Formulary Updates

Published March 28, 2022

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for **January 2022**. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in January 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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B. Changes to the Highmark Healthcare Reform Essential Formulary
C. Changes to the Highmark Core Formulary
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As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (accessible via NaviNet® or our website). Click the **Pharmacy Program/Formularies** link from the menu on the left.

HIGHMARK

Important Drug Safety Updates

Metformin HCl 750 MG ER Tablets by Viona Pharmaceuticals Inc.: Recall – NDMA Impurity

On January 12th, 2022, Viona Pharmaceuticals Inc. recalled the above product due to N-nitrosodimethylamine (NDMA) above the recommended limit.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant found in water and foods, including meats, dairy products, and vegetables. Patients who have received impacted lots of Metformin Hydrochloride Extended-Release Tablets, USP 750 mg are advised to continue taking their medication and contact their physician for advice regarding an alternative treatment. According to the Food and Drug Administration (FDA), it could be dangerous for patients with this serious condition to stop taking their Metformin without first talking to their healthcare professionals. To date, neither Viona Pharmaceuticals Inc., nor Cadila Healthcare Limited have received any reports of adverse events related to this recall.

Semglee (insulin glargine injection),100 units/mL Mylan Pharmaceuticals Inc.: Recall – Missing Label

On January 19th, 2022, Mylan Pharmaceuticals Inc., a Viatris company, recalled the above product due to the potential for the label to be missing on some prefilled pens.

A missing label on Semglee® (insulin glargine) prefilled pens, for patients receiving treatment with more than one type of insulin (e.g., both short and long-acting insulin), could lead to a mix-up of products/strengths, resulting in administration of the wrong insulin. Administration of the wrong insulin could result in less optimal glycemic control (either high or low blood sugar) which could result in serious complications. To date, the company has not received any reports of adverse events related to this recall.

02/03/2022 FDA Drug Safety Communication: FDA investigating possible increased risk of death with lymphoma medicine Ukoniq (umbralisib). Consider risks and benefits of continued use versus other treatments.

The FDA has identified a possible increased risk of death in patients taking Ukoniq (umbralisib) based on initial findings from the clinical trial UNITY. In this trial, Ukoniq is being used to treat chronic lymphocytic leukemia (CLL). CLL is currently not an FDA-approved indication for Uknoiq, but it is related to the two specific types of lymphomas for which the drug is currently FDA-approved to treat (marginal zone lymphoma [MZL] and follicular lymphoma [FL]).

While the FDA continues to review the UNITY findings, the enrollment of new patients into other ongoing clinical trials of Ukoniq has been suspended. The FDA will communicate their final conclusions and recommendations when they have completed their review. Adverse events involving Ukoniq should be reported to the FDA MedWatch program.

01/12/2022 FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain. Benefits for use outweigh these risks and oral care can help.

The FDA has issued a warning that dental problems such as tooth decay, cavities, oral infections, and loss of teeth have been reported with the use of medicines containing buprenorphine that are dissolved in the mouth. These problems can be serious and have even occurred in patients with no history of dental issues. Even with these risks, the benefits of these medicines clearly outweigh the risks.

As a result of these issues, the FDA is requiring that a new warning regarding dental problems be added to the prescribing information and the patient Medication Guide for all buprenorphine-containing medications that are dissolved in the mouth. In addition to the warning, strategies to maintain or improve oral health while undergoing treatment with buprenorphine will also be included. Adverse events involving buprenorphine should be reported to the FDA MedWatch program.

Highmark Formulary Update – January 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 January 2022, unless otherwise noted.

Brand Name	Generic Name	Comments
Xarelto oral suspension	rivaroxaban oral suspension	Venous thromboembolism
Highmark Commercial Comprehensive Formulary Only		
PreHevbrio	hepatitis B vaccine (recombinant)	Prevention of hepatitis B

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Adbry	tralokinumab-ldrm	mometasone furoate cream (gram); Dupixent; Dupixent Pen
Besremi	ropeginterferon alfa-2b-njft	Pegasys
Dyanavel XR	amphetamine ER tablets	dextroamphetamine sulfate er capsule, extended release; methylphenidate er capsule,extended release biphasic 30-70
Entadfi	finasteride/tadalafil	finasteride 5 mg, dutasteride capsule, tamsulosin hcl
Eprontia oral solution	topiramate oral solution	gabapentin solution, oral 250 mg/5ml; valproic acid solution, oral 250 mg/5ml; propranolol hcl solution, oral

Brand Name	Generic Name	Preferred Alternatives
Lyvispah oral granules	baclofen oral granules	baclofen 10 mg tablet, baclofen 20 mg tablet
Oxbryta tablets for oral suspension	voxelotor tablets for oral suspension	hydroxyurea capsule
Recorlev	levoketoconazole	ketoconazole tablet
Rezvoglar	insulin glargine-aglr	Basaglar Kwikpen U-100, Lantus Solostar, Toujeo Solostar
Scemblix	asciminib	Iclusig
Tarpeyo	budesonide	methyprednisolone tablet, prednisone tablet
Xaciato 2% vaginal gel	clindamycin phosphate 2% vaginal gel	clindamycin phosphate cream with applicator, metronidazole gel with applicator (gram)
Yusimry	adalimumab-aqvh	Humira
Dartisla ODT	glycopyrrolate	glycopyrrolate 2 mg
Livtencity	maribavir	Provider Discretion
Voxzogo	vosoritide	Provider Discretion
Highmark Healthcare Reform Comprehensive Only		
PreHevbrio	hepatitis B vaccine (recombinant)	Provider 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
Besremi	ropeginterferon alfa-2b-njft
Dartisla ODT	glycopyrrolate
Livtencity	maribavir
Oxbryta	voxelotor
Recorlev	levoketoconazole
Scemblix	asciminib
Tarpeyo	budesonide
Voxzogo	vosoritide
Yusimry	adalimumab-aqvh

