Formulary Updates

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Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for June 2022. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in June by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Please reference the guide below to navigate this communication:

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

Anagrelide Capsules, USP 0.5 mg by Teva: Recall – Dissolution Test Failure

On May 23, 2022, Teva recalled the above product due to dissolution test failure detected during routine stability testing.

Administration of this product with lower dissolution—taking longer to dissolve once ingested—may result in decreased effectiveness or ineffectiveness of the drug to exert its platelet-reducing effect. Failed dissolution can result in a slower rate and extent of drug release leading to less anagrelide available in the body. For seriously ill patients with elevated platelet counts, less available anagrelide in the body could increase the risk of clotting (blood coagulation) and clotting or bleeding events such as a heart attack or stroke, which could be life threatening. To date, Teva has not received any product quality complaints or adverse event reports, of this nature, for the recalled lot.

Magnesium Citrate Saline Laxative Oral Solution by Vi-Jon, LLC: Recall – Microbial Contamination

On June 22, 2022, Vi-Jon, LLC recalled the above product due to microbial contamination.

Immunocompromised patients, who consume this product, may be at increased risk for invasive infections caused by Gluconacetobacter liquefaciens that could lead to serious, life-threatening, adverse health consequences. To date, Vi-Jon, LLC has not received any complaints related to this recall.

Morphine Sulfate 30 mg ER and Morphine Sulfate 60 mg ER by Bryant Ranch: Recall – Label-Mix Up

On June 29, 2022, Bryant Ranch Prepack Inc. recalled the above product due to a label mix-up.

Patients prescribed the 30 mg dose who receive the 60 mg dose could be at risk for overdose and death. Patients prescribed the 60 mg dose who receive the 30 mg dose may experience withdrawal and untreated pain if the dose given is too low. To date, Bryant Ranch Prepack Inc. has not received any reports of adverse events related to this recall.

Insulin Glargine Injection Pens by Mylan Pharmaceuticals Inc.: Recall – Missing Labels

On July 6, 2022, Mylan Pharmaceuticals Inc. recalled the above product due to the potential of missing labels on some pens.

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 pens 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.

Magnesium Citrate Laxative Oral Solution by Vi-Jon, LLC: Recall – Microbial Contamination

On July 15, 2022, Vi-Jon, LLC recalled the above product due to microbial contamination.

Immunocompromised patients, who consume this product, may be at increased risk for invasive infections caused by Gluconacetobacter liquefaciens that could lead to serious, life-threatening, adverse health consequences. To date, Vi-Jon, LLC has received one report of an adverse reaction potentially related to this recall. Vi-Jon, LLC is in the process of investigating this report.

06/30/2022 FDA warns about possible increased risk of death and serious side effects with cancer drug Copiktra (duvelisib)

On June 30, 2022, The FDA warned that Copkitra may lead to a possible increased risk of death compared to ofatumumab for the treatment of leukemia and lymphoma

Patients should talk to their doctors about Copkitra and discuss the risks and benefits of taking the medication with their doctor. Health care professionals should consider the risks versus the benefits in comparison to other available treatments.

Highmark Formulary Update – June 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 June 2022 unless otherwise noted.

Brand Name	Generic Name	Comments
Omnipod 5 G6 (Gen 5) Pods		Type 1 Diabetes
Omnipod DASH (Gen4) Intro Kit		Type 1 Diabetes
Omnipod 5 G6 (Gen 5) Intro Kit		Type 1 Diabetes
(Include Preferred Formulary that were added to Specialty Tier (e.g. Adbry, Cibinqo, Triumeq PD)		

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Adlarity transdermal system	donepezil transdermal system	donepezil tablets; donepezil tablets, disintegrating; rivastigmine capsules
Epsolay 5% cream	benzoyl peroxide 5% cream	metronidazole gel (gram), metronidazole cream (gram), metronidazole lotion (ML)
Ermeza	levothyroxine sodium	Levothyroxine sodium tablet, Euthyrox, Unithroid
Tlando	testosterone undecanoate	testosterone cypionate, testosterone gel in metered-dose pump 20.25/1.25g, testosterone gel in packet (gram)
Vivjoa	oteseconazole	fluconazole

Brand Name	Generic Name	Preferred Alternatives
Xelstrym	dextroamphetamine	dextroamphetamine sulfate ER; dextroamphetamine-amphet ER; methylphenidate HCL CD
Cuvrior	trientine tetrahydrochloride	penicillamine
Voquezna Dual Pak	vonoprazan, amoxicillin	Lansoprazole-Amoxicillin-Clarithromycin
Voquezna Triple Pak	vonoprazan, amoxicillin, clarithromycin	Lansoprazole-Amoxicillin-Clarithromycin
Ztalmy	ganaxolone	levetiracetam tablets, levetiracetam oral solution, topiramate tablets
Camzyos	mavacamten	Prescriber Discretion
Hyftor	sirolimus	Prescriber Discretion
Vijoice	alpelisib	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..

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
Adbry	tralokinumab-ldrm
Cibinqo	abrocitinib
Triumeq PD	dolutegravir/lamivudine/abacavir
Add Nonpreferred Specialty products too (e.g. Ztalmy, Hyftor, plus many additional products)	

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 June 2022, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Omnipod 5 G6 (Gen 5) Intro Kit		3	Type 1 Diabetes

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Omnipod 5 G6 (Gen 5) Pods		3	Type 1 Diabetes
Omnipod DASH (Gen4) Intro Kit		3	Type 1 Diabetes
Triumeq PD	dolutegravir/lamivudine/abacavir	3	HIV-1 infection
Adbry	tralokinumab-ldrm	4	Atopic Dermatitis
Cibinqo	abrocitinib	4	Atopic Dermatitis
Items listed below were not added to the formulary			
Adlarity transdermal system	donepezil transdermal system	NF	donepezil tablets; donepezil tablets, disintegrating; galantamine tablets
Cuvrior	trientine tetrahydrochloride	NF	penicillamine, trientine HCL
Epsolay 5% cream	benzoyl peroxide 5% cream	NF	metronidazole gel (gram) 0.75%, metronidazole cream (gram) 0.75%, azelaic acid
Ermeza	levothyroxine sodium	NF	Levothyroxine sodium tablet, Euthyrox, Unithroid
Tlando	testosterone undecanoate	NF	testosterone cypionate, testosterone enanthate, testosterone gel in packet (gram) 25mg (1%)
Vivjoa	oteseconazole	NF	fluconazole
Xelstrym	dextroamphetamine	NF	dextroamphetamine sulfate ER; dextroamphetamine-amphet ER; methylphenidate HCL CD
Ztalmy	ganaxolone	NF	levetiracetam tablets, levetiracetam oral solution, topiramate tablets
Camzyos	mavacamten	NF	Prescriber Discretion
Hyftor	sirolimus	NF	Prescriber Discretion
Vijoice	alpelisib	NF	Prescriber Discretion
Voquezna Dual Pak	vonoprazan, amoxicillin	NF	Prescriber Discretion
Voquezna Triple Pak	vonoprazan, amoxicillin, clarithromycin	NF	Prescriber Discretion

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

C. Changes to the Highmark Core Formulary

The Core Formulary is a closed formulary for select Commercial Individual plans. A list of drugs included on the Core Formulary, listed by therapeutic class, is available here.

