril HCl\) by Pfizer: Recall – N-Nitroso-Quinapril Content](#)

On April 22, 2022, Pfizer recalled the above product due to the presence of a nitrosamine, N-nitroso-quinapril, observed in recent testing above the 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.

Accupril is indicated for the treatment of hypertension, to lower blood pressure. Accupril is also indicated in the management of heart failure as adjunctive therapy when added to conventional therapy including diuretics and/or digitalis. Accupril has a safety profile that has been established over 30 years. To date, Pfizer is not aware of reports of adverse events that have been assessed to be related to this recall.

[03/30/2022 FDA recommends thyroid monitoring in babies and young children who receive injections of iodine-containing contrast media for medical imaging: Children with underlying conditions and newborns at higher risk](#)

The FDA has issued a recommendation that newborns and children 3 years of age or younger have follow-up thyroid monitoring within three weeks of receiving an injection of contrast media that contains iodine (“contrast dye”) used for X-rays and other medical imaging procedures. In addition, a new warning and monitoring recommendations within the prescribing information for the entire class of iodinated contrast media (ICM) have been approved.

While underactive thyroid or a temporary decrease in thyroid hormone levels were uncommon, all efforts should be made to identify and treat these conditions as early as possible to prevent future complications. Note that the risks and recommendations pertain to ICM injections given through an artery or vein, and this announcement is an update to a 2015 FDA alert regarding cases of underactive thyroid in infants receiving ICM.

[06/01/2022 FDA approval of lymphoma medicine Ukonig \(umbralisib\) is withdrawn due to safety concerns: Possible increased risk of death outweighs the benefits](#)

The FDA has withdrawn its approval for the cancer medicine Ukoniq (umbralisib) due to safety concerns. Prior to the withdrawal, Ukoniq was approved for both marginal zone lymphoma (MZL) and follicular lymphoma (FL). It was determined that risks of treatment with Ukoniq outweigh its benefits after a review of updated findings from the UNITY-CLL clinical trial continued to show a possible increased risk of death in patients receiving Ukoniq. After this determination, TG Therapeutics, the manufacturer of Ukoniq, voluntarily withdrew Ukoniq from the market for the uses of MZL and FL. Patients should stop taking Ukoniq and talk to their health care professionals regarding alternative treatments.

Highmark Formulary Update – April 2022

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 2022, unless otherwise noted.

Brand Name	Generic Name	Comments
Spikevax (COVID-19 vaccine)*	-	Prevention of COVID-19

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Aspruzo Sprinkle*	ranolazine	ranolazine ER, propranolol HCL solution, oral, amlodipine besylate tablet
Citalopram 30 mg capsule	citalopram	citalopram HBR tablet, escitalopram oxalate tablet, sertraline HCL tablet
Norliqva oral suspension	amlodipine oral suspension	amlodipine besylate, nifedipine ER, verapamil HCL tablet
Quviviq	daridorexant	zolpidem tartrate tablet, temazepam 15 mg, eszopiclone [^]
Ryaltris*	olopatadine/mometasone furoate	azelastine HCL aerosol, spray with pump (ML); fluticasone propionate spray, suspension
naloxone 10 mg/0.4 mL autoinjector*	-	Prescriber Discretion

Coverage may be contingent upon plan benefits.

*Effective date to be determined.

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

[^]alternative for Commercial Comprehensive only

Table 3. Additions to the Specialty Tier Copay Option

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

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

Brand Name	Generic Name
Cibinqo	abrocitinib
Fleqsuvy oral suspension	baclofen oral suspension
Ibsrela	tenapanor
Pyrukynd	mitapivat
Releuko	filgrastim-ayow
Vonjo	pacritinib

Table 4. Products to Be Removed or Shifted to Higher Tier – Effective July 2022

Brand name	Generic Name	Preferred Alternatives
All Commercial & Healthcare Reform Comprehensive products		
Afinitor 10 mg	everolimus	everolimus 10 mg tablet
Afinitor disperz 2 mg	everolimus	everolimus 2 mg tab for susp
Afinitor disperz 3 mg	everolimus	everolimus 3 mg tab for susp
Afinitor disprez 5 mg	everolimus	everolimus 5 mg tab for susp
butalbital/apap/caffeine 50-325-40	butalb/acetaminophen/caffeine	acetaminophen w/butalbital; butalbital-aspirin-caffeine tablet
Lanoxin	digoxin	digoxin tablet
Selzentry 150 mg	maraviroc	maraviroc
Selzentry 300 mg	maraviroc	maraviroc
Zebutal 50-325-40	butalb/acetaminophen/caffeine	butalbital-aspirin-caffeine tablet

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 2022, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
naloxone 10 mg/0.4 mL autoinjector*	-	3	Opioid overdose reversal
Spikevax (COVID-19 vaccine)*	-	3	Prevention of COVID-19

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were not added to the formulary			
Aspruzyo Sprinkle*	ranolazine	NF	ranolazine ER, propranolol HCL solution, oral, amlodipine besylate tablet
Cibinqo	abrocitinib	NF	Rinvoq ER; Dupixent Syringe (ML) 300 mg/2ML; Dupixent Pen-Pen Injector (ML) 300 mg/2ML
Citalopram 30 mg capsule	citalopram	NF	citalopram HBR tablet, escitalopram oxalate tablet, sertraline HCL tablet
Fleqsuvy oral suspension	baclofen oral suspension	NF	baclofen 10 mg, baclofen 20 mg, tizanidine HCL tablet
Ibsrela	tenapanor	NF	Linzess, Amitiza
Norliqva oral suspension	amlodipine oral suspension	NF	amlodipine besylate tablet, nifedipine ER, verapamil HCL tablet
Quviviq	daridorexant	NF	zolpidem tartrate tablet, temazepam 15 mg, eszopiclone
Releuko	filgrastim-ayow	NF	Zarxio
Ryaltris*	olopatadine/mometasone furoate	NF	azelastine HCL aerosol, spray with pump (ML); fluticasone propionate spray, suspension
Pyrukynd	mitapivat	NF	Prescriber Discretion
Vonjo	pacritinib	NF	Prescriber Discretion

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

*Effective date to be determined.