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 January 2022, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
PreHevbrio	hepatitis B vaccine (recombinant)	3	Prevention of hepatitis B
Xarelto oral suspension	rivaroxaban oral suspension	3	Venous thromboembolism
Items listed below were not added to the formulary			
Adbry	tralokinumab-ldrm	4	mometasone furoate cream (gram); Dupixent; tacrolimus ointment (gram)
Besremi	ropeginterferon alfa-2b-njft	4	Pegasys
Dartisla ODT	glycopyrrolate	4	glycopyrrolate 2 mg tablets
Dyanavel XR	amphetamine ER tablets	4	dextroamphetamine sulfate er capsule, extended release; methylphenidate er capsule,extended release biphasic 30-70
Entadfi	finasteride/tadalafil	4	finasteride 5 mg, dutasteride capsule, tadalafil 5 mg
Eprontia	topiramate oral solution	4	gabapentin solution, oral 250 mg/5ml; valproic acid solution, oral 250 mg/5ml; propranolol hcl solution, oral
Livtencity	maribavir	4	valganciclovir hcl tablet
Lyvispah oral granules	baclofen oral granules	4	baclofen 10 mg tablet; baclofen 20 mg tablet; tizanidine hcl tablet
Oxbryta tablets for oral suspension	voxelotor tablets for oral suspension	4	hydroxyurea capsule
Recorlev	levoketoconazole	4	ketoconazole tablet
Rezvoglar	insulin glargine-aglr	4	Basaglar Kwikpen U-100
Scemblix	asciminib	4	Iclusig
Tarpeyo	budesonide	4	methlyprednisone tablet, prednisone tablet
Xaciato 2% vaginal gel	clindamycin phosphate 2% vaginal gel	4	clindamycin phosphate cream with applicator, metronidazole gel with applicator (gram)
Yusimry	adalimumab-aqvh	4	Humira
Voxzogo	vosoritide	4	Provider 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 January 2022, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
PreHevbrio	hepatitis B vaccine (recombinant)	3	Prevention of hepatitis B
Xarelto oral suspension	rivaroxaban oral suspension	3	Venous thromboembolism
Items listed below were not added to the formulary			
Adbry	tralokinumab-ldrm	NF	mometasone furoate cream (gram); Dupixent; tacrolimus ointment (gram)
Besremi	ropeginterferon alfa-2b-njft	NF	Pegasys
Dartisla ODT	glycopyrrolate	NF	glycopyrrolate 2 mg tablets
Dyanavel XR	amphetamine ER tablets	NF	dextroamphetamine sulfate er capsule, extended release; methylphenidate er capsule,extended release biphasic 30-70
Entadfi	finasteride/tadalafil	NF	finasteride 5 mg, dutasteride capsule, tamsulosin hcl
Eprontia oral solution	topiramate oral solution	NF	gabapentin solution, oral 250 mg/5ml; valproic acid solution, oral 250 mg/5ml; propranolol hcl solution, oral
Livtencity	maribavir	NF	valganciclovir hcl
Lyvispah oral granules	baclofen oral granules	NF	baclofen 10 mg tablet, baclofen 20 mg tablet; tizanidine hcl tablet
Oxbryta tablets for oral suspension	voxelotor tablets for oral suspension	NF	hydroxyurea capsule
Recorlev	levoketoconazole	NF	ketoconazole tablet
Rezvoglar	insulin glargine-aglr	NF	Basaglar Kwikpen U-100, Levemir Flextouch, Tresiba Flextouch U-100
Scemblix	asciminib	NF	Iclusig
Tarpeyo	budesonide	NF	methyprednisolone tablet, prednisone tablet
Xaciato 2% vaginal gel	clindamycin phosphate 2% vaginal gel	NF	clindamycin phosphate cream with applicator, metronidazole gel with applicator (gram)
Yusimry	adalimumab-aqvh	NF	Humira
Voxzogo	vosoritide	NF	Provider 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)			
Xarelto oral suspension	rivaroxaban oral suspension	2	Venous thromboembolism
Items listed below were added to the formulary (Non-Preferred)			
Recorlev*	levoketoconazole	3	ketoconazole tablet
Scemblix	asciminib	3	imatinib, Bosulif, Iclusig, Sprycel, Tasigna
Tarpeyo	budesonide	3	methyprednisolone tablet, prednisone tablet
Livtencity	maribavir	3	Provider Discretion
PreHevbrio*	hepatitis B vaccine (recombinant)	3	Provider Discretion
Voxzogo	vosoritide	3	Provider Discretion
Items listed below were not added to the formulary			
Oxbryta for oral suspension	voxelotor tablets for oral suspension	NF	Hydroxyurea, Droxia
Dartisla ODT	glycopyrrolate	NF	glycopyrrolate 2 mg tablets
Eprontia oral solution	topiramate oral solution	NF	topiramate sprinkle caps