Table 1. Formulary Updates

All formulary changes effective June 2022, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Omnipod 5 G6 (Gen 5) Intro Kit		3	Type 1 Diabetes
Omnipod 5 G6 (Gen 5) Pods		3	Type 1 Diabetes
Omnipod DASH (Gen4) Intro Kit		3	Type 1 Diabetes
Triumeq PD	dolutegravir/lamivudine/abacavir	3	HIV-1 infection
Adbry	tralokinumab-ldrm	4	Atopic Dermatitis
Cibinqo	abrocitinib	4	Atopic Dermatitis
Items listed below were not added to the formulary			
Adlarity transdermal system	donepezil transdermal system	NF	donepezil tablets; donepezil tablets, disintegrating; rivastigmine capsules
Cuvrior	trientine tetrahydrochloride	NF	penicillamine tablet, trientine HCL
Epsolay 5% cream	benzoyl peroxide 5% cream	NF	metronidazole gel (gram) 0.75%, metronidazole cream (gram) 0.75%
Ermeza	levothyroxine sodium	NF	Levothyroxine sodium tablet, Euthyrox, Unithroid
Tlando	testosterone undecanoate	NF	testosterone cypionate, testosterone enanthate, testosterone gel in metered-dose pump 20.25/1.25g
Vivjoa	oteseconazole	NF	fluconazole
Xelstrym	dextroamphetamine	NF	dextroamphetamine sulfate ER; dextroamphetamine-amphet ER; methylphenidate HCL CD
Ztalmy	ganaxolone	NF	levetiracetam tablets, topiramate tablets, phenobarbital tablets
Camzyos	mavacamten	NF	Prescriber Discretion
Hyftor	sirolimus	NF	Prescriber Discretion
Vijoice	alpelisib	NF	Prescriber Discretion
Voquezna Dual Pak	vonoprazan, amoxicillin	NF	Prescriber Discretion
Voquezna Triple Pak	vonoprazan, amoxicillin, clarithromycin	NF	Prescriber Discretion

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

*Effective date to be determined.

D. Changes to the Highmark National Select Formulary

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

Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (Preferred)			
Adbry	tralokinumab-ldrm	2	Atopic Dermatitis
Omnipod 5 G6 (Gen 5) Intro Kit		2	Type 1 Diabetes
Omnipod 5 G6 (Gen 5) Pods		2	Type 1 Diabetes
Omnipod DASH (Gen4) Intro Kit		2	Type 1 Diabetes
Triumeq PD	dolutegravir/lamivudine/abacavir	2	HIV-1 infection
Vijoice	alpelisib	2	PIK3CA-Related Overgrowth Spectrum (PROS)
Items listed below were added to the formulary (Non-Preferred)			
Adlarity transdermal system	donepezil transdermal system	3	donepezil tablets; donepezil tablets, disintegrating; rivastigmine capsules
Cuvrior*	trientine tetrahydrochloride	3	penicillamine
Epsolay 5% cream	benzoyl peroxide 5% cream	3	metronidazole gel (gram), metronidazole cream (gram), metronidazole lotion (ML)
Ermeza*	levothyroxine sodium	3	Levothyroxine sodium tablet
Tlando	testosterone undecanoate	3	testosterone cypionate, testosterone gel in metered-dose pump 20.25/1.25g, testosterone gel in packet (gram)
Xelstrym*	dextroamphetamine	3	dextroamphetamine sulfate ER; dextroamphetamine-amphet ER; methylphenidate HCL CD
Voquezna Dual Pak	vonoprazan, amoxicillin	3	Lansoprazole-Amoxicillin-Clarithromycin
Voquezna Triple Pak	vonoprazan, amoxicillin, clarithromycin	3	Lansoprazole-Amoxicillin-Clarithromycin
Ztalmy	ganaxolone	3	levetiracetam tablets, levetiracetam oral solution, topiramate tablets
Vivjoa*	oteseconazole	3	Prescriber Discretion
Hyftor*	sirolimus	3	Prescriber Discretion

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Hyftor*	sirolimus	3	Prescriber Discretion
Camzyos	mavacamten	3	Prescriber Discretion
Items listed below were not added to the formulary			

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
Omnipod 5 G6 (Gen 5) Intro Kit	
Omnipod 5 G6 (Gen 5) Pods	
Omnipod DASH (Gen4) Intro Kit	
Triumeq PD	dolutegravir/lamivudine/abacavir
Add all other products being added to Specialty Copay DL (should mirror the Comprehensive Specialty Tier table)	

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Acyclovir Topical Cream Products – Commercial	10/01/2022	Policy revised to include new criteria for Zovirax (acyclovir) topical cream for use in members 12 years of age or older with a diagnosis of recurrent herpes labialis (cold sores) after experiencing therapeutic failure or intolerance to all of the following: generic oral acyclovir, either generic oral valacyclovir or famciclovir (or both valacyclovir and famciclovir are contraindicated), and plan-preferred acyclovir 5% ointment. Policy revised for both Xerese (acyclovir 5% and hydrocortisone 1%) topical cream and Zovirax (acyclovir) topical cream to require that the member has experienced positive clinical response to therapy and therapeutic failure or intolerance to plan-preferred acyclovir 5% ointment.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Adbry (tralokinumab) – Commercial and Healthcare Reform	06/23/2022	Policy revised for Adbry (tralokinumab-ldrm) in atopic dermatitis (AD) to remove double topical step and now require therapeutic failure or intolerance to one topical corticosteroid or one topical calcineurin inhibitor, or attestation that the member has severe AD where topical therapy is not advisable evidenced by a large proportion of body surface area or severely damaged skin. If the patient has already had a trial of at least one biologic agent, the patient is not required to "step back" and try a non-biologic agent. Criteria revised to remove trial/failure step of Rinvoq (upadacitinib) or Dupixent (dupilumab).
Anti-EGFR and HER2 Kinase Inhibitors – Commercial and Healthcare Reform	07/08/2022	Policy revised for Tykerb (lapatinib) to require step through generic lapatinib.
Bynfezia (octreotide acetate) – Commercial and Healthcare Reform	07/01/2022	Policy for Bynfezia (octreotide acetate) terminated as drug is no longer on market.
CGRP Inhibitors – Commercial and Healthcare Reform	05/23/2022	Policy revised to exclude the national select formulary.
CGRP Inhibitors and Reyvow (lasmiditan) – Commercial National Select Formulary	05/23/2022	New policy for Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm), Emgality (galcanezumab-gnlm), Nurtec (rimegepant), Qulipta (atogepant), Reyvow (lasmiditan), and Ubrelvy (ubrogepant) requiring age and diagnosis based on FDA-approved indications. For prophylactic use, attestation of baseline average monthly migraine days, not caused by medication rebound/overuse/lifestyle, and trial/failure/contraindication to one agent from two different prophylactic classes. Reauthorization for preventive use requires a 50% reduction in number of headache days per month, 4 from baseline (episodic), or 5 from baseline (chronic). When

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		used for acute use, trial/failure/contraindication to one generic triptan (sumatriptan, rizatriptan, or zolmitriptan) with reauthorization of a positive clinical response to therapy. For concomitant acute and preventive use, attestation that benefits outweigh risks.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	06/23/2022	Policy revised for Rinvoq (upadacitinib) in atopic dermatitis (AD) to remove double topical step and now require therapeutic failure or intolerance to one topical corticosteroid or one topical calcineurin inhibitor, or attestation that the member has severe AD where topical therapy is not advisable evidenced by a large proportion of body surface area or severely damaged skin.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	06/17/2022	Policy revised for Rinvoq (upadacitinib) to add new indication of ankylosing spondylitis added requiring age, diagnosis based on FDA-approved indication, trial/failure of 1 NSAID or contraindication to all, and trial/failure of Humira or Enbrel. Expanded indication for Olumiant (baricitinib) for treatment of COVID-19 in hospitalized adults not covered under the pharmacy benefit.
Chronic Inflammatory Diseases – Commercial National Select Formulary	06/23/2022	Policy revised for Rinvoq (upadacitinib) in atopic dermatitis (AD) to remove double topical step and now require therapeutic failure or intolerance to one topical corticosteroid or one topical calcineurin inhibitor, or attestation that the member has severe AD where topical therapy is not advisable evidenced by a large proportion of body surface area or severely damaged skin.
Chronic Inflammatory Diseases – Commercial National Select Formulary	06/17/2022	Policy revised for Rinvoq (upadacitinib) to add new indication of ankylosing spondylitis added requiring