Table 2. Products to Be Removed or Shifted to Higher Tier – Effective July 2022

Brand Name	Generic Name	Preferred Alternatives
All Healthcare Reform Essential Products		
Afinitor 10 mg	everolimus	everolimus 10 mg tablet
Afinitor disperz 2 mg	everolimus	everolimus 2 mg tab for susp
Afinitor disperz 3 mg	everolimus	everolimus 3 mg tab for susp
Afinitor disprez 5 mg	everolimus	everolimus 5 mg tab for susp
butalbital/apap/caffeine 50-325-40	butalb/acetaminophen/caffeine	acetaminophen w/butalbital;
Lanoxin 62.5 mcg	digoxin	digoxin 62.5 mcg tablet
Selzentry 150 mg	maraviroc	maraviroc
Selzentry 300 mg	maraviroc	maraviroc
Zebutal 50-325-40	butalb/acetaminophen/caffeine	acetaminophen w/butalbital;
Zortress 1 mg	everolimus	everolimus 1 mg tablet

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 2022, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Spikevax (COVID-19 vaccine)*	-	3	Prevention of COVID-19
naloxone 10 mg/0.4 mL autoinjector*	-	4	Opioid overdose reversal
Items listed below were not added to the formulary			
Aspruzyo Sprinkle*	ranolazine	NF	propranolol HCL solution, oral, amlodipine besylate tablet, metoprolol tartrate tablet
Cibinqo	abrocitinib	NF	Rinvoq ER; Dupixent Syringe (ML) 300 mg/2ML; Dupixent Pen-Pen Injector (ML) 300 mg/2ML
Citalopram 30 mg capsule	citalopram	NF	citalopram HBR tablet, escitalopram oxalate tablet, sertraline HCL tablet
Fleqsuvy oral suspension	baclofen oral suspension	NF	baclofen 10 mg, baclofen 20 mg, tizanidine HCL tablet
Ibsrela	tenapanor	NF	Linzess, Amitiza
Norliqva oral suspension	amlodipine oral suspension	NF	amlodipine besylate, nifedipine ER, verapamil HCL tablet
Quviviq	daridorexant	NF	zolpidem tartrate tablet, temazepam 15 mg, eszopiclone
Releuko	filgrastim-ayow	NF	Nivestym
Ryaltris*	olopatadine/mometasone furoate	NF	azelastine HCL aerosol, spray with pump (ML); fluticasone propionate spray, suspension
Pyrukynd	mitapivat	NF	Prescriber Discretion
Vonjo	pacritinib	NF	Prescriber Discretion

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

*Effective date to be determined.

Table 2. Products to Be Removed or Shifted to Higher Tier – Effective July 2022

Brand Name	Generic Name	Preferred Alternatives
All Core Products		
Afinitor 10 mg	everolimus	everolimus 10 mg tablet
Afinitor disperz 2 mg	everolimus	everolimus 2 mg tab for susp
Afinitor disperz 3 mg	everolimus	everolimus 3 mg tab for susp
Afinitor disprez 5 mg	everolimus	everolimus 5 mg tab for susp
butalbital/apap/caffeine 50-325-40	butalb/acetaminophen/caffeine	acetaminophen w/butalbital; butalbital-aspirin-caffeine tablet
Selzentry 150 mg	maraviroc	maraviroc
Selzentry 300 mg	maraviroc	maraviroc

Zebutal 50-325-40	butalb/acetaminophen/ caffeine	acetaminophen w/butalbital; butalbital- aspirin-caffeine tablet
Zortress 1 mg	everolimus	everolimus 1 mg tablet

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)			
Cibinqo	abrocitinib	2	Treatment of atopic dermatitis
Vonjo	pacritinib	2	Treatment of myelofibrosis
Items listed below were added to the formulary (Non-Preferred)			
Aspruzyo Sprinkle*	ranolazine	3	ranolazine ER, propranolol HCL solution, oral, amlodipine besylate tablet
naloxone 10 mg/0.4 mL autoinjector*	-	3	Prescriber Discretion
Norliqva oral suspension*	amlodipine oral suspension	3	amlodipine besylate, nifedipine ER, verapamil HCL tablet
Pyrukynd	mitapivat	3	Prescriber Discretion
Quviviq*	daridorexant	3	zolpidem tartrate tablet, temazepam 15 mg, eszopiclone
Ryaltris*	olopatadine/mometasone furoate	3	azelastine HCL aerosol, spray with pump (ML); fluticasone propionate spray, suspension
Spikevax (COVID-19 vaccine) *	-	3	Prescriber Discretion
Items listed below were not added to the formulary			
Citalopram 30 mg capsule	citalopram	NF	citalopram tablets
Fleqsuvy	baclofen oral suspension	NF	baclofen tablets
Ibsrela	tenapanor	NF	Linzess, Trulance
Releuko	filgrastim-ayow	NF	Nivestym, Zarxio

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
Cibinqo	abrocitinib
Fleqsuvy oral suspension	baclofen oral suspension
Ibsrela	tenapanor
Pyrukynd	mitapivat
Releuko	filgrastim-ayow
Vonjo	pacritinib

Table 3. Products to Be Removed or Shifted to Higher Tier – Effective July 2022

Brand Name	Generic Name	Preferred Alternatives
All National Select Products		
Absorica Id 16 mg	isotretinoin, micronized	Accutane, Claravis
Absorica Id 24 mg	isotretinoin, micronized	Accutane, Claravis
Absorica Id 32 mg	isotretinoin, micronized	Accutane, Claravis
Absorica Id 8 mg	isotretinoin, micronized	Accutane, Claravis
Afinitor 10 mg	everolimus	everolimus
Afinitor 5mg	everolimus	everolimus
Afinitor 2.5 mg	everolimus	everolimus
Afinitor 7.5 mg	everolimus	everolimus
Afinitor disperz 2 mg	everolimus	everolimus
Afinitor disperz 3 mg	everolimus	everolimus
Afinitor disperz 5 mg	everolimus	everolimus
Antara 30 mg	fenofibrate, micronized	fenofibrate, fenofibric acid
Antara 90 mg	fenofibrate, micronized	fenofibrate, fenofibric acid
Bonjesta 20 mg	doxylamine succinate/vit b6	doxylamine succ-pyridoxine HCL
Bupropion xl 450 mg	bupropion hcl	bupropion HCL XL 150 mg tablet
Carospir 25 mg/ 5 ML	spironolactone	spironolactone tablet
Durezol 0.05%	difluprednate	difluprednate
Ertaczo 2%	sertaconazole nitrate	ciclopirox cream
Fabior 0.1%	tazarotene	tazarotene, tretinoin
Forfivo XL 450 mg	bupropion hcl	bupropion HCL XL 150 mg tablet
Halobetasol propionate 0.05%	halobetasol propionate	betamethasone dipropionate, clobetasol propionate
Hemangeol 4.28 mg/ML	propranolol hcl	propranolol HCL
Impoyz 0.025%	clobetasol propionate	betamethasone dipropionate, clobetasol propionate
Indocin 25 mg/5 ML	indomethacin	ibuprofen, naproxen
Indocin 50 mg	indomethacin	ibuprofen, naproxen
Lexette 0.05%	halobetasol propionate	betamethasone dipropionate, clobetasol propionate
Noritate 1 %	metronidazole	metronidazole
Oracea 40 mg	doxycycline monohydrate	doxycycline hyclate, doxycycline monohydrate
Qbrexza 2.4%	glycopyrronium tosylate	bromi-lotion

Sernivo 0.05%	betamethasone dipropionate	betamethasone dipropionate, betamethasone valerate
Tazorac 0.05% cream	tazarotene	tazarotene 0.1% cream
Tazorac 0.05% gel	tazarotene	tazarotene 0.1% cream, tretinoin gel
Tazorac 0.01% gel	tazarotene	tazarotene 0.1% cream, tretinoin gel
Ultravate 0.05% cream	halobetasol propionate	halobetasol propionate
Ultravate 0.05% lotion	halobetasol propionate	betamethasone dipropionate, clobetasol propionate
Ultravate 0.05% ointment	halobetasol propionate	halobetasol propionate
Veregen	sinecatechins	imiquimod, podofilox
Xerese	acyclovir/hydrocortisone	acyclovir, famciclovir