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
Adbry	tralokinumab-ldrm
Besremi	ropeginterferon alfa-2b-njft
Dartisla ODT	glycopyrrolate
Livtencity	maribavir
Oxbryta tablets for oral suspension	voxelotor tablets for oral suspension
Recorlev (levoketoconazole)	Recorlev (levoketoconazole)
Scemblix (asciminib)	Scemblix (asciminib)
Tarpeyo (budesonide)	Tarpeyo (budesonide)
Voxzogo (vosoritide)	Voxzogo (vosoritide)
Yusimry (adalimumab-aqvh)	Yusimry (adalimumab-aqvh)

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Adbry (tralokinumab-ldrm) - Commercial and Healthcare Reform	02/02/2022	New policy created for Adbry (tralokinumab-ldrm) to require the member is 18 years of age or older; specialist (dermatologist, allergist, or immunologist) attests a diagnosis of moderate-to-severe 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; and therapeutic failure or intolerance to plan-preferred Dupixent (dupilumab). Reauthorization of positive clinical response to therapy. Initial authorization duration of 6 months, and reauthorization duration of 12 months.
Anabolic Steroids - Commercial and Healthcare Reform	02/03/2022	Policy revised for Anabolic Steroids to remove Anadrol-50 (oxymetholone) as both brand and generic are off market. Criteria revised for Oxandrin (oxandrolone) to require a diagnosis of weight loss when being used to promote weight gain.
Anti-Angiogenesis and VEGF Kinase Inhibitors - Commercial and Healthcare Reform	02/03/2022	Policy revised for Stivarga (regorafenib) to require for metastatic colorectal cancer that if the member is RAS wild-type, then the member has had previous treatment with an anti-EGFR therapy.
BCR-ABL Kinase Inhibitors - Commercial and Healthcare Reform	02/05/2022	Policy revised to add to Healthcare Reform a step through generic imatinib for brand Gleevec (imatinib).
CDK Inhibitors - Commercial and Healthcare Reform	02/01/2022	Policy revised for Kisqali (ribociclib) in adult members (criteria were removed which required the member to be pre/post-menopausal, except when Kisqali (ribociclib) is used in combination with fulvestrant following disease progression on endocrine therapy in postmenopausal women or

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		in men). Policy revised for Kisqali Femara Co-Pack (ribociclib; letrozole) for use in adult members (criteria were removed which required the member to be a pre/post-menopausal woman).
Chronic Inflammatory Diseases - Commercial and Healthcare Reform	02/01/2022	Preferred products updated to move Rinvoq (upadacitinib) and Xeljanz/Xeljanz XR (tofacitinib) tablets from Step 1 Preferred to Step 2 Non-Preferred for rheumatoid arthritis (RA), psoriatic arthritis (PsA). Xeljanz/Xeljanz XR (tofacitinib) tablets added as a Step 2 Non-Preferred for ankylosing spondylitis (AS) and Xeljanz (tofacitinib) tablets/oral solution as Step 2 Non-preferred for juvenile idiopathic arthritis (JIA). Rinvoq (upadacitinib) and Xeljanz (tofacitinib) are directed specifically to Enbrel (etanercept) or Humira (adalimumab). Policy criteria revised for Cosentyx (secukinumab) to lower age requirement to 2 years of age or older for a diagnosis of PsA. New indication added for enthesitis-related arthritis (ERA) for the member to be 4 years of age or older, have a diagnosis of active ERA, and experience therapeutic failure or intolerance to 1 non-biologic disease modifying anti-rheumatic drug (DMARD). Quantity limitations updated to allow induction therapy of 5 pens/prefilled syringes (150mg/mL or 75 mg/mL) within the first 4 weeks of therapy and maintenance therapy of one pen/prefilled syringe (150mg/mL or 75 mg/mL). Criteria revised for Otezla (apremilast) to remove disease severity requirement from plaque psoriasis diagnosis from expanded indication. Criteria revised for Rinvoq (upadacitinib) to require the member has trialed Humira (adalimumab) or Enbrel (etanercept) for rheumatoid arthritis (RA). New indication added for PsA requiring the member is 18 years or older; spinal or axial PsA with trial of at least one nonsteroidal anti-inflammatory drug (NSAID), or PsA without spinal disease with trial of at least one non-biologic disease modifying antirheumatic

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		drug (DMARD), or enthesitis and/or dactylitis associated with PsA with trial of at least 1 NSAID or local glucocorticoid injection; and the member has trialed Humira (adalimumab) or Enbrel (etanercept) for all PsA subsets. Xeljanz (tofacitinib) criteria revised for new indication of ankylosing spondylitis (AS) requiring the member is 18 years or older, diagnosis of AS, trialed at least 1 nonsteroidal anti-inflammatory drug (NSAID), and added the member has trialed Humira (adalimumab) or Enbrel (etanercept) for all indications except ulcerative colitis.
Chronic Inflammatory Diseases - Commercial and Healthcare Reform	02/25/2022	Policy revised for Rinvoq (upadacitinib) to require the member is 12 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; and therapeutic failure or intolerance to 1 systemic therapy, or all are contraindicated. Skyrizi (risankizumab) added as Step 1 Preferred Agent for Psoriatic Arthritis (PsA) requiring the member is 18 years or older; spinal or axial PsA with trial of at least one nonsteroidal anti-inflammatory drug (NSAID), or PsA without spinal disease with trial of at least one non-biologic disease modifying antirheumatic drug (DMARD), or enthesitis and/or dactylitis associated with PsA with trial of at least 1 NSAID or local glucocorticoid injection.
Chronic Inflammatory Diseases - Commercial National Select Formulary	02/01/2022	Preferred products updated to move Rinvoq (upadacitinib) and Xeljanz/Xeljanz XR (tofacitinib) tablets from Step 1 Preferred to Step 2 Non-