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		age, diagnosis based on FDA-approved indication, trial/failure of 1 NSAID or contraindication to all, and trial/failure of Humira or Enbrel. Expanded indication for Olumiant (baricitinib) for treatment of COVID-19 in hospitalized adults not covered under the pharmacy benefit.
Cibinqo (abrocitinib) – Commercial and Healthcare Reform	06/23/2022	Policy revised for Cibinqo (abrocitinib) in atopic dermatitis (AD) to remove double topical step and now require therapeutic failure or intolerance to one topical corticosteroid or one topical calcineurin inhibitor, or attestation that the member has severe AD where topical therapy is not advisable evidenced by a large proportion of body surface area or severely damaged skin. If the patient has already had a trial of at least one biologic agent, the patient is not required to "step back" and try a non-biologic agent. Criteria revised to remove trial/failure step of Rinvoq (upadacitinib) or Dupixent (dupilumab).
Conjupri (levamlodipine) – Commercial and Healthcare Reform	07/08/2022	Policy revised for Conjupri (levamlodipine) to target the generic and if request is for brand Conjupri, trial and failure of generic levamlodipine tablets.
Cresemba (isavuconazonium sulfate) – Commercial and Healthcare Reform	10/01/2022	New policy created for Cresemba (isavuconazonium sulfate) for a diagnosis of invasive aspergillosis infection treatment to require the member is 18 years of age or older, and experienced therapeutic failure, contraindication, or intolerance to voriconazole. For a diagnosis of invasive mucormycosis infection treatment, the member is 18 years of age or older. Maintenance criteria requiring attestation of continued indicators of active disease (e.g., histopathology, fungal culture). Authorization duration of 3 months.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Cuvposa (glycopyrrolate) oral solution – Commercial and Healthcare Reform	07/06/2022	Policy revised for Cuvposa (glycopyrrolate oral solution) to require trial/failure to generic glycopyrrolate solution for initial authorization and reauthorization.
Dupixent (dupilumab) – Commercial and Healthcare Reform	06/23/2022	Policy revised for Dupixent (dupilumab) in atopic dermatitis (AD) to remove double topical step and now require therapeutic failure or intolerance to one topical corticosteroid or one topical calcineurin inhibitor, or attestation that the member has severe AD where topical therapy is not advisable evidenced by a large proportion of body surface area or severely damaged skin. If the patient has already had a trial of at least one biologic agent, the patient is not required to "step back" and try a non-biologic agent.
Fertility – Commercial and Select Healthcare Reform Plans	07/05/2022	Policy revised for Fertility to combine NSF and Commercial (non-NSF)/Healthcare Reform (all non-NY) lines of business into a single policy (J-0001) and add requirement that if a member does not have the NSF formulary and the request is for Gonal-f, Gonal-f RFF, or Gonal-f RFF Redi-ject, they have experienced therapeutic failure or intolerance to Follistim AQ. Specified Crinone strength of 8% throughout policy because 4% strength is not indicated for fertility and not part of Fertility benefit, so this policy is not applicable to the 4% strength. Split out Gonal-f RFF and Gonal-f RFF Redi-ject criteria to only include criteria related to their FDA-approved indications of assisted reproductive technology and ovulation induction.
Fertility – Commercial National Select Formulary	07/01/2022	Policy for Fertility terminated so that NSF and Commercial (non-NSF)/Healthcare Reform (all non-New York) lines of business can be

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		combined into a single policy (Policy J-0001).
Fertility – New York Commercial and Healthcare Reform	07/08/2022	Policy revised for Fertility to specify Crinone strength of 8% throughout policy because 4% strength is not indicated for fertility and not part of Fertility benefit, so this policy is not applicable to the 4% strength. Split out Gonal-f RFF and Gonal-f RFF Redi-ject criteria to only include criteria related to their FDA-approved indications of assisted reproductive technology and ovulation induction.
Fertility – Pennsylvania Healthcare Reform Individual Plans	07/08/2022	Policy revised for Fertility to specify Crinone strength of 8% throughout policy because 4% strength is not indicated for fertility and not part of Fertility benefit, so this policy is not applicable to the 4% strength. Identified Gonal-f RFF and Gonal-f RFF Redi-ject as distinct products.
Fintepla (fenfluramine) – Commercial and Healthcare Reform	07/07/2022	Policy revised to add new indication for Lennox-Gastaut syndrome in patients 2 years of age or older who have experienced therapeutic failure, contraindication, or intolerance to two of the following: valproic acid/divalproex sodium, lamotrigine, topiramate, or clobazam. Reauthorization requiring prescriber attestation of reduction in seizure frequency from baseline.
Gattex (teduglutide) – Commercial and Healthcare Reform	07/06/2022	Policy revised for Gattex (teduglutide) to change documentation of colonoscopy or fecal occult blood testing to attestation and moved short bowel syndrome defined as < 200 cm of functional small bowel to limitations of coverage.
Hereditary Angioedema – Commercial and Healthcare Reform	07/08/2022	Policy revised to add Sajazir (icatibant) – new generic of icatibant – to generic icatibant criteria.
Hyftor (sirolimus) – Commercial and Healthcare Reform	TBD	New policy for Hyftor (sirolimus) requiring diagnosis based on FDA-approved indication supported by a

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		diagnosis of tuberous sclerosis complex (TSC), member is 6 years of age or older, member has facial angiofibromas (≥ 2 mm in diameter with redness in each) present. Reauthorization requires that member has met the initial authorization criteria and experienced decrease in size and/or redness of facial angiofibromas.
Interleukin-1β blockers – Commercial and Healthcare Reform	07/08/2022	Policy revised for Arcalyst (rilonacept) to add quantity level limit exceptions for induction therapy in Cryopyrin-Associated Periodic Syndromes (CAPS), Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and Recurrent Pericarditis (RP) to allow 5 vials within the first 4 weeks of therapy and allow for Deficiency of Interleukin-1 Receptor Antagonist (DIRA) maintenance dosing of 8 vials every 4 weeks. Initial authorization duration revised for Arcalyst (rilonacept) and Ilaris (canakinumab) to 6 months, and reauthorization duration remains 12 months.
Kristalose (lactulose) and Lactulose Powder Packets – Commercial and Healthcare Reform	10/01/2022	New policy for Kristalose (lactulose) and lactulose powder packets requiring diagnosis based on FDA-approved indication, trial/failure to polyethylene glycol and lactulose oral solution. Reauthorization to require positive response to therapy.
Market Watch Programs – Delaware	06/28/2022	Policy revised to add Nexiclon XR (clonidine) and trial/failure of clonidine hcl immediate-release tablet. Policy revised to add Ermeza (levothyroxine sodium) to require trial/failure/contraindication to generic levothyroxine oral tablets, Euthyrox (levothyroxine), or Unithroid (levothyroxine). Policy revised to add Epsolay (benzoyl peroxide) to require trial/failure/contraindication to metronidazole topical and azelaic acid.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		Policy revised to remove Qmiiz; product is no longer commercially available. Policy revised to add Orphenadrine/Aspirin/Caffeine to Norgesic Forte, Orphengesic Forte references. Policy revised to add Levamlodipine to require trial/failure of amlodipine, felodipine and nifedipine ER. Policy revised to add diclofenac sodium solution in metered dose pump to require trial/failure of diclofenac, ibuprofen, and meloxicam.
Market Watch Programs – New York, Pennsylvania and West Virginia	06/28/2022	Policy revised to add Nexiclon XR (clonidine) and trial/failure of clonidine hcl immediate-release tablet. Policy revised to add Ermeza (levothyroxine sodium) to require trial/failure/contraindication to generic levothyroxine oral tablets, Euthyrox (levothyroxine), or Unithroid (levothyroxine). Policy revised to add Epsolay (benzoyl peroxide) to require trial/failure/contraindication to topical metronidazole and azelaic acid. Policy revised to remove Qmiiz; product is no longer commercially available. Policy revised to add Orphenadrine/Aspirin/Caffeine to Norgesic Forte, Orphengesic Forte listing. Policy revised to add Levamlodipine to require trial/failure of amlodipine, felodipine and nifedipine ER. Policy revised to add diclofenac sodium solution in metered dose pump to require trial/failure of diclofenac, ibuprofen and meloxicam.
Ocaliva (obeticholic acid) – Commercial and Healthcare Reform	07/08/2022	Policy revised for Ocaliva (obeticholic acid) to add if the member has primary biliary cholangitis with compensated cirrhosis the member does not have evidence of portal hypertension in limitations of coverage.
PARP Kinase Inhibitors – Commercial and Healthcare Reform	07/08/2022	Policy revised for Lynparza (olaparib) requiring age, diagnosis based on FDA-approved expanded indication, supported by companion diagnostic