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors – Commercial and Healthcare Reform	4/26/22	Policy revised for Nexletol (bempedoic acid) and Nexlizet (bempedoic acid/ezetimibe) to allow for diagnosis of heterozygous familial hypercholesterolemia (HeFH) using the Make Early Diagnosis to Prevent Early Deaths (MEDPED) tool familial hypercholesterolemia possibility of “definite”.
ALK-Targeting Kinase Inhibitors – Commercial and Healthcare Reform	4/26/22	Policy revised for both Alecensa (alectinib) and Zykadia (ceritinib) for use in members 18 years of age or older. Policy revised for Xalkori (crizotinib) for metastatic non-small cell lung cancer in members 18 years of age or older with the respective genomic FDA-approved test. Policy revised for Zykadia (ceritinib) for use with the respective genomic FDA-approved test.
Benlysta (belimumab) – Commercial and Healthcare Reform	4/26/22	Reauthorization criteria revised for Benlysta (belimumab) for systemic lupus erythematosus (SLE) to require the member will continue to receive concomitant standard of care treatment with any of the following: corticosteroids, antimalarials, or immunosuppressants. Reauthorization criteria revised for Benlysta (belimumab) for lupus nephritis (LN) to require the member will continue to receive concomitant standard of care treatment with mycophenolate or azathioprine.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
BTK Inhibitors – Commercial and Healthcare Reform	3/21/22	Policy revised for Zydelig (idelalisib) to remove per the FDA withdrawn indication criteria for relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies and to remove criteria for relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.
Cibinqo (abrocitinib) – Commercial and Healthcare Reform	TBD	New policy created for Cibinqo (abrocitinib) to require the member is 18 years of age or older; specialist (dermatologist, allergist, immunologist) attests the member has a diagnosis of moderate to severe, refractory, atopic dermatitis (AD); therapeutic failure or intolerance to 1 generic topical corticosteroid, or AD with facial or anogenital involvement, or severe AD that topical therapy is not advisable for maintenance therapy if the member is incapable of applying topical therapies due to the extent of body surface (BSA) involvement or topical therapies are contraindicated due to severely damaged skin; therapeutic failure or intolerance to 1 generic topical calcineurin inhibitor, or severe AD and topical therapy is not advisable for maintenance therapy if the member is incapable of applying topical therapies due to the extent of body surface (BSA) involvement or topical therapies are contraindicated due to damaged skin; therapeutic failure or intolerance to 1 systemic therapy, or all are contraindicated; and therapeutic failure or intolerance to plan-preferred Rinvoq (upadacitinib) or Dupixent (dupilumab). Reauthorization criteria that the member has experienced a positive clinical response to therapy. Authorization duration of 12 months.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	4/27/22	Policy revised for Rinvoq (upadacitinib) for expanded indication in ulcerative colitis (UC) to require the member is 18 years of age or older; has a diagnosis of moderate or severe UC; and has experienced therapeutic failure or intolerance to Humira for the treatment of UC.
Chronic Inflammatory Diseases – Commercial National Select Formulary	4/27/22	Policy revised for Rinvoq (upadacitinib) for expanded indication in ulcerative colitis (UC) to require the member is 18 years of age or older; has a diagnosis of moderate or severe UC; and

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		has experienced therapeutic failure or intolerance to Humira for the treatment of UC.
Firdapse (amifampridine) – Commercial and Healthcare Reform	5/9/22	Policy revised to completely remove Ruzurgi (amifampridine) from policy because its indication has been invalidated. Step through Ruzurgi (amifampridine) to get Firdapse (amifampridine) removed.
Glatiramer Acetate – Commercial and Healthcare Reform	TBD	Policy revised to add brand and generic Copaxone (glatiramer) and Glatopa (glatiramer). Policy revised to add reauthorization criteria requiring disease stability, disease improvement, or delayed disease progression.
Gonadotropin-Releasing Hormone Agonists – Commercial and Healthcare Reform	TBD	New policy created for Lupron Depot (leuprolide acetate for depot suspension) and Lupron Depot-Ped (leuprolide acetate for depot suspension) to require appropriate FDA-approved indication. Lupron Depot 3.75 mg and 11.25 mg require trial and failure of Eligard
Hedgehog Pathway Inhibitors – Commercial and Healthcare Reform	4/27/22	Policy revised for Erivedge (vismodegib) to clarify criteria to label for members with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.
Homozygous Familial Hypercholesterolemia – Commercial and Healthcare Reform	3/28/22	Policy revised for Juxtapid (lomitapide) to remove that the member is not using in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Reauthorization criteria added that member will continue to receive concurrent lipid-lowering therapies.
Interferon Beta – Commercial and Healthcare Reform	TBD	New policy for Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Extavia (interferon beta-1b), Plegridy (peginterferon beta-1a), and Rebif (interferon beta-1a) requiring age 18 years of age or older and diagnosis of multiple sclerosis (clinically isolated syndrome, relapsing-remitting syndrome, or active secondary progressive disease). Patients with the commercial or healthcare reform comprehensive formularies on Extavia (interferon beta-1b) require therapeutic failure, contraindication, or intolerance to two plan preferred products: Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Extavia (interferon beta-1b), Plegridy (peginterferon beta-1a), and Rebif (interferon beta-1a). Reauthorization

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		requires prescriber attestation of disease stability, disease improvement or delayed disease progression.
Interleukin (IL)-5 Antagonists – Commercial and Healthcare Reform	TBD	Policy revised for Nucala (mepolizumab) to add criteria for newly approved strength (40 mg/0.4 mL). Initial authorization criteria updated for severe asthma to require the member to be 6 to 11 years of age if the request is for the 40 mg/0.4 mL prefilled syringe or 12 years of age or older if the request is for the 100 mg/mL prefilled syringe or autoinjector. This requirement was also added for reauthorization for severe asthma. For all other Nucala (mepolizumab) indications (eosinophilic granulomatosis with polyangiitis, hypereosinophilic syndrome, and chronic rhinosinusitis with nasal polyps), criterion added for initial authorization and reauthorization to ensure the request is for the 100 mg/mL prefilled syringe or autoinjector.
Katerzia (amlodipine benzoate) and Norliqva (amlodipine) – Commercial and Healthcare Reform	TBD	Policy revised to add Norliqva (amlodipine) oral solution that member is 18 years of age or older with diagnosis of coronary artery disease or is 6 years of age or older with diagnosis of hypertension, member has an inability to swallow tablets, and tried and failed amlodipine besylate tablets. Reauthorization attesting positive response and continues to have inability to swallow tablets.
Livmarli (maralixibat) – Commercial and Healthcare Reform	5/2/22	Policy revised for Livmarli (maralixibat) to add the NOTCH2 deletion or mutation into the approval criteria for diagnosis of Alagille syndrome.
Livtency (maribavir) – Commercial and Healthcare Reform	5/2/22	Policy revised for Livtency (maribavir) to additionally allow reauthorization if the member is requiring continued antiviral treatment to achieve virologic clearance. Quantity level limits revised to allow FDA-approved dosing for an additional total quantity corresponding to up to 24 weeks of therapy per 365 days if reauthorization criteria is met. Reauthorization duration updated to 16 weeks and total cumulative authorizations should not exceed 24 weeks.
Lotronex (alosetron) – Commercial and Healthcare Reform	5/4/22	Policy revised for Lotronex (alosetron) to remove bile acid sequestrants and selective serotonin reuptake inhibitors as a step therapy option for irritable bowel syndrome with diarrhea (IBS-D). Reauthorization criteria revised to add that if the