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		Preferred for rheumatoid arthritis (RA), psoriatic arthritis (PsA). Xeljanz/Xeljanz XR (tofacitinib) tablets added as a Step 2 Non-Preferred for ankylosing spondylitis (AS) and Xeljanz (tofacitinib) tablets/oral solution as Step 2 Non-preferred for juvenile idiopathic arthritis (JIA). Rinvoq (upadacitinib) and Xeljanz (tofacitinib) are directed specifically to Enbrel (etanercept) or Humira (adalimumab). Policy criteria revised for Cosentyx (secukinumab) to lower age requirement to 2 years of age or older for a diagnosis of PsA. Step through preferred biologics for PsA only required if the member is 18 years of age or older. New indication added for enthesitis-related arthritis (ERA) for the member to be 4 years of age or older, have a diagnosis of active ERA, and experience therapeutic failure or intolerance to 1 non-biologic disease modifying anti-rheumatic drug (DMARD). Quantity limitations updated to allow induction therapy of 5 pens/prefilled syringes (150mg/mL or 75 mg/mL) within the first 4 weeks of therapy and maintenance therapy of one pen/prefilled syringe (150mg/mL or 75 mg/mL). Criteria revised for Otezla (apremilast) to remove disease severity requirement from plaque psoriasis diagnosis from expanded indication. Criteria revised for Rinvoq (upadacitinib) to require the member has trialed Humira (adalimumab) or Enbrel (etanercept) for rheumatoid arthritis (RA). New indication added for PsA requiring the member is 18 years or older; spinal or axial PsA with trial of at least one nonsteroidal anti-inflammatory drug (NSAID), or PsA without spinal disease with trial of at least one non-biologic disease modifying antirheumatic drug (DMARD), or enthesitis and/or dactylitis associated with PsA with trial of at least 1 NSAID or local glucocorticoid injection; and the member has trialed Humira (adalimumab) or Enbrel (etanercept) for all PsA subsets. Xeljanz (tofacitinib) criteria revised for new

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		indication of ankylosing spondylitis (AS) requiring the member is 18 years or older, diagnosis of AS, trialed at least 1 nonsteroidal anti-inflammatory drug (NSAID), and added the member has trialed Humira (adalimumab) or Enbrel (etanercept) for all indications except ulcerative colitis.
Chronic Inflammatory Diseases - Commercial National Select Formulary	02/25/2022	Policy revised for Rinvoq (upadacitinib) to require the member is 12 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; and therapeutic failure or intolerance to 1 systemic therapy, or all are contraindicated. Skyrizi (risankizumab) added as Step 1 Preferred Agent for Psoriatic Arthritis (PsA) requiring the member is 18 years or older; spinal or axial PsA with trial of at least one nonsteroidal anti-inflammatory drug (NSAID), or PsA without spinal disease with trial of at least one non-biologic disease modifying antirheumatic drug (DMARD), or enthesitis and/or dactylitis associated with PsA with trial of at least 1 NSAID or local glucocorticoid injection.
Direct Oral Anticoagulants (DOACs) – Commercial and Healthcare Reform	TBD	Policy created for Pradaxa (dabigatran etexilate) oral pellets that member is 11 years of age or younger, diagnosis of venous thromboembolic events (VTE), and if member is 8 years of age or older the member has an inability to swallow Pradaxa capsules. Policy created for Xarelto (rivaroxaban) oral suspension that member is 17 years of age or younger, diagnosis of VTE or thromboprophylaxis in those with congenital heart disease after the Fontan procedure, and for VTE if

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		member is ≥ 30 kg or for thromboprophylaxis if the member is ≥ 50 kg the member has an inability to swallow Xarelto tablets. For reauthorization of both drugs, member is 11 years of age or younger for Pradaxa (dabigatran etexilate) oral pellets or 17 years of age or younger for Xarelto (rivaroxaban) oral suspension, experienced a positive clinical response, and continues to have an inability to swallow.
EGFR-Targeting Kinase Inhibitors - Commercial and Healthcare Reform	02/07/2022	Policy revised to add to Healthcare Reform a step through generic erlotinib for brand Tarceva (erlotinib).
Hepatitis C Oral Agents – Commercial and Healthcare Reform	TBD	Policy revised for Mavyret (glecaprevir/pibrentasvir) that if the request is for 12 weeks of therapy, the member is either HIV/HCV co-infected or the member had a prior liver transplant. In treatment-naive, genotype 1a with no cirrhosis, Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir) + ribavirin (RBV) x 12 weeks removed as a regimen. In treatment-naive, genotype 1a with compensated cirrhosis, Zepatier (elbasvir/grazoprevir) removed as regimen. Treatment duration for Mavyret (glecaprevir/pibrentasvir) revised to 12 weeks for members who are treatment-naïve, genotype 3, post-liver transplant, with no cirrhosis. For all genotypes and treatment-experienced, criteria revised for those who have had prior treatment with interferon or interferon + first generation protease inhibitor. For all genotypes (except for genotype 3), in treatment-experienced members with no prior liver transplant and no cirrhosis or with compensated cirrhosis, Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks included and Mavyret (glecaprevir/pibrentasvir) x 16 weeks included as regimens when prior treatment was sofosbuvir/ribavirin +/- interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir; for genotype 3, Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks included as a regimen for prior treatment failure of sofosbuvir/ribavirin +/- interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir (ribavirin added to regimen when compensated