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		test. Policy revised for Zejula (niraparib) to include criterion for a companion diagnostic test.
PI3K Inhibitors – Commercial and Healthcare Reform	07/08/2022	Policy revised for Ukoniq (umbralisib) to apply criteria to continuation of therapy only due to manufacturer voluntary withdrawal of Ukoniq from sale. Policy revised for Vijoice (alpelisib) requiring age and diagnosis based on FDA-approved indication; if the request is for Vijoice (alpelisib) 250 mg, the member has experienced therapeutic failure or intolerance to Piqray (alpelisib) 250 mg.
Provigil (modafinil) and Nuvigil (armodafinil) – Commercial and Healthcare Reform	07/05/2022	Policy revised to include the state of Delaware. Policy revised to include the diagnosis of Shift-Work Disorder with criteria requiring age of 18 years or older, diagnosis of shift work disorder, excessive sleepiness or insomnia that is temporarily associated with a recurring work schedule that overlaps the usual time for sleep, symptoms accompanied by a reduction of total sleep time, symptoms for at least 3 months, sleep log or actigraphy monitoring for at least 14 days including both work and free days, the sleep disturbance is not better explained by another current disorder, and if the request is for brand Provigil or Nuvigil, the member has tried both generics armodafinil and modafinil. Reauthorization criteria requiring the member's symptoms have improved.
Provigil (modafinil) and Nuvigil (armodafinil) – Commercial and Healthcare Reform – Delaware	07/01/2022	Policy terminated since the state of Delaware was added to policy J-0007.
Relistor (methylnaltrexone bromide) – Commercial and Healthcare Reform	07/08/2022	Policy revised for Relistor (methylnaltrexone bromide) subcutaneous injection to add that the member has been taking opioid medications for at least one month.
Sublingual Immunotherapy – Commercial and Healthcare Reform	07/08/2022	Policy limitations of coverage revised to require the member does not have

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		severe, unstable, or uncontrollable asthma, and Ragwitek (Short Ragweed Pollen Allergen Extract) and Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergens Extract) treatment should not be initiated during active allergy season.
Sucraid (sacrosidase) – Commercial and Healthcare Reform	07/06/2022	Policy revised for Sucraid (sacrosidase) to require that disaccharidase assay shows absent or reduced sucrase activity, reduced or normal isomaltase activity, reduced maltase activity, and reduced or normal lactase activity. Sucrase deficiency can now be evidenced by either sucrose breath hydrogen test or 13-Carbon-sucrose breath test instead of just hydrogen breath test.
Testosterone (Androgens) – Commercial and Healthcare Reform	07/06/2022	Policy revised to add new product Tlando (testosterone undecanoate) to require that the member is male; has a diagnosis of hypogonadism; has tried and failed one generic topical testosterone product; has documented low testosterone levels supported by one of the following: at least two documented low total testosterone levels or attestation the member is not producing testosterone; and meets one of the following: 1) has testicular failure, 2) has multiple symptoms including at least 1 documented specific symptom, 3) has hypopituitarism, 4) is experiencing weight loss due to HIV-infection, or 5) is on chronic steroid treatment. For a diagnosis of double orchidectomy, the member is male; has a diagnosis of primary or secondary hypogonadism with testicular failure; and has tried and failed one generic topical testosterone product. For a diagnosis of gender dysphoria, the member has a diagnosis of gender dysphoria; and if the member is 15 years of age or

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		younger, the drug is prescribed by a clinician competent in the evaluation and induction of pubertal development. For reauthorization, prescriber attestation that the member has experienced a positive clinical response and requires continued therapy with testosterone. Policy revised for Methitst (methyltestosterone) to require trial and failure of generic methyltestosterone capsules for diagnoses of hypogonadism in males, double orchidectomy, and palliative treatment in metastatic breast cancer.
Tretinoin Products – Commercial and Healthcare Reform	07/06/2022	Policy revised to remove Tretin-X (tretinoin) cream as the product is no longer available on the market.
Trientine and Penicillamine Products – Commercial and Healthcare Reform	TBD	Policy revised to add Cuvrior (trientine tetrahydrochloride) requiring age, FDA-approved diagnosis, and trial/failure of generic trientine hydrochloride. Policy removed Clovique (trientine hydrochloride) as product is no longer on the market.
valsartan oral solution – Commercial and Healthcare Reform	06/15/2022	New policy for valsartan oral solution requiring age, diagnosis based on FDA-approved indication, trial/failure of valsartan tablets and inability to swallow tablets. Reauthorization to require positive response to therapy and continued inability to swallow tablets.
Vimpat (lacosamide) – Healthcare Reform	05/19/2022	Policy revised to add options of therapeutic failure or intolerance to generic lacosamide or inability to swallow tablets.
Vivjoa (oteseconazole) – Commercial and Healthcare Reform	TBD	New policy for Vivjoa (oteseconazole) requiring FDA-approved diagnosis substantiated by at least 3 episodes of vulvovaginal candidiasis in less than one year and trial/failure/contraindication to a six-month maintenance course of oral fluconazole.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Voquezna Triple Pak (vonoprazan/amoxicillin/clarithromycin) and Voquezna Dual Pak (vonoprazan/amoxicillin) – Commercial and Healthcare Reform	06/28/2022	New policy for Voquezna Triple Pak (vonoprazan/amoxicillin/clarithromycin) and Voquezna Dual Pak (vonoprazan tablets/amoxicillin capsules) to require FDA-labeled age and diagnosis.
Xolair (omalizumab) syringe – Commercial and Healthcare Reform	07/08/2022	Policy revised for Xolair (omalizumab) prefilled syringe to require diagnosis of nasal polyps based on FDA-approved indication supported by current weight and pretreatment serum IgE. Reauthorization revised to require documentation of current weight and pretreatment serum IgE. Plan-preferred language added where appropriate.
Ztalmy (ganoxolone) – Commercial and Healthcare Reform	07/15/2022	New policy for Ztalmy (ganaxolone) requiring diagnosis of CDKL5 deficiency disorder based on FDA-approved indication supported by genetic testing, patient must be 2 years of age or older, prescriber is neurologist, member has had trial/failure or intolerance to two previous antiepileptic medications and prescriber provides documentation of baseline monthly seizure frequency. Reauthorization to require a decrease in monthly seizure frequency compared to baseline.