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		request is for brand Lotronex, the member has experienced therapeutic failure or intolerance to generic alosetron.
Lupkynis (voclosporin) – Commercial and Healthcare Reform	5/4/22	Reauthorization criteria revised for Lupkynis (voclosporin) to require the member will continue to receive concomitant standard of care for treatment of active lupus nephritis including a corticosteroid and mycophenolate mofetil.
Market Watch Programs – Delaware	TBD	Policy revised to add citalopram 30 mg capsules to require that member has tried and failed citalopram tablet, escitalopram, sertraline (generic). Policy revised to add Fleqsuvy (baclofen) to require that member has tried and failed baclofen and tizanidine. Policy revised to add Aspruzyo Sprinkle (ranolazine) to require that member has tried and failed generic ranolazine extended-release tablets. Policy revised to add Katerzia (amlodipine benzoate) oral suspension and Norliqva (amlodipine) oral solution to require member tried and failed amlodipine tablets. Policy revised to add Soanz (torsemide) to require member tried and failed bumetanide, furosemide, and torsemide tablets.
Market Watch Programs – New York, Pennsylvania and West Virginia	TBD	Policy revised to add citalopram 30 mg capsules to require that member has tried and failed citalopram tablet, escitalopram, sertraline (generic). Policy revised to add Fleqsuvy (baclofen) to require that member has tried and failed baclofen and tizanidine. Policy revised to add Aspruzyo Sprinkle (ranolazine) to require that member has tried and failed generic ranolazine extended-release tablets. Policy revised to add Katerzia (amlodipine benzoate) oral suspension and Norliqva (amlodipine) oral solution to require member tried and failed amlodipine tablets. Policy revised to add Soanz (torsemide) to require member tried and failed bumetanide, furosemide, and torsemide tablets.
New to Market Drug Policy – Commercial and Healthcare Reform	5/4/22	Policy revised to include more utilization management programs which could drive the prior authorization. Specific criteria added for authorized generics to require the trial and failure of the brand product and all other medications in the drug's category.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Non-Preferred Baclofen Products – Commercial and Healthcare Reform	5/4/22	Policy revised to include Fleqsuvy (baclofen) oral suspension for patients 12 years of age or older with a diagnosis of spasticity, flexor spasms, pain, clonus, or muscular rigidity resulting from multiple sclerosis, spinal cord injuries, or other spinal cord diseases, inability to swallow tablets, and therapeutic failure, contraindication, or intolerance to plan-preferred generic baclofen tablets. If the member is 18 years of age or older, the member must have therapeutic failure, contraindication, or intolerance to plan-preferred generic tizanidine. Reauthorization requiring positive clinical response to therapy and continued inability to swallow tablets.
Noxafil (posaconazole) – Commercial and Healthcare Reform	4/14/22	Policy revised for Noxafil (posaconazole) oral suspension for a diagnosis of oropharyngeal candidiasis to require therapeutic failure or intolerance to one of the following or all are contraindicated: clotrimazole or fluconazole; and therapeutic failure or intolerance to one of the following or all are contraindicated: itraconazole or nystatin.
Onpattro (patisiran) – Commercial and Healthcare Reform	5/9/22	Policy for Onpattro (patisiran) updated to remove the reauthorization requirement that members meet all initial authorization criteria.
Oral Isotretinoin Therapy – Commercial and Healthcare Reform	5/9/22	Policy revised for Absorica (isotretinoin) and Absorica LD (isotretinoin) to combine clindamycin-benzoyl peroxide gel and erythromycin-benzoyl peroxide gel as options with other topical antibiotic step. Oral antibiotic step updated to require the member has experienced therapeutic failure or intolerance to at least 1 oral antibiotic indicated for the treatment of acne, instead of listing out specific agents.
PCSK9 Inhibitors – Commercial and Healthcare Reform	5/9/22	Policy revised for Praluent (alirocumab) and Repatha (evolocumab) to remove limitation of coverage that member is not using in combination with Juxtapid (lomitapide). Added that Praluent (alirocumab) and Repatha (evolocumab) is not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor or small interfering RNA directed to PCSK9.
Procysbi (cysteamine bitartrate) – Commercial and Healthcare Reform	5/5/22	Policy revised for Procysbi (cysteamine bitartrate) to combine criteria for capsules and granules because removed step in granules criteria that

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		required member to either be unable to swallow capsules or have a gastrostomy tube (g-tube) in place. Removed reauthorization criteria step that required member to continue to be unable to swallow capsules or have a gastrostomy tube (g-tube) in place if requesting granules. Added initial authorization criteria that requires medication be prescribed by or in consultation with a physician who specializes in treating nephropathic cystinosis (e.g. nephrologist) and reauthorization criteria that the member has experienced therapeutic failure or intolerance to plan-preferred Cystagon (cysteamine bitartrate immediate-release).
Provigil (modafinil) and Nuvigil (armodafinil) – Commercial and Healthcare Reform	5/5/22	Policy revised for Provigil (modafinil) and Nuvigil (armodafinil) to include diagnosis of Idiopathic Hypersomnia (IH) in the Quantity Level Limits for Provigil section. In order to obtain up to 400 mg, the member must be inadequately controlled on Provigil (modafinil) 200 mg daily.
Provigil (modafinil) and Nuvigil (armodafinil) – Commercial and Healthcare Reform - Delaware	5/4/22	Policy revised for Provigil (modafinil) and Nuvigil (armodafinil) to include diagnosis of Idiopathic Hypersomnia (IH) in the Quantity Level Limits for Provigil section. In order to obtain up to 400 mg, the member must be inadequately controlled on Provigil (modafinil) 200 mg daily.
Pyrukynd (mitapivat) – Commercial and Healthcare Reform	5/2/22	New policy created for Pyrukynd (mitapivat) to require the member is 18 years of age or older; has a diagnosis of pyruvate kinase deficiency with hemolytic anemia; the provider submits documentation that the member has at least 2 mutant alleles in the PKLR gene, of which at least one (1) is a missense mutation; the provider submits documentation of both of the following: the member is not homozygous for the R479H mutation and the member does not have 2 non-missense variants, without the presence of another missense variant in the PKLR gene; the member meets one (1) of the following: the member's hemoglobin is 10 g/dL or less or the member has required at least 6 transfusions in the previous year; and the member is receiving concomitant treatment with folic acid. For reauthorization, the prescriber provides attestation that the member has experienced a hemoglobin increase of at least 1.5 g/dL from baseline or a