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		cirrhosis is present); Mavyret (glecaprevir/pibrentasvir) x 16 weeks included as a regimen for prior treatment failure of sofosbuvir/ribavirin +/- interferon. For all genotypes, Mavyret (glecaprevir/pibrentasvir) + sofosbuvir + ribavirin x 24 weeks and Vosevi (sofosbuvir/velpatasvir/voxilaprevir) + ribavirin x 24 weeks included as regimens when prior treatment was sofosbuvir + glecaprevir/pibrentasvir. For genotype 2 and 3, treatment experienced, prior liver transplant, no cirrhosis, and prior treatment with interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon, Harvoni (ledipasvir/ Sofosbuvir) x 12 weeks removed as regimen; Mavyret (glecaprevir/pibrentasvir) x 12 weeks added. For genotype 3, treatment experienced, no prior liver transplant, decompensated cirrhosis, and prior treatment with NS5A inhibitor, Harvoni + ribavirin x 24 weeks removed as regimen.
Hepatitis C Oral Agents – Commercial Core	TBD	Policy revised for Mavyret (glecaprevir/pibrentasvir) that if the request is for 12 weeks of therapy, the member is either HIV/HCV co-infected or the member had a prior liver transplant. In treatment-naive, genotype 1a with no cirrhosis, Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir) + ribavirin (RBV) x 12 weeks removed as a regimen. In treatment-naive, genotype 1a with compensated cirrhosis, Zepatier (elbasvir/grazoprevir) removed as regimen. Treatment duration for Mavyret (glecaprevir/pibrentasvir) revised to 12 weeks for members who are treatment-naïve, genotype 3, post-liver transplant, with no cirrhosis. For all genotypes and treatment-experienced, criteria revised for those who have had prior treatment with interferon or interferon + first generation protease inhibitor. For all genotypes (except for genotype 3), in treatment-experienced members with no prior liver transplant and no cirrhosis or with compensated cirrhosis, Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks included and Mavyret (glecaprevir/pibrentasvir) x 16 weeks included as regimens when prior

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		treatment was sofosbuvir/ribavirin +/- interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir; for genotype 3, Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks included as a regimen for prior treatment failure of sofosbuvir/ribavirin +/- interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir (ribavirin added to regimen when compensated cirrhosis is present); Mavyret (glecaprevir/pibrentasvir) x 16 weeks included as a regimen for prior treatment failure of sofosbuvir/ribavirin +/- interferon. For all genotypes, Mavyret (glecaprevir/pibrentasvir) + sofosbuvir + ribavirin x 24 weeks and Vosevi (sofosbuvir/velpatasvir/voxilaprevir) + ribavirin x 24 weeks included as regimens when prior treatment was sofosbuvir + glecaprevir/pibrentasvir. For genotype 2 and 3, treatment experienced, prior liver transplant, no cirrhosis, and prior treatment with interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon, Harvoni (ledipasvir/ Sofosbuvir) x 12 weeks removed as regimen; Mavyret (glecaprevir/pibrentasvir) x 12 weeks added. For genotype 3, treatment experienced, no prior liver transplant, decompensated cirrhosis, and prior treatment with NS5A inhibitor, Harvoni + ribavirin x 24 weeks removed as regimen.
Hepatitis C Oral Agents – Commercial National Select Formulary	TBD	Policy revised for Mavyret (glecaprevir/pibrentasvir) that if the request is for 12 weeks of therapy, the member is either HIV/HCV co-infected or the member had a prior liver transplant. In treatment-naive, genotype 1a with no cirrhosis, Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir) + ribavirin (RBV) x 12 weeks removed as a regimen. In treatment-naive, genotype 1a with compensated cirrhosis, Zepatier (elbasvir/grazoprevir) removed as regimen. Treatment duration for Mavyret (glecaprevir/pibrentasvir) revised to 12 weeks for members who are treatment-naïve, genotype 3, post-liver transplant, with no cirrhosis. For all genotypes and treatment-experienced, criteria revised for those who have had prior treatment