*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
Adlarity (donepezil) – Commercial and Healthcare Reform	07/06/2022	New policy for Adlarity (donepezil) requiring diagnosis based on FDA-approved indication, trial/failure or intolerance to donepezil tablets or inability to take daily oral donepezil because of impaired memory and trial/failure/contraindication or intolerance to daily transdermal rivastigmine or inability to use daily transdermal rivastigmine because of impaired memory.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Antiviral Therapies – Healthcare Reform	10/01/2022	Policy revised to include new criteria for Zovirax (acyclovir) topical cream for use in members 12 years of age or older with a diagnosis of recurrent herpes labialis (cold sores) after experiencing therapeutic failure or intolerance to all of the following: generic oral acyclovir, either generic oral valacyclovir or famciclovir (or both valacyclovir and famciclovir are contraindicated), and plan-preferred acyclovir 5% ointment. Policy revised for both Xerese (acyclovir 5% and hydrocortisone 1%) topical cream and Zovirax (acyclovir) topical cream to require that the member has experienced positive clinical response to therapy and therapeutic failure or intolerance to plan-preferred acyclovir 5% ointment.
Antiviral Therapy (Sitavig & Denavir) – Commercial	TBD	Policy revised for Denavir (penciclovir) to require trial/failure/contraindication to generic acyclovir 5% ointment for initial authorization and reauthorization.
Authorized Generics of Inhaler Products – Commercial and Healthcare Reform	06/23/2022	Policy revised to add authorized generic products fluticasone furoate/vilanterol (Breo Ellipta) and fluticasone propionate HFA (Flovent HFA) to require diagnosis based on FDA-approved indication and trial/failure of brand Breo Ellipta if the request is for fluticasone furoate/vilanterol or brand Flovent HFA if the request is for fluticasone propionate HFA. Reauthorization to require attestation of positive clinical response.
Azilect (rasagiline) – Commercial and Healthcare Reform	07/06/2022	Policy revised for Azilect (rasagiline) to require trial/failure to generic rasagiline
Clemastine Fumarate Oral Syrup – Commercial and Healthcare Reform	10/01/2022	New policy for clemastine fumarate oral syrup to require that the member is 6 years of age or older; has a diagnosis of allergic rhinitis or mild, uncomplicated allergic skin manifestations of urticaria and angioedema; has experienced therapeutic failure or intolerance to generic clemastine fumarate tablets; has experienced therapeutic failure, contraindication, or intolerance to 2 generic oral antihistamine products; and has an inability to swallow tablets.
Digitized Inhalers – Commercial and Healthcare Reform	07/06/2022	Policy revised for ArmonAir Digihaler (fluticasone propionate) to expand age to 4 years and older.
Fibrates – Commercial and Healthcare Reform	07/06/2022	Policy revised to remove Triglide (fenofibrate) as the drug is off market.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Glycate (glycopyrrolate) – Commercial and Healthcare Reform	07/06/2022	Policy recreated for Glycate (glycopyrrolate) 1.5 mg tablets to require the member is using Glycate (glycopyrrolate) as adjunctive treatment for peptic ulcer disease and experienced therapeutic failure or intolerance to glycopyrrolate 1 mg tablets. Reauthorization that the member has experienced positive clinical response to therapy and requires additional courses of treatment. Authorization duration of 12 months.
Nexiclon XR – Commercial and Healthcare Reform	07/06/2022	Policy created for Nexiclon XR (clonidine) to ask for age, diagnosis of hypertension, and trial and failure of clonidine hcl immediate-release tablet.
Non-Preferred Basal Insulins – Commercial and Healthcare Reform	06/15/2022	Policy revised to add insulin glargine to require diagnosis based on FDA-approved indication, trial and failure of metformin or using with metformin if member has type 2 diabetes, and trial and failure through all of the following: Basaglar (insulin glargine), Lantus (insulin glargine), Levemir (insulin detemir), Toujeo (insulin glargine), and Tresiba (insulin degludec).
Non-Preferred Erectile Dysfunction Therapy – Healthcare Reform	07/01/2022	Policy terminated. Combined with J-0758 Non-Preferred Erectile Dysfunction Therapy - Commercial to make single policy.
Non-Preferred Extended-Release Stimulant Products – Commercial and Healthcare Reform	TBD	Policy revised to add in new drug Xelstrym (dextroamphetamine) for treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years of age or older with a diagnosis of ADHD and therapeutic failure or intolerance to two plan-preferred generic alternatives, or contraindication to all: dexmethylphenidate extended release (ER), dextroamphetamine-amphetamine ER, dextroamphetamine ER, or methylphenidate ER; or the member has an inability to swallow tablets or capsules. Reauthorization requiring prescriber attestation of member experiencing positive clinical response to therapy.
Non-preferred Generic NSAIDs – Healthcare Reform Essential Formulary	07/06/2022	Policy revised to remove mefenamic acid, meclofenamate sodium, and fenoprofen. These medications have been added to policy J-0759.
Non-Preferred NSAIDs – Commercial and Healthcare Reform	TBD	Policy revised to add Tivorbex 20 mg, indomethacin 20 mg, and Indocin suppository as targets requiring use for an FDA-approved indication and trial and failure of plan-preferred generic indomethacin

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		capsules or plan-preferred generic indomethacin extended-release capsules and trial and failure of two additional more cost-effective plan-preferred generic NSAID alternatives.
Non-Preferred Ophthalmic NSAIDs – Commercial and Healthcare Reform	10/01/2022	New policy created for non-preferred ophthalmic non-steroidal anti-inflammatory drugs Acuvail (ketorolac tromethamine), bromfenac sodium, Ilevro (nepafenac), Nevanac (nepafenac) requiring FDA-approved diagnosis and trial/failure of 1 generic ophthalmic product: diclofenac 0.1%, ketorolac tromethamine 0.5%. For Acular (ketorolac tromethamine) and Acular LS (ketorolac tromethamine) requiring FDA-approved diagnosis and trial/failure of respective generic product.
Non-Stimulant Treatment of ADHD/ADD – Commercial and Healthcare Reform	07/06/2022	Policy revised for Qelbree (viloxazine) to include expanded indication of adult attention deficit hyperactivity disorder and to add options of therapeutic failure/intolerance/contraindication to guanfacine extended release (ER) for patients 6 to 17 years of age or inability to swallow tablets. Criteria for Intuniv (guanfacine ER) updated to remove age requirement for trial/failure of generic guanfacine ER.
Orphenadrine, Aspirin, Caffeine Combination Products	07/06/2022	Policy revised to include new generic orphenadrine, caffeine, aspirin product. Criteria remains the same as for previously listed products. Name of policy changed to Orphenadrine, Aspirin, Caffeine Combination Products to properly reflect all of the products included in the policy.
Oxycodone-Acetaminophen Combination Products – Commercial and Healthcare Reform	07/06/2022	Policy revised to add oxycodone-acetaminophen 5 mg-325 mg/5 mL oral solution to policy. Approval for use of this product requires that the member meet FDA approved indication and has an inability to swallow tablets. Reauthorization requires physician attestation that member has experienced positive clinical response to therapy and the member still has an inability to swallow tablets.
Rhopressa (netarsudil) – Commercial Core	07/01/2022	Policy terminated. Combined with J-0732.
Rhopressa (netarsudil) – Commercial NSF	07/01/2022	Policy terminated. Combined with J-0732.
Non-Preferred Levothyroxine Products – Commercial and Healthcare Reform	TBD	Policy revised to add Ermeza (levothyroxine sodium) to require diagnosis based on FDA-approved indication and trial/failure/contraindication to generic levothyroxine oral tablets, Euthyrox