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		decrease in transfusion burden from baseline; and the member will continue to receive concomitant treatment with folic acid. For Pyrukynd (mitapivat) 50 mg tablets only, quantity level limit override criteria to require that the member is taking Pyrukynd (mitapivat) concomitantly with a moderate CYP3A inducer and the request is for 4 tablets per day. Initial authorization duration of 24 weeks and reauthorization duration of 12 months.
Siklos (hydroxyurea) – Commercial and Healthcare Reform	5/9/22	Policy revised for Siklos (hydroxyurea) to expand age to 2 years of age or older and the member meets one of the following: has an inability to swallow tablets or has experienced therapeutic failure or intolerance to generic hydroxyurea. Reauthorization criteria added to require prescriber attestation that the member has experienced a positive clinical response to therapy.
Symproic (naldemedine) – Commercial and Healthcare Reform	5/9/22	Policy revised to reflect FDA-approved indications: In addition to treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain, added patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation as an acceptable diagnosis. In addition, added another criterion to the reauthorization: in addition to attestation of clinical improvement or response to Symproic, the member must currently be receiving opioid pain management medication.
Urea Cycle Disorder Medications – Commercial and Healthcare Reform	5/9/22	Policy revised to include criteria for a new indication for Carbaglu (carglumic acid): adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) in adults and pediatric patients. If the request is for brand Buphenyl (sodium phenylbutyrate), the member has experienced therapeutic failure or intolerance to generic sodium phenylbutyrate. For Ravicti (glycerol phenylbutyrate), added criteria that UCD cannot be managed by amino acid supplementation alone. Removed limitation of coverage that stated Buphenyl (sodium phenylbutyrate) will not be approved for coverage of UCDs due to NAGS deficiency.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Viberzi (eluxadoline) – Commercial and Healthcare Reform	5/9/22	Policy revised for Viberzi (eluxadoline) to remove bile acid sequestrants and selective serotonin reuptake inhibitors as a step therapy option for irritable bowel syndrome with diarrhea (IBS-D). Reauthorization criteria revised to add the member's IBS-D symptoms continue to persist.
Vimpat (lacosamide) – Healthcare Reform	5/9/22	Policy revised to require therapeutic failure or intolerance to generic lacosamide for requests for brand Vimpat (lacosamide).
Vivlodex (meloxicam) – Commercial and Healthcare Reform	5/9/22	Policy revised to account for generic version of Vivlodex now available. In addition, added in New York, plan-preferred language for generic meloxicam tablets, our plan-preferred step product.
Vonjo (pacritinib) – Commercial and Healthcare Reform	5/24/22	New policy created to require age of 18 years or older, diagnosis of intermediate or high-risk myelofibrosis, and platelet count of less than $50 \times 10^9/L$. Reauthorization criteria that the member experienced disease improvement or delayed disease progression and has a platelet count of less than $50 \times 10^9/L$.
Welchol (colesevelam) chewable bars – Commercial and Healthcare Reform	TBD	Policy revised for Welchol (colesevelam) chewable bars to add familial hypercholesterolemia possibility of “definite” on the Make Early Diagnosis to Prevent Early Deaths (MEDPED) tool for diagnosis of heterozygous familial hypercholesterolemia (HeFH). Revised statin step to be fail maximally tolerated statin or be statin intolerant for HeFH. Revised current low-density lipoprotein cholesterol (LDL-C) to be $> 130 \text{ mg/dL}$ and statin step to be fail maximally tolerated statin or be statin intolerant for HeFH.
Zytiga and Yonsa (abiraterone acetate) – Commercial and Healthcare Reform	TBD	Policy revised for Zytiga (abiraterone acetate) to require for brand Zytiga therapeutic failure or intolerance to generic abiraterone 250 mg tablets; and if the request is for generic abiraterone acetate 500 mg tablets, the member is unable to tolerate generic abiraterone 250 mg tablets. Policy revised for Yonsa (abiraterone acetate micronized) to require for brand Yonsa that plan-preferred abiraterone acetate 250 mg tablets is ineffective or not tolerated. Reauthorization criteria added to require prescriber attestation of therapeutic response defined as either disease improvement or delayed disease progression; and if the request is for brand Zytiga or generic

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		abiraterone 500 mg, documentation that the AB-rated generic 250 mg tablets are ineffective or not tolerated; and if the request is for brand Yonsa, documentation that plan-preferred abiraterone acetate 250 mg tablets is ineffective or not tolerated.