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		with interferon or interferon + first generation protease inhibitor. For all genotypes (except for genotype 3), in treatment-experienced members with no prior liver transplant and no cirrhosis or with compensated cirrhosis, Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks included and Mavyret (glecaprevir/pibrentasvir) x 16 weeks included as regimens when prior treatment was sofosbuvir/ribavirin +/- interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir; for genotype 3, Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks included as a regimen for prior treatment failure of sofosbuvir/ribavirin +/- interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir (ribavirin added to regimen when compensated cirrhosis is present); Mavyret (glecaprevir/pibrentasvir) x 16 weeks included as a regimen for prior treatment failure of sofosbuvir/ribavirin +/- interferon. For all genotypes, Mavyret (glecaprevir/pibrentasvir) + sofosbuvir + ribavirin x 24 weeks and Vosevi (sofosbuvir/velpatasvir/voxilaprevir) + ribavirin x 24 weeks included as regimens when prior treatment was sofosbuvir + glecaprevir/pibrentasvir. For genotype 2 and 3, treatment experienced, prior liver transplant, no cirrhosis, and prior treatment with interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon, Harvoni (ledipasvir/ Sofosbuvir) x 12 weeks removed as regimen; Mavyret (glecaprevir/pibrentasvir) x 12 weeks added. For genotype 3, treatment experienced, no prior liver transplant, decompensated cirrhosis, and prior treatment with NS5A inhibitor, Harvoni + ribavirin x 24 weeks removed as regimen.
Hetlioz and Hetlioz LQ (tasimelteon) - Commercial and Healthcare Reform	02/07/2022	Policy revised for Hetlioz (tasimelteon) capsules to require age of 18 years or older for Non-24-Hour Sleep-Wake Disorder and reauthorization criteria for Non-24 Hour Sleep-Wake Disorder revised to require attestation of an increase in total nighttime sleep time or a decrease in daytime nap duration. Reauthorization criteria for diagnosis of Smith Magenis Syndrome updated to require an increase in total nighttime sleep time or increase in sleep quality.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Interferons - Commercial and Healthcare Reform	02/07/2022	Policy revised to add Besremi (ropeginterferon alfa-2b-njft) for treatment of polycythemia vera in adults after therapeutic failure, intolerance, or contraindication to Pegasys (peginterferon alpha-2a). Removed discontinued medication, Pegintron (peginterferon alfa-2b).
Klisyri (tirbanibulin) – Commercial and Healthcare Reform	02/07/2022	Policy revised for Klisyri (tirbanibulin) to reduce to a single step through generic topical imiquimod 5% cream, fluorouracil 5% cream, or fluorouracil solution, or have contraindication to all. Reauthorization criteria for Klisyri (tirbanibulin) revised to require attestation that the member previously experienced complete or partial clearance of actinic keratosis (AK) lesions with Klisyri (tirbanibulin); an additional course of therapy is required for recurrence of AK; and the member is restarting therapy at least 60 days after cessation of an initial Klisyri 5-day course.
Livtencity (maribavir) - Commercial and Healthcare Reform	02/07/2022	New policy created for Livtencity (maribavir) to require the member is 12 years of age or older weighing at least 35 kg; documentation of diagnosis of refractory cytomegalovirus (CMV) infection or disease as evidenced by an antigenemia or polymerase chain reaction (PCR) test; recipient of hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT); and experienced therapeutic failure to ganciclovir, valganciclovir, cidofovir, or foscarnet. Reauthorization criteria to require attestation the member previously experienced a reduction in CMV deoxyribonucleic acid (DNA) level; and experiencing either new onset symptomatic CMV infection or virologic relapse without treatment-emergent maribavir resistance. Limitations of coverage added that Livtencity has not been studied in CMV disease involving the central nervous system (CNS) including the retina and is not indicated for CMV prophylaxis. Quantity limitation exception to allow for 448 tablets per 365 days if co-administered with carbamazepine, or 672 tablets per 365 days if co-administered with phenytoin or phenobarbital. Authorization duration of 2 months.
Luxturna (voretigene neparvovec-rzyl) -	02/09/2022	Policy revised for Luxturna (voretigene neparvovec-rzyl) quantity level limits to require the

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Commercial and Healthcare Reform		second injection to be given no fewer than 6 days from the first injection.
Market Watch Programs – Delaware	01/25/2022	Policy revised to add Entadfi (finasteride/tadalafil) that member tried and failed finasteride and tadalafil available separately and taken together. Policy revised to add Lyvispah (baclofen) to require that member has tried and failed generic baclofen and tizanidine. Policy revised to add Dartisla ODT (glycopyrrolate) to require that member has tried and failed generic glycopyrrolate 2 mg tablets.
Market Watch Programs – New York, Pennsylvania and West Virginia	01/25/2022	Policy revised to add Entadfi (finasteride/tadalafil) that member tried and failed finasteride and tadalafil available separately and taken together. Policy revised to add Lyvispah (baclofen) to require that member has tried and failed generic baclofen and tizanidine. Policy revised to add Dartisla ODT (glycopyrrolate) to require that member has tried and failed generic glycopyrrolate 2 mg tablets.
Non-Preferred Baclofen Products - Commercial and Healthcare Reform	TBD	Policy revised to add Lyvispah (baclofen) to require the member is 12 years of age or older; has a diagnosis of spasticity, flexor spasms, pain, clonus, or muscular rigidity resulting from multiple sclerosis, spinal cord injury, or other spinal cord diseases; if the member is 18 years of age or older, they have experienced therapeutic failure, contraindication, or intolerance to generic tizanidine tablets; has experienced therapeutic failure or intolerance to generic baclofen tablets; and has an inability to swallow tablets. Reauthorization criteria to require prescriber attestation that the member has experienced positive clinical response to therapy and continues to have an inability to swallow tablets.
Non-Preferred Basal Insulins - Commercial and Healthcare Reform	02/09/2022	Policy revised to add Rezvoglar (insulin glargine-aglr) to require diagnosis of diabetes, 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).