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		(levothyroxine), or Unithroid (levothyroxine). Reauthorization revised to require positive response to therapy.
Tivorbex (indomethacin) and Indomethacin 20 mg – Commercial and Healthcare Reform	07/01/2022	Policy was terminated; Tivorbex and Indomethacin were incorporated into J-0759 Non-Preferred NSAIDs – Commercial and Healthcare Reform.
Topical Acne Products – Commercial and Healthcare Reform	10/01/2022	Policy revised for topical acne products to add Epiduo Forte (adapalene/benzoyl peroxide) brand as a target agent requiring a diagnosis of acne vulgaris and therapeutic failure or intolerance to 3 of the following: adapalene, clindamycin or clindamycin/benzoyl peroxide, erythromycin, sulfacetamide, or tretinoin.
Topical Rosacea Treatments – Commercial and Healthcare Reform	07/06/2022	Policy revised to add Epsolay (benzoyl peroxide) requiring age and diagnosis based on FDA-approved indication; trial/ failure of topical metronidazole cream, lotion, or gel; generic azelaic acid; and generic over-the-counter benzoyl peroxide 5% topical gel.
Topical Rosacea Treatments – Healthcare Reform	07/01/2022	Policy terminated; criteria combined into J-0601 Topical Rosacea Treatments - Commercial and Healthcare Reform
Vimpat (lacosamide) – Commercial	TBD	New policy for brand Vimpat (lacosamide) to require FDA-labeled age and diagnosis and trial/failure/contraindication to generic lacosamide or inability to swallow tablets.
Vimpat (lacosamide) – Commercial National Select Formulary	06/09/2022	Policy revised to add options of therapeutic failure or intolerance to generic lacosamide or inability to swallow tablets.
Xelstrym (dextroamphetamine) – Commercial and Healthcare Reform	TBD	New policy for Xelstrym (dextroamphetamine) for treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years of age or older with a diagnosis of ADHD and therapeutic failure or intolerance to two plan-preferred generic alternatives, or contraindication to all: dexmethylphenidate extended release (ER), dextroamphetamine-amphetamine ER, dextroamphetamine ER, or methylphenidate ER. Reauthorization requiring prescriber attestation of member experiencing 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
Hyftor (sirolimus)	3 tubes (30 g) per 30 days	9 tubes (90 g) per 90 days
Omnipod 5 G6 (Gen 5) Intro Kit	1 kit per 720 days	1 kit per 720 days
Omnipod 5 G6 (Gen 5) Pods	10 pods per 25 days	30 pods per 75 days
Omnipod DASH (Gen4) Intro Kit	1 kit per 720 days	1 kit per 720 days
Ozempic (semaglutide) 0.25 mg or 0.5 mg (2 mg/1.5 mL)	1.5 mL (1 pen) for 21 days	4.5 mL (3 pens) per 63 days
Ozempic (semaglutide) 1 mg (4 mg/3 mL or 1/0.75 (3))	3 mL (1 pen) per 21 days	9 mL (3 pens) per 63 days
Ozempic (semaglutide) 2 mg (8 mg/3 mL or 2 mg/0.75 mL)	3 mL (1 pen) per 21 days	9 mL (3 pens) per 63 days
Paxlovid (nirmatrelvir tablets; ritonavir tablets) 4 tablet blister cards & 20 tablet cartons	20 tablets per 365 days	20 tablets per 365 days
Vijoice (alpelisib) 125 mg tablets	28 tablets per 28 days	28 tablets per 28 days
Vijoice (alpelisib) 250 mg daily dose pack	56 tablets per 28 days	56 tablets per 28 days
Vijoice (alpelisib) 50 mg tablets	28 tablets per 28 days	28 tablets per 28 days
Vivjoa (oteseconazole)	18 capsules (1 blister pack) per 91 days	18 capsules (1 blister pack) per 91 days
Voquezna Dual Pak (vonoprazan, amoxicillin)	2 packs per 360 days	2 packs per 360 days
Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin)	2 packs per 360 days	2 packs per 360 days
Xifaxan (rifaximin) 200 mg tablets	27 tablets per 365 days	27 tablets per 365 days
Ztalmy (ganaxolone)	10 bottles (1,100 mL) per 30 days	30 bottles (3,300 mL) per 90 days

*Effective date to be determined.

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

Drug Name	Retail Edit Limit	Mail Edit Limit

Epsolay (benzoyl peroxide) 5% cream	30 grams (1 pump) per dispensing event	30 grams (1 pump) per dispensing event

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

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

Drug Name	Daily Limit
Camzyos (mavacamten)	1 capsule per day
Caplyta (lumateperone) 10.5 mg and 21 mg	1 capsule per day
Cuvrior (trientine tetrahydrochloride)	10 tablets per day
Nexiclon XR (clonidine)	3 tablets per day
Qelbree (viloxazine HCl)	3 capsules per day
Tlando (testosterone undecanoate)	4 capsules per day
Triumeq PD (dolutegravir/lamivudine/abacavir)	6 tablets per day
Xelstrym (dextroamphetamine)	1 patch 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
Adlarity transdermal system	donepezil transdermal system	donepezil tablet; rivastigmine tablet; rivastigmine transdermal
Ermeza	levothyroxine sodium	levothyroxine sodium tablet
Tlando	testosterone undecanoate	testosterone cypionate, testosterone gel in metered-dose pump, testosterone gel in packet
Xelstrym	dextroamphetamine	dexmethylphenidate capsule, ER biphasic 50-50; methylphenidate HCl tablet extended release 24hr; dextroamphetamine-amphetamine capsule, extended release 24hr
Epsolay 5% cream	benzoyl peroxide 5% cream	Prescriber Discretion
Omnipod 5 G6 (Gen 5) Intro Kit		Prescriber Discretion
Omnipod 5 G6 (Gen 5) Pods		Prescriber Discretion
Omnipod DASH (Gen4) Intro Kit		Prescriber Discretion
Vivjoa	oteseconazole	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.)

Brand Name	Generic Name	Preferred Alternatives
Vivjoa	oteseconazole	Prescriber Discretion

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

Brand Name	Generic Name	Preferred Alternatives
Adlarity transdermal system	donepezil transdermal system	donepezil tablets; donepezil tablets, disintegrating; rivastigmine capsules**
Cuvrior	trientine tetrahydrochloride	trientine, penicillamine
Epsolay 5% cream	benzoyl peroxide 5% cream	metronidazole topical cream, metronidazole topical gel, metronidazole topical lotion
Ermeza	levothyroxine sodium	levothyroxine sodium tablet
Tlando	testosterone undecanoate	testosterone cypionate, testosterone gel in metered-dose pump, testosterone gel in packet
Xelstrym	dextroamphetamine	dexmethylphenidate capsule, ER biphasic 50-50; methylphenidate HCl tablet extended release 24hr; dextroamphetamine-amphetamine capsule, extended release 24hr
Camzyos	mavacamten	Prescriber Discretion
Hyftor	sirolimus	Prescriber Discretion
Omnipod 5 G6 (Gen 5) Intro Kit		Prescriber Discretion
Omnipod 5 G6 (Gen 5) Pods		Prescriber Discretion
Omnipod DASH (Gen4) Intro Kit		Prescriber Discretion

*Physicians may request coverage of these products using the Prescription Drug Medication Request Form.
**rivastigmine capsules preferred on Venture formulary only.

C. Additions to the Specialty Tier

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

Brand Name	Generic Name
Alymsys	bevacizumab-maly
Camzyos*	mavacamten
Cuvrior*	trientine tetrahydrochloride
Hyftor*	sirolimus
Igalmi	dexmedetomidine
Opdualag	nivolumab/relatlimab-rmbw
Syprine	trientine hydrochloride
Triumeq PD	dolutegravir/lamivudine/abacavir
Vijoice	alpelisib
Voquezna Dual Pak	vonoprazan, amoxicillin
Voquezna Triple Pak	vonoprazan, amoxicillin, clarithromycin
Ztalmy	ganaxolone
Alymsys	bevacizumab-maly

*Product OFF on Venture and Performance Formularies

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Adbry (tralokinumab) – Medicare	01/01/2023	Policy revised for Adbry (tralokinumab-ldrm) in atopic dermatitis (AD) to remove double topical step and now require therapeutic failure or intolerance to one topical corticosteroid or one topical calcineurin inhibitor, or attestation that the member has severe AD where topical therapy is not advisable evidenced by a large proportion of body surface area or severely damaged skin. If the patient has already had a trial of at least one biologic agent, the patient is not required to “step back” and try a non-biologic agent.
Adlarity (donepezil) – Medicare	06/29/2022	New policy for Adlarity (donepezil) requiring diagnosis based on FDA-approved indication, trial/failure or intolerance to donepezil tablets or inability to take daily oral donepezil because of impaired memory.
CDK Inhibitors – Medicare	01/01/2023	Policy revised for Kisqali (ribociclib) and Kisqali Femara Co-Pack (ribociclib; letrozole) to require that the member is not a candidate for therapy with both preferred products, Ibrance and Verzenio.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
CGRP Inhibitors – Medicare	01/01/2023	Policy revised for Nurtec ODT (rimegepant) for acute treatment of migraine to require therapeutic failure, contraindication, or intolerance to one generic triptan. Policy revised for Ubrelvy (ubrogepant) to require therapeutic failure, contraindication, or intolerance to one generic triptan and Nurtec ODT (rimegepant).
Chelating Agents – Medicare	07/07/2022	Policy revised for Exjade (deferasirox), Jadenu (deferasirox), and Ferriprox (deferiprone) to remove age requirements.
Chronic Inflammatory Diseases – Medicare	07/01/2022	Policy revised for Rinvoq (upadacitinib) to add new indication of ankylosing spondylitis added requiring age, diagnosis based on FDA-approved indication, trial/failure of 1 NSAID or contraindication to all, and trial/failure of one tumor necrosis factor (TNF) blocker therapy. Olumiant (baricitinib) for treatment of hospitalized COVID-19 adults is not eligible for Medicare Part D coverage as drugs administered in an inpatient setting are covered under Medicare Part A.
Chronic Inflammatory Diseases – Medicare 2023	01/01/2023	Policy revised for Rinvoq (upadacitinib) in atopic dermatitis (AD) to remove double topical step and now require therapeutic failure or intolerance to one topical corticosteroid or one topical calcineurin inhibitor, or attestation that the member has severe AD where topical therapy is not advisable evidenced by a large proportion of body surface area or severely damaged skin.
Cibinqo (abrocitinib) – Medicare	01/01/2023	Policy revised for Cibinqo (abrocitinib) in atopic dermatitis (AD) to remove double topical step and now require therapeutic failure or intolerance to one topical corticosteroid or one topical calcineurin inhibitor, or attestation that the member has severe AD where topical therapy is not advisable evidenced by a large proportion of body surface area or severely damaged skin. If the patient has already had a trial of at least one biologic agent, the patient is not required to “step back” and try a non-biologic agent.
Clemastine Fumarate Oral Syrup – Medicare	01/01/2023	New policy created for clemastine fumarate to require diagnosis of allergic rhinitis or mild, uncomplicated allergic skin manifestations of urticaria and angioedema; therapeutic failure, contraindication, or intolerance to one generic antihistamine product; and one of the following: therapeutic failure or intolerance to generic