*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
Additional Antibiotic Quantities – Commercial and Healthcare Reform	4/26/22	Policy revised for Vancocin (vancomycin) and Dificid (fidaxomicin) that the member has a recurrence of C. difficile infection confirmed by an episode of symptom onset.
Beta Blocker Management – Commercial and Healthcare Reform	4/27/22	Policy revised to remove Lopressor HCT (metoprolol tartrate; hydrochlorothiazide), Trandate (labetalol), and Zebeta (bisoprolol) as the drugs are off-market. Clarified brand Bystolic (nebivolol) is a target not its generic.
Gout Therapy – Commercial and Healthcare Reform	5/11/22	Policy revised to add Gloperba (colchicine) oral solution. Criteria that must be met for coverage of Gloperba requires that the member is 18 years of age or older, the member is using the medication for prophylaxis of gout attacks, the member has experienced therapeutic failure, contraindication, or intolerance to plan-preferred allopurinol OR the member is unable to swallow oral capsules or tablets, and the member has experienced therapeutic failure or intolerance to plan-preferred generic colchicine tablets OR the member is unable to swallow oral capsules or tablets. Gloperba has not been added to the automatic approval section.
Ibsrela (tenapanor) – Commercial and Healthcare Reform	TBD	Policy recreated for Ibsrela (tenapanor) since now available on the market to require the member is 18 years of age or older, has a diagnosis of irritable bowel syndrome with constipation (IBS-C), and has experienced therapeutic failure, contraindication, or intolerance to Linzess (linaclotide) [male and female] and Amitiza (lubiprostone) [female only]. Authorization duration of 12 months.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Insomnia Medications – Commercial and Healthcare Reform	TBD	Policy revised to add Quviviq (daridorexant) to require that the member requires therapy for insomnia characterized by difficulty with sleep onset and/or sleep maintenance and has experienced therapeutic failure, contraindication, or intolerance to two (2) of the following: zolpidem tartrate, zolpidem tartrate extended-release (ER), eszopiclone, or zaleplon. For Lunesta (eszopiclone), policy revised to require therapeutic failure or intolerance to generic eszopiclone and one (1) of the following: zolpidem tartrate, zolpidem tartrate ER, or zaleplon. For Rozerem (ramelteon), policy revised to require that if the request is for brand Rozerem (ramelteon), the member has experienced therapeutic failure or intolerance to generic ramelteon. For Silenor (doxepin), policy revised to require that if the request is for brand Silenor (doxepin), the member has experienced therapeutic failure or intolerance to one (1) of the following: generic doxepin 3 mg or generic doxepin 6 mg.
Minocycline Products – Commercial and Healthcare Reform	4/26/22	Policy for minocycline products for Commercial merged with J-0321 Minocycline Products - Healthcare Reform. Criteria for Minocin (minocycline) updated to require failure on generic minocycline immediate-release when used for bacterial infections. Coremino (minocycline ER) added to the policy (already coded).
Minocycline Products – Commercial National Select	5/2/22	Criteria for Minocin (minocycline) updated to require failure on generic minocycline immediate-release when used for bacterial infections.
Non-Preferred Extended-Release Stimulant Products – Commercial and Healthcare Reform	TBD	Policy revised to combine commercial and healthcare reform into one policy. Policy benefit updated to deterrent/patent extenders. Adzenys ER (amphetamine) oral suspension removed from policy since it is off-market. Narcolepsy criteria updated to require baseline data of excessive daytime sleepiness via the Epworth Sleepiness Scale (ESS) or Maintenance of Wakefulness Test (MWT) and baseline number of cataplexy episodes if applicable. Reauthorization criteria for narcolepsy updated to require a decrease in daytime sleepiness via the ESS or MWT compared to baseline and a decrease in cataplexy episodes if applicable.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Non-Preferred Extended-Release Stimulant Products – Commercial and Healthcare Reform	TBD	Policy revised to add Dyanavel XR (amphetamine) tablets for members with attention deficit hyperactivity disorder 6 years of age and older with therapeutic failure or intolerance to two plan preferred generic products (dexamethylphenidate extended release, dextroamphetamine/amphetamine extended release, dextroamphetamine extended release, or methylphenidate extended release (excluding 72 mg tablets and generic Aptensio XR)
Non-Preferred Topical Antifungals – Commercial and Healthcare Reform	5/2/22	Policy revised for Ertaczo (sertaconazole) cream, Ecoza (econazole) foam, and Naftin (naftifine) 2% gel to remove step option through ketoconazole 2% shampoo for a diagnosis of tinea pedis.
Proton Pump Inhibitors (PPIs) – Commercial	3/28/22	Policy revised for Dexilant (dexlansoprazole) to add authorized generic dexlansoprazole DR as a non-preferred product requiring ST.
Proton Pump Inhibitors (PPIs) – Commercial National Select Formulary	4/26/22	Policy revised for Dexilant (dexlansoprazole) to add authorized generic dexlansoprazole DR as a non-preferred product requiring ST.
Proton Pump Inhibitors (PPIs) – Healthcare Reform	3/28/22	Policy revised for Dexilant (dexlansoprazole) to add authorized generic dexlansoprazole DR as a non-preferred product requiring ST.
Tivorbex (indomethacin) and Indomethacin 20 mg – Commercial and Healthcare Reform	5/2/22	Policy revised to account for new single-source indomethacin 20 mg product now available. In addition, added in New York plan-preferred language for formulary oral generic indomethacin and oral generic NSAIDs. Also, specified plan-preferred indomethacin products as 25 mg and 50 mg
Xifaxan 550 mg (rifaximin) – Commercial and Healthcare Reform	5/2/22	Policy revised for Xifaxan (rifaximin) 550 mg to remove bile acid sequestrants and selective serotonin reuptake inhibitors as a step therapy option for irritable bowel syndrome with diarrhea (IBS-D). Reauthorization for IBS-D revised to add that the member's IBS-D symptoms continue to persist, and the member has experienced positive clinical response to therapy.

*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
Mayzent 0.25 mg (7) Dose Pack	1 pack per 720 days	1 pack per 720 days
COVID-19 Vaccines	5 doses per 720 days	5 doses per 720 days
Norliqva (amlodipine) oral suspension	2 bottles (300 mL) per 30 days	6 bottles (900 mL) per 90 days
Nurtec (rimegepant) ODT	24 tablets (3 packs) per 25 days	56 tablets (7 packs) per 75 days
Pyrukynd (mitapivat) taper pack	1 pack per 720 days	1 pack per 720 days
Rinvoq (upadactinib) 45 mg tablet	56 tablets per 365 days	56 tablets per 365 days
Ryaltris (olopatadine/mometasone furoate)	1 bottle (29 g) per 25 days	3 bottles (87 g) per 75 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
Aspruzyo Sprinkle (ranolazine)	2 sachets of extended-release granules per day
Cibinqo (abrocitinib)	1 tablet per day
citalopram 30 mg capsule	1 capsule per day
Fleqsuvy (baclofen) oral suspension	16 mL per day
Talzenna (talazoparib) 0.5 mg and 0.75 mg	1 capsule per day
Vonjo (pacritinib)	4 capsules per day
Mayzent 1 mg	1 tablet per day
Pyrukynd (mitapivat) tablets	2 tablets per day
Quviviq (daridorexant)	1 tablet 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](#)

Table 1. Preferred Products

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

No changes at this time.

Table 2. Non-Preferred Products

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

Brand Name	Generic Name	Preferred Alternatives
citalopram 30 mg capsule	-	citalopram tablet, escitalopram tablet, sertraline tablet
Fleqsuvy oral suspension	baclofen oral suspension	baclofen 10 mg, baclofen 20 mg
Norliqva oral suspension	amlodipine oral suspension	amlodipine besylate, nifedipine ER, verapamil tablet
Quviviq	daridorexant	zolpidem oral tablet, temazepam, doxepin oral tablet 3 mg
Ryaltris	olopatadine/mometasone furoate	azelastine aerosol,spray; azelastine spray,non-aerosol; fluticasone propionate spray,suspension
Aspruzyo Sprinkle	ranolazine	Prescriber Discretion
naloxone 10 mg/0.4 mL autoinjector	-	Prescriber Discretion

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

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

[Performance Formulary](#)

[Venture Formulary](#)

Table 1. Preferred Products

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

No changes at this time.

Table 2. Non-Preferred Products

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

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
Aspruzyo Sprinkle	ranolazine	ranolazine tablet; propranolol oral solution
citalopram 30 mg capsule		citalopram tablet, escitalopram tablet, sertraline tablet
Fleqsuvy oral suspension	baclofen oral suspension	baclofen 10 mg, baclofen 20 mg
Norliqva oral suspension	amlodipine oral suspension	amlodipine besylate, nifedipine ER, verapamil tablet
Quviviq	daridorexant	zolpidem oral tablet, temazepam, doxepin oral tablet 3 mg
Ryaltris	olopatadine/mometason e furoate	azelastine aerosol,spray; fluticasone propionate spray,suspension
naloxone 10 mg/0.4 mL autoinjector		Prescriber 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
Cibinqo	abrocitinib
Enjaymo	sutimlimab-jome
Ibsrela	tenapanor
Kimmtrak	tebentafusp-tebn
Pyrukynd tablets	mitapivat
Releuko	filgrastim-ayow
Vonjo	pacritinib