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Non-Preferred Basal Insulins - Commercial and Healthcare Reform	02/09/2022	Policy revised to require diagnosis of diabetes mellitus (type removed) and clarified that trial and failure of metformin or using with metformin if member has type 2 diabetes.
Oxbryta (voxelotor) - Commercial and Healthcare Reform	02/09/2022	Policy revised to add Oxbryta (voxelotor) tablets for oral suspension to require the member is 4 years of age or older, has a diagnosis of sickle cell disease (SCD), clinical documentation that the member's hemoglobin level is ≤ 10.5 g/dL, has experienced therapeutic failure, contraindication, or intolerance to generic hydroxyurea, and is 11 years of age or younger. Reauthorization criteria that the member has experienced a therapeutic response defined as one of the following: improvement in SCD signs, symptoms, or complications; hemoglobin increase of > 1 g/dL from baseline without use of concurrent transfusions; decreased number of transfusions from baseline. Quantity limit override criteria added to allow quantities > 3 tablets for oral suspension per day if: 1) the member weighs ≥ 40 kg, is unable to swallow tablets, and the requested quantity is for 5 tablets per day or 2) if the member is using Oxbryta (voxelotor) concomitantly with a strong or moderate CYP3A4 inducer, the request is for ≤ 8 tablets per day and is unable to swallow tablets or is 4 to 11 years of age. Policy revised for Oxbryta (voxelotor) oral tablets for use in members 4 years of age and older and hemoglobin level is ≤ 10.5 g/dL.
Parathyroid Hormone Analogs – Commercial National Select Formulary	02/09/2022	Policy revised to allow for treatment duration of Forteo (teriparatide) to extend beyond 24 months if the member is at high risk or has returned to high risk of fracture.
PI3K Inhibitors – Commercial and Healthcare Reform	02/09/2022	Policy revised for Copiktra (duvelisib) to remove criteria for adults 18 years of age or older with a diagnosis of follicular lymphoma after no response or intolerance to at least two prior systemic therapies, per the FDA-withdrawn indication.
Prolia (denosumab) and Evenity (romosozumab-aqqg) - Commercial and Healthcare Reform	02/09/2022	Policy revised for Prolia (denosumab) to ask for diagnosis of non-metastatic prostate cancer or breast cancer.
Provigil (modafinil) and Nuvigil (armodafinil) -	02/09/2022	Policy revised to require therapeutic failure, intolerance, or contraindication to generic central nervous system stimulant for narcolepsy and

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Commercial and Healthcare Reform		idiopathic hypersomnia. If a member has narcolepsy and cataplexy, baseline cataplexy episodes must be documented. Criteria added to reauthorization for narcolepsy with cataplexy that there must be a reduction in baseline cataplexy episodes. Limitations of coverage removed for prescriber specializing in neurology or sleep medicine, reduction of sleepiness due to Alzheimer's disease, Parkinson's disease, and depression, and counteracting sedating effects of other medications.
Provigil (modafinil) and Nuvigil (armodafinil) - Commercial and Healthcare Reform - DE only	02/09/2022	Policy revised to require therapeutic failure, intolerance, or contraindication to generic central nervous system stimulant for narcolepsy and idiopathic hypersomnia. If a member has narcolepsy and cataplexy, baseline cataplexy episodes must be documented. Criteria added to reauthorization for narcolepsy with cataplexy that there must be a reduction in baseline cataplexy episodes. Limitations of coverage removed for prescriber specializing in neurology or sleep medicine, reduction of sleepiness due to Alzheimer's disease, Parkinson's disease, and depression, and counteracting sedating effects of other medications.
Recorlev (levoketoconazole) - Commercial and Healthcare Reform	02/10/2022	New policy created for Recorlev (levoketoconazole) to require Recorlev (levoketoconazole) to be prescribed by an endocrinologist, the member to be 18 years of age or older, have a diagnosis of endogenous Cushing's syndrome, the member to not be a candidate for surgery or have experienced therapeutic failure to surgery (i.e., surgery has not been curative), and to have experienced therapeutic failure on, intolerance to, or contraindication to ketoconazole tablets. Reauthorization criteria also included to require the member to have a urinary free cortisol level that is < 100 mcg/24 hours, < 276 nmol/day, or within a normal range per the laboratory reference range.
Repository Corticotropin Injection – Commercial and Healthcare Reform	02/11/2022	Policy revised to add Purified Cortrophin Gel (repository corticotropin injection) with no approval criteria as the drug is not FDA labeled for infantile spasms.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Solaraze (diclofenac sodium 3%) gel and Carac (fluorouracil 0.5%) cream - Commercial and Healthcare Reform	02/11/2022	Policy revised for Solaraze (diclofenac sodium 3%) gel and Carac (fluorouracil 0.5%) cream for the member to experience therapeutic failure or intolerance to generic topical fluorouracil solution or fluorouracil 5% cream, or contraindication to all; additionally, must experience therapeutic failure or intolerance to generic imiquimod 5% topical cream. Reauthorization added for Solaraze (diclofenac sodium 3%) to require attestation the member has previously responded to Solaraze (diclofenac sodium 3%) topical gel therapy, is restarting therapy at least 30 days after cessation of therapy, and if the request is for brand Solaraze, the member has experienced therapeutic failure or intolerance to generic diclofenac sodium 3% gel. Reauthorization added for Carac (fluorouracil 0.5%) to require attestation the member has previously responded to Carac (fluorouracil 0.5%) topical therapy, is experiencing recurrence of actinic keratosis, and if the request is for brand Carac, the member has experienced therapeutic failure or intolerance to generic fluorouracil 0.5% cream.
Sunosi (solriamfetol) - Commercial and Healthcare Reform	02/11/2022	Policy revised for Sunosi (solriamfetol). Narcolepsy initial authorization revised to require member to be 18 years of age or older, provider to provide documentation of baseline data of either excessive daytime sleepiness (EDS) via the Epworth Sleepiness Scale (ESS) or Maintenance of Wakefulness Test (MWT), members with cataplexy to provide a baseline number of cataplexy episodes and experience therapeutic failure, contraindication, or intolerance to a generic Central Nervous System (CNS) stimulant (e.g. dextroamphetamine), and members without cataplexy to experience therapeutic failure, contraindication, or intolerance to both plan-preferred generic modafinil and a plan-preferred generic CNS stimulant (e.g. dextroamphetamine, methylphenidate). For Narcolepsy reauthorization, members with cataplexy must experience a decrease in cataplexy episodes compared to baseline and all members must experience a decrease in daytime sleepiness as proven by improvement on the ESS or MWT. For Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS)