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		clemastine fumarate tablets or an inability to swallow tablets.
Combination Prescription Drug Safety – Medicare	01/01/2023	Policy revised to remove criteria for 7-day opioid naïve safety limit.
Digitized Inhalers – Medicare	07/07/2022	Policy revised for ArmonAir Digihaler (fluticasone propionate), AirDuo Digihaler (fluticasone propionate/salmeterol), and Proair Digihaler (albuterol sulfate) to remove age requirements.
Direct Oral Anticoagulants (DOACs) – Medicare	04/28/2022	Policy revised for Pradaxa (dabigatran etexilate) oral pellets and Xarelto (rivaroxaban) oral suspension to remove age.
Dupixent (dupilumab) – Medicare	01/01/2023	Policy revised for Dupixent (dupilumab) in atopic dermatitis (AD) to remove double topical step and now require therapeutic failure or intolerance to one topical corticosteroid or one topical calcineurin inhibitor, or attestation that the member has severe AD where topical therapy is not advisable evidenced by large proportion body surface area or severely damaged skin. If the patient has already had a trial of at least one biologic agent, the patient is not required to "step back" and try a non-biologic agent.
Fintepla (fenfluramine) – Medicare	07/01/2022	Policy revised to add new indication for Lennox-Gastaut syndrome in patients 2 years of age or older who have experienced therapeutic failure, contraindication, or intolerance to two standard of care treatments (e.g., lamotrigine, clobazam). Criteria for Dravet syndrome revised to remove step through 2 agents.
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) – Medicare	01/01/2023	Policy revised for Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) to add Adlyxin (lixisenatide), Ozempic (semaglutide), Rybelsus (semaglutide), Trulicity (dulaglutide), and Victoza (liraglutide) based on FDA-approved indication.
Glycate (glycopyrrolate) – Medicare	07/01/2022	Policy recreated for Glycate (glycopyrrolate) 1.5 mg tablets to require the member is using Glycate (glycopyrrolate) as adjunctive treatment for peptic ulcer disease and experienced therapeutic failure or intolerance to glycopyrrolate 1 mg tablets. Reauthorization that the member has experienced positive clinical response to therapy and requires additional courses of treatment. Authorization duration of 12 months.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
High Risk Medications in the Elderly – Medicare	07/07/2022	Addition of non-RxCUI drugs based on High-Risk medication guidelines. Removal of off-market drugs.
Hyftor (sirolimus) – Medicare	TBD	New policy for Hyftor (sirolimus) requiring diagnosis based on FDA-approved indication of a diagnosis of tuberous sclerosis complex (TSC) with facial angiofibromas present. Reauthorization requires that member has met the initial authorization criteria and experienced decrease in size and/or redness of facial angiofibromas.
Igalmi (dexmedetomidine) – Medicare	TBD	New policy for Igalmi (dexmedetomidine) requiring diagnosis based on FDA-approved indication and the member to be experiencing agitation associated with schizophrenia or bipolar disorder.
Injectable Octreotide Products – Medicare	07/07/2022	Policy revised for Bynfezia (octreotide acetate) to remove drug from policy as no longer on market.
Lyrica/Lyrica CR (pregabalin/pregabalin ER) – Medicare	01/01/2023	Policy revised to clarify seizure diagnosis as partial-onset seizures.
Non-Preferred Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) and Basal Insulins – Medicare	07/01/2022	Policy terminated.
Non-stimulant Treatment of ADHD/ADD – Medicare	07/01/2022	Policy revised to remove age requirement for Qelbree (viloxazine).
Ocaliva (obeticholic acid) – Medicare	01/01/2023	Policy revised for Ocaliva (obeticholic acid) to add if the member has primary biliary cholangitis with compensated cirrhosis the member does not have evidence of portal hypertension in limitations of coverage.
Omega 3 Fatty Acid Products – Medicare	06/01/2022	Policy revised to remove Vascepa (icosapent ethyl). Will apply to Lovaza (omega-3-acid ethyl esters) only.
PARP Kinase Inhibitors – Medicare	07/01/2022	Policy revised for Lynparza (olaparib) requiring age and diagnosis based on FDA-approved expanded indication.
PI3K Inhibitors – Medicare	07/08/2022	Policy revised for Vijoice (alpelisib) requiring diagnosis based on FDA-approved indication.
Programmed Death Receptor Therapies – Medicare	07/08/2022	Policy revised to add criteria for new drug Opdualag (nivolumab and relatlimab-rmbw) to require that the member has a diagnosis of

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		unresectable or metastatic melanoma. Policy revised for Keytruda (pembrolizumab) for use in members with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) advanced endometrial carcinoma, who have experienced disease progression following prior systemic therapy and who are not candidates for curative surgery or radiation.
Provigil (modafinil) & Nuvigil (armodafinil) – Medicare	01/01/2023	Policy revised for shift work disorder for criteria to include that the member has excessive sleepiness or insomnia that is temporarily associated with a recurring work schedule that overlaps the usual time for sleep; the member's symptoms are accompanied by a reduction of total sleep time; the member has experienced symptoms for at least 3 months; the member has sleep log or actigraphy monitoring for at least 14 days including both work and free days; and the sleep disturbance is not better explained by another current sleep disorder, medical or neurological disorder, mental disorder, medication use, or substance use disorder.
Repository Corticotropin Injections – Medicare	01/01/2023	Policy revised to remove the diagnosis of adrenal insufficiency.
Stromectol (ivermectin) – Medicare	01/01/2023	New policy for Stromectol (ivermectin) requiring diagnosis based on FDA-approved indications and minimum weight as per prescribing information.
Synarel (nafarelin acetate) – Medicare	01/01/2023	New policy for Synarel (nafarelin acetate) for central precocious puberty (CPP) requiring age, diagnosis based on FDA-approved indication supported by elevated basal luteinizing hormone (LH) levels or elevated leuprolide-stimulated LH levels and bone age. Reauthorization of positive response to therapy through normalization of lab levels or pre-pubertal slowing or decline. New policy for Synarel (nafarelin acetate) for endometriosis requiring age, diagnosis based on FDA-approved indication, female and not pregnant, and trial/failure/contraindication to two (2) of the following: NSAIDs, combination hormonal contraceptive, progestin (i.e., medroxyprogesterone injection), GnRH agonist (i.e., Leuprolide) or danazol.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Testosterone (Androgens) – Medicare	07/05/2022	Policy revised to add new product Tlando (testosterone undecanoate) to require that the member is male; has a diagnosis of hypogonadism; meets one of the following: has primary or secondary hypogonadism with testosterone deficiency, is experiencing weight loss due to HIV-infection, or is on chronic steroid treatment; and the member has low testosterone levels per the laboratory reference range. For a diagnosis of double orchidectomy, the member is male and has a diagnosis of primary or secondary hypogonadism with testicular failure. For a diagnosis of gender dysphoria, the member has a diagnosis of gender dysphoria or gender identity disorder.
Ultomiris (ravulizumab-cwvz) – Medicare	07/07/2022	Policy revised for Ultomiris (ravulizumab-cwvz) to add expanded indication of generalized myasthenia gravis requiring appropriate age, diagnosis, and trial/failure to generic pyridostigmine. Reauthorization to require improvement from baseline.
Vancocin (vancomycin) Oral Capsules – Medicare 2023	01/01/2023	New policy for Vancocin (vancomycin) oral capsules to require that the member has a diagnosis of Clostridioides difficile-associated diarrhea, or a diagnosis of enterocolitis caused by Staphylococcus aureus (including methicillin resistant strains); and if the request is for brand Vancocin, the member has experienced therapeutic failure or intolerance to generic vancomycin capsules. Authorization duration of 3 months.
Vivjoa (oteseconazole) – Medicare	TBD	New policy for Vivjoa (oteseconazole) requiring FDA-approved diagnosis substantiated by at least 3 episodes of vulvovaginal candidiasis in less than one year.
Ztalmy (ganoxolone) – Medicare	TBD	New policy for Ztalmy (ganaxolone) requiring diagnosis of CDKL5 deficiency disorder based on FDA-approved indication supported by attestation of genetic testing by prescriber, trial/failure of two previous antiepileptic therapies.