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors – Medicare	4/26/22	Policy revised for Nexletol (bempedoic acid) and Nexlizet (bempedoic acid/ezetimibe) to allow for diagnosis of heterozygous familial hypercholesterolemia (HeFH) using the Make Early Diagnosis to Prevent Early Deaths (MEDPED) tool familial hypercholesterolemia possibility of “definite”.
Administrative Prior Authorizations for Medicare Part D Plans – Medicare	4/26/22	Policy revised to add PreHevbrio (hepatitis B vaccine (recombinant)) to require criteria for Hepatitis B Vaccine, to add Covid-19 vaccine to 'Excluded From Coverage Under Medicare Part D' section, and to remove ICD-10 codes from Intravenous Immune Globulins (IVIG) section.
BTK Inhibitors – Medicare	4/26/22	Policy revised for Zydelig (idelalisib) to remove per the FDA withdrawn indication criteria for relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies and to remove criteria for relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.
Chronic Inflammatory Diseases – Medicare	4/26/22	Policy revised for Rinvoq (upadacitinib) for expanded indication in ulcerative colitis (UC) to require the member is 18 years of age or older; has a diagnosis of moderate or severe UC; and has experienced therapeutic failure or intolerance to at least 1 tumor necrosis factor (TNF) blocker therapy.
Cibinqo (abrocitinib) – Medicare	4/26/22	New policy created for Cibinqo (abrocitinib) to require the member has a diagnosis of moderate to severe, refractory, atopic dermatitis (AD); therapeutic failure or intolerance to 1 generic topical corticosteroid, or AD with facial or anogenital involvement, or severe AD that topical therapy is not advisable for maintenance therapy if the member is incapable of applying topical therapies due to the extent of body surface (BSA) involvement or topical therapies are contraindicated due to severely damaged skin; therapeutic failure or intolerance to 1 generic topical calcineurin inhibitor, or severe AD and topical therapy is not advisable for maintenance therapy if the member is incapable of applying topical therapies due to the extent of body surface (BSA) involvement or topical therapies are contraindicated due to damaged skin;

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		therapeutic failure or intolerance to 1 systemic therapy, or all are contraindicated; and therapeutic failure or intolerance to Rinvoq (upadacitinib) and Dupixent (dupilumab). Reauthorization criteria that the member has experienced a positive clinical response to therapy. Authorization duration of 12 months.
Enjaymo (sutimlimab-jome) – Medicare	4/27/22	New policy for Enjaymo (sutimlimab-jome) for patients with cold agglutinin disease which is not due to an underlying disease. Patients must meet one of the following: chronic hemolysis, positive direct antiglobulin test for C3d, or cold agglutinin titer of at least 64 at 4 degrees Celsius. Reauthorization requiring a decreased number of red blood cell transfusions compared to baseline.
Firdapse (amifampridine) – Medicare	TBD	Policy revised to completely remove Ruzurgi (amifampridine) from policy because its indication has been invalidated.
Fleqsuvy (baclofen) – Medicare	4/27/22	New policy for Fleqsuvy (baclofen) for patients with a diagnosis of spasticity, flexor spasms, pain, clonus, or muscular rigidity resulting from multiple sclerosis, spinal cord injuries, or other spinal cord diseases. The patient must have an inability to swallow generic baclofen tablets.
Homozygous Familial Hypercholesterolemia – Medicare	4/27/22	Policy revised for Juxtapid (lomitapide) to remove that the member is not using in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.
Ibsrela (tenapanor) – Medicare	4/28/22	Policy recreated for Ibsrela (tenapanor) since now available on the market to require the member is 18 years of age or older, has a diagnosis of irritable bowel syndrome with constipation (IBS-C), and has experienced therapeutic failure, contraindication, or intolerance to Linzess (linaclotide) [male and female] and lubiprostone [female only]. Authorization duration of 12 months.
IG for Medicare Part D – Medicare	4/28/22	Policy revised for immune globulin products for kawasaki disease to require the member is using immune globulin to prevent coronary artery aneurisms. For immune thrombocytopenic purpura, requiring a diagnosis classified as idiopathic and chronic.
IG for Medicare Part D – Medicare 2023	TBD	Policy revised for immune globulin products for B-cell Chronic Lymphocytic Leukemia to require

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		a diagnosis associated with recurrent bacterial infections OR hypogammaglobulinemia defined as Immunoglobulin G (IgG) level less than 600 mg/dL or evidence of specific antibody deficiency.
Katerzia (amlodipine benzoate) – Medicare	TBD	Policy revised for Katerzia (amlodipine benzoate) oral suspension to remove age when used for coronary artery disease and to remove trial and failure of amlodipine besylate tablets as an option keeping just member has an inability to swallow amlodipine tablets.
Katerzia (amlodipine benzoate) and Norliqva (amlodipine) – Medicare	TBD	Policy revised to add Norliqva (amlodipine) oral solution that member has diagnosis of coronary artery disease or is 6 years of age or older with diagnosis of hypertension and member has an inability to swallow amlodipine tablets.
Kimmtrak (tebentafusp-tebn) – Medicare	5/2/22	New policy created for Kimmtrak (tebentafusp-tebn) to label for members with HLA-A*02:01-positive unresectable or metastatic uveal melanoma.
Lupkynis (voclosporin) – Medicare	TBD	Reauthorization criteria revised for Lupkynis (voclosporin) to require the member will continue to receive concomitant standard of care for treatment of active lupus nephritis including a corticosteroid and mycophenolate mofetil.
Lyvispah (baclofen) – Medicare	TBD	Policy revised for Lyvispah (baclofen) to remove the member has experienced therapeutic failure or intolerance to generic baclofen tablets.
Margenza (margetuximab-cmkb) – Medicare	5/2/22	Policy created for Margenza (margetuximab) for use in combination with chemotherapy for the treatment of members 18 years of age or older with metastatic HER2 (human epidermal growth factor receptor 2)-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.
Non-Preferred Selective Serotonin Reuptake Inhibitors (SSRIs) – Medicare	5/4/22	Policy revised for sertraline 150 mg and 200 mg capsules to remove that member has used a sertraline product other than sertraline 150 mg or 200 mg capsules for initial dosage and titration. Policy revised to add citalopram 30 mg capsules to require that member has diagnosis of major depressive disorder, has received citalopram 20 mg ≥ 7 days, tried and failed generic citalopram