*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	06/15/2022	New policy for authorized generic products fluticasone furoate/vilanterol (Breo Ellipta) and fluticasone propionate HFA (Flovent HFA) to require diagnosis based on FDA-approved indication and trial/failure of brand Breo Ellipta if the request is for fluticasone furoate/vilanterol or brand Flovent HFA if the request is for fluticasone propionate HFA.
Brand ADHD Step Therapy – Medicare	TBD	Policy revised to add in new drug Xelstrym (dextroamphetamine) for treatment of attention deficit hyperactivity disorder (ADHD) with therapeutic failure, contraindication, or intolerance to two generic medications: methylphenidate, dextroamphetamine/amphetamine, atomoxetine, or dexmethylphenidate.
Cequa (cyclosporine) – Medicare	07/01/2022	Removed Xiidra from being a target in the policy. Revised policy criteria to require therapeutic failure, contraindication, or intolerance to Restasis, cyclosporine (generic Restasis) **or** Xiidra.
Cequa (cyclosporine) – Medicare	01/01/2023	Revised policy criteria to require therapeutic failure, contraindication, or intolerance to Restasis/cyclosporine (generic Restasis) **and** Xiidra.
Conjupri (levamlodipine) – Medicare	07/01/2022	Policy revised for Conjupri (levamlodipine) to require diagnosis based on FDA-approved indication and trial/failure/contraindication to generic tablets amlodipine, felodipine extended-release, or nifedipine extended-release.
Fensolvi (leuprolide acetate) – Medicare	01/01/2023	Policy revised for Fensolvi (leuprolide acetate) to require age less than 8 years for females or less than 9 years for males.
Gonadotropin-releasing Hormone Agonists (GnRH) – Medicare	07/01/2022	Policy revised for Lupron Depot (leuprolide acetate for depot suspension) requiring diagnosis based on FDA-approved indication.
Gonadotropin-releasing Hormone Agonists (GnRH) – Medicare	01/01/2023	Policy revised for Lupron Depot-Ped (leuprolide acetate for depot suspension) and Supprelin LA (histrelin acetate) to require age less than 8 years for females or less than 9 years for males.
Nexiclon XR – Medicare	TBD	Policy created for Nexiclon XR (clonidine) to ask diagnosis of hypertension and trial and failure of clonidine hcl immediate-release tablet.
Non-Preferred Sodium-Glucose Co-Transporter	07/01/2022	Policy revised for Xigduo XR (dapagliflozin/metformin) to require diagnosis

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
2 (SGLT2) Inhibitors – Medicare		based on FDA-approved indication and trial/failure/contraindication to canagliflozin (Invokana, Invokamet, or Invokamet XR) and/or empagliflozin (Jardiance, Synjardy, or Synjardy XR) when being utilized for the same indication.
Non-Preferred Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Medicare	01/01/2023	Policy revised for Farxiga (dapagliflozin) to require diagnosis based on FDA-approved indication and trial/failure/contraindication to canagliflozin (Invokana, Invokamet, or Invokamet XR) and/or empagliflozin (Jardiance, Synjardy, or Synjardy XR) when being utilized for the same indication.
Roszet (rosuvastatin/ezetimibe) – Medicare	01/01/2023	Policy revised for Roszet (rosuvastatin and ezetimibe) to require diagnosis based on FDA-approved indication.
Tyrvaya (varenicline solution) – Medicare	07/01/2022	Revised policy criteria to require therapeutic failure, contraindication, or intolerance to Restasis, cyclosporine (generic Restasis) or Xiidra.
Tyrvaya (varenicline solution) – Medicare	01/01/2023	Revised policy criteria to require therapeutic failure, contraindication, or intolerance to Restasis/cyclosporine (generic Restasis) and Xiidra.

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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)
Adlarity (donepezil) transdermal system	4 transdermal patches per 28 days	12 transdermal patches per 84 days
Camzyos (mavacamten)	1 capsule per day	1 capsule per day
Caplyta (lumateperone) 10.5 mg and 21 mg	1 capsule per day	1 capsule per day
Cuvrior (trientine tetrahydrochloride)	10 tablets per day	10 tablets per day
Hyftor (sirolimus)	3 tubes (30 g) per 30 days	9 tubes (90 g) per 90 days
Igalmi (dexmedetomidine)	2 sublingual films per day	2 sublingual films per day
Omnipod 5 G6 (Gen 5) Intro Kit	1 kit per 365 days	1 kit per 365 days
Omnipod 5 G6 (Gen 5) Pods	10 pods per 30 days	30 pods per 90 days
Omnipod DASH (Gen4) Intro Kit	1 kit per 365 days	1 kit per 365 days
Opdualag (nivolumab/relatlimab-rmbw)	Two (2) vials per 28 days	Six (6) vials per 84 days

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Ozempic (semaglutide) 0.25 mg or 0.5 mg (2 mg/1.5 mL)	1.5 mL (1 pen) per 28 days	4.5 mL (3 pens) per 90 days
Ozempic (semaglutide) 2 mg (8 mg/3 mL or 2 mg/0.75 mL)	3 mL (1 pen) per 28 days	9 mL (3 pens) per 90 days
Paxlovid (nirmatrelvir tablets; ritonavir tablets) 4 tablet blister cards & 20 tablet cartons	180 tablets per 365 days	180 tablets per 365 days
Qelbree (viloxazine HCl)	Qelbree 200 mg: 3 capsules per day	Qelbree 200 mg: 3 capsules per day
Tlando (testosterone undecanoate)	4 capsules per day	4 capsules per day
Triumeq PD (dolutegravir/lamivudine/abacavir)	6 tablets per day	6 tablets per day
Vijoice (alpelisib) 125 mg tablets	1 tablet per day	1 tablet per day
Vijoice (alpelisib) 250 mg daily dose pack	2 tablets per day	2 tablets per day
Vijoice (alpelisib) 50 mg tablets	1 tablet per day	1 tablet per day
Vivjoa (oteseconazole)	18 capsules (1 blister pack) per 91 days	18 capsules (1 blister pack) per 91 days
Voquezna Dual Pak (vonoprazan, amoxicillin)	1 pack per 14 days	1 pack per 14 days
Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin)	1 pack per 14 days	1 pack per 14 days
Xelstrym (dextroamphetamine)	1 patch per day	1 patch per day
Xifaxan (rifaximin) 200 mg tablets	27 tablets per 365 days	27 tablets per 365 days
Ztalmy (ganaxolone)	10 bottles (1,100 mL) per 30 days	30 bottles (3,300 mL) per 90 days

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