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		tablets and one (1) other preferred antidepressant.
Onpattro (patisiran) – Medicare	TBD	New policy for Onpattro (patisiran) created to ensure the member has a diagnosis of polyneuropathy associated with hereditary transthyretin-mediated amyloidosis supported by both a mutation in the TTR gene confirmed by genetic testing and a complete neurologic examination that shows clinical signs and symptoms of the disease. Policy also requires prescriber attestation that the member has a peripheral neuropathy impairment score (NIS) of 5 or greater and that the member is not simultaneously utilizing other gene targeted therapy for polyneuropathy of hereditary transthyretin-mediated amyloidosis. Policy also requires the member has experienced an improvement in polyneuropathy from baseline for reauthorization.
PCSK9 Therapies – Medicare	TBD	Policy revised to add "The member is not using Leqvio (inclisiran), Praluent (alirocumab), or Repatha (evolocumab) in combination with another siRNA directed to PCSK9" in limitations of coverage.
Procysbi (cysteamine bitartrate) – Medicare	5/4/22	Policy revised for Procysbi (cysteamine bitartrate) to combine criteria for capsules and granules because removed step in granules criteria that required member to either be unable to swallow capsules or have a gastrostomy tube (g-tube) in place.
Programmed Death Receptor Therapies – Medicare	5/9/22	Policy revised for Opdivo (nivolumab) for use in adults with resectable (tumors \geq 4 cm or node positive) non-small cell lung cancer in the neoadjuvant setting, in combination with platinum-doublet chemotherapy.
Pyrukynd (mitapivat) – Medicare	5/2/22	New policy created for Pyrukynd (mitapivat) to require that the member is 18 years of age or older and has a diagnosis of pyruvate kinase deficiency with hemolytic anemia, confirmed by one (1) the following: mutations in the PKLR gene or reduced activity of the pyruvate kinase enzyme. Reauthorization to require prescriber attestation of a positive clinical response defined as one of the following: an increase in hemoglobin level or a decrease in transfusion

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		burden from baseline. Initial authorization duration of 24 weeks and reauthorization duration of 12 months.
Symproic (naldemedine) and Relistor (methylnaltrexone bromide) – Medicare	5/9/22	Policy revised to reflect Relistor (methylnaltrexone bromide) and Symproic (naldemedine) FDA approved indications. For Symproic (naldemedine) and Relistor (methylnaltrexone bromide) tablet and injection, added a criterion allowing diagnosis of opioid induced constipation due to chronic pain related to prior cancer or its treatment and does not require frequent (e.g., weekly) opioid dosage escalation. Changed all references referring to Amitiza to lubiprostone.
Urea Cycle Disorder Medications – Medicare	TBD	Policy revised such that if the request is for brand Buphenyl, the member has experienced therapeutic failure or intolerance to generic sodium phenylbutyrate.
Vonjo (pacritinib) – Medicare	5/2/22	New policy created to require diagnosis of intermediate or high-risk myelofibrosis and attestation of a platelet count of less than $50 \times 10^9/L$.
Vuity (pilocarpine hydrochloride) – Medicare	2/23/22	Policy revised for Vuity (pilocarpine hydrochloride) to change age to 18 years of age or older from 40.
Welchol (colesevelam) chewable bars – Medicare	TBD	Policy revised for Welchol (colesevelam) chewable bars to add familial hypercholesterolemia possibility of “definite” on the Make Early Diagnosis to Prevent Early Deaths (MEDPED) tool for diagnosis of heterozygous familial hypercholesterolemia (HeFH). Revised current low-density lipoprotein cholesterol (LDL-C) to be $> 130 \text{ mg/dL}$ and statin step to be fail maximally tolerated statin or be statin intolerant for HeFH.
Zelnorm (tegaserod) – Medicare	5/9/22	Policy revised for Zelnorm (tegaserod) to require therapeutic failure or intolerance to lubiprostone authorized generic.

*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
Aspruzo Sprinkle (ranolazine) – Medicare	TBD	Policy created for Aspruzo Sprinkle (ranolazine) to require a diagnosis of chronic angina; the member has experienced therapeutic failure, contraindication, or intolerance to one (1) beta blocker; and has an inability to swallow ranolazine tablets.
Dymista (azelastine hydrochloride/fluticasone propionate) and Ryaltris (olopatadine hydrochloride/mometasone furoate monohydrate) – Medicare	TBD	Policy for Dymista (azelastine/fluticasone) updated to add Ryaltris (olopatadine /mometasone furoate) as a target drug. Approval criteria requires diagnosis of seasonal allergic rhinitis (SAR) and member to have experienced therapeutic failure or intolerance to generic azelastine hydrochloride/fluticasone propionate nasal spray. Name of policy updated to reflect addition.
Intravitreal Injections – Medicare	4/28/22	Policy updated to add Vabysmo (faricimab-svoa) and require diagnosis of Neovascular (Wet) Age-Related Macular Degeneration and trial, failure, or contraindication to Avastin (bevacizumab), or diagnosis of Diabetic Macular Edema.
Nonpreferred Topical Antifungals – Medicare	5/4/22	Policy revised to remove Ecoza (econazole) foam from policy criteria since MedD=N. Criteria revised for Ertaczo (sertaconazole) to remove ketoconazole 2% shampoo as a step option for a diagnosis of tinea pedis.
Rytary and Dhivy (carbidopa/levodopa) – Medicare	5/4/22	Policy revised to add in Dhivy (carbidopa-levodopa) for patients with FDA-labeled diagnosis and therapeutic failure or intolerance to one of the following: carbidopa/levodopa tablets or orally disintegrating tablets (ODT), carbidopa/levodopa ER tablets, or carbidopa/levodopa/entacapone tablets.
Soanz (torsemide) – Medicare	5/2/22	New policy created for Soanz (torsemide) to require member has a diagnosis of heart failure or renal disease, experiencing edema, and tried and failed generic furosemide and torsemide tablets. Authorization duration 12 months.

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)
Aspruzyo Sprinkle (ranolazine)	2 sachets of extended-release granules per day	2 sachets of extended-release granules per day
Cibinqo (abrocitinib)	1 tablet per day	1 tablet per day
citalopram 30 mg capsule	1 capsule per day	1 capsule per day
Enjaymo (sutimlimab-jome)	14 vials per 28 days	14 vials per 28 days
Fleqsuvy (baclofen) oral suspension	16 mL per day	16 mL per day
Kimmtrak (tebentafusp-tebn)	4 vials (2 mL) per 28 days	4 vials (2 mL) per 28 days
Mayzent 0.25 mg (7) Dose Pack	2 packs per 365 days	2 packs per 365 days
Mayzent 1 mg	1 tablet per day	1 tablet per day
Moderna COVID-19 Vaccine and Pfizer COVID-19 Vaccine	5 doses per 720 days	5 doses per 720 days
Norliqva (amlodipine) oral suspension	2 bottles (300 mL) per 30 days	6 bottles (900 mL) per 90 days
Pyrukynd (mitapivat) tablets	2 tablets per day	2 tablets per day
Pyrukynd (mitapivat) taper pack	2 packs per 365 days	2 packs per 365 days
Quiviviq (daridorexant)	1 tablet per day	1 tablet per day
Rinvoq (upadactinib) 45 mg tablet	112 tablets per 365 days	112 tablets per 365 days
Ryaltris (olopatadine/mometasone furoate)	1 bottle (29 g) per 30 days	3 bottles (87 g) per 90 days
Spikevax (COVID-19 vaccine)	5 doses per 720 days	5 doses per 720 days
Talzenna (talazoparib)	1 capsule per day	1 capsule per day
Talzenna (talazoparib) 0.25 mg	1 capsule per day	1 capsule per day
Vonjo (pacritinib)	4 capsules per day	4 capsules per day

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