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		initial authorization, member must be 18 years of age or older.
Tarpeyo (budesonide) - Commercial and Healthcare Reform	02/11/2022	New policy created for Tarpeyo (budesonide) delayed-release capsules requiring members to be 18 years of age or older, have a diagnosis of primary immunoglobulin A nephropathy at risk of rapid disease progression, concurrent use, intolerance, or contraindication to at least one angiotensin converting enzyme inhibitor and at least one aldosterone receptor blocker, and experience therapeutic failure, intolerance, or contraindication to at least one systemic corticosteroid.
Testosterone (Androgens) – Commercial and Healthcare Reform	02/11/2022	Policy revised for testosterone (androgens) to allow for surgery damage as a cause for primary or secondary hypogonadism with testicular failure. Additionally, for hypogonadism allow a diagnosis of secondary hypogonadism due to hypopituitarism (pituitary hormone deficiencies).
Thiola and Thiola EC (tiopronin) - Commercial and Healthcare Reform	02/11/2022	Policy for Thiola (tiopronin) and Thiola EC updated to remove the criteria that the member may be 9 years of age or older.
Voxzogo (Vosoritide) - Commercial and Healthcare Reform	02/11/2022	New policy created for Voxzogo (vosoritide) to require the following criteria for coverage: 1. The member is 5 years of age or older; 2. The member has a diagnosis of achondroplasia verified by genetic testing for the FGFR3 gene mutation; 3. The prescriber has provided a baseline annualized growth velocity (AGV); 4. The prescriber attests that the member's epiphyses have not closed. For reauthorization, the following criteria must be met: 1. The prescriber provides documentation of an increase in AGV compared to baseline; 2. the prescriber attests that the member's epiphyses have not closed.
Xermelo (telotristat ethyl) - Commercial and Healthcare Reform	02/11/2022	Reauthorization criteria revised for Xermelo (telotristat ethyl) to require prescriber attestation that the member has experienced reduction in average number of daily bowel movements and will continue to use Xermelo (telotristat ethyl) in combination with a somatostatin analog. Initial authorization duration updated to 3 months, and reauthorization of 12 months.

*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 Quantities of COVID-19 Oral Therapies – Commercial and Healthcare Reform	02/16/2022	New policy to authorize additional courses of Paxlovid (nirmatrelvir/ritonavir) and molnupiravir if the prescriber attests the member is experiencing a repeat diagnosis of coronavirus disease 2019 (COVID-19) unrelated to the initial diagnosis of COVID-19 treated with the respective agent. Authorization duration of 14 days.
Atypical Antipsychotics - Commercial	TBD	Policy revised for Vraylar (cariprazine) for diagnosis of Bipolar I Disorder, Bipolar II Disorder. The member has experienced therapeutic failure, contraindication, or intolerance to one (1) of the following: aripiprazole tablets or a generic quetiapine product. Policy revised for Caplyta (lumateperone) to require that the member is 18 years of age or older, has a diagnosis of depressive episodes associated with bipolar I or bipolar II disorder, and has experienced therapeutic failure, contraindication, or intolerance to either a generic quetiapine product or generic aripiprazole tablets.
Atypical Antipsychotics - Commercial	TBD	Policy revised for Caplyta (lumateperone) to require therapeutic failure, contraindication, or intolerance to either a generic quetiapine product or adjunctive olanzapine and fluoxetine therapy for a diagnosis of bipolar disorder. Policy revised for Rexulti (brexpiprazole) to allow use in adults and pediatric patients 13 years of age and older for a diagnosis of schizophrenia.
Atypical Antipsychotics - Healthcare Reform	TBD	Policy revised for Vraylar (cariprazine) for diagnosis of Bipolar I Disorder, Bipolar II Disorder. The member has experienced therapeutic failure, contraindication, or intolerance to one (1) of the following: generic quetiapine extended-release (ER) changed to generic quetiapine product. Policy revised for Caplyta (lumateperone) to require that the member is 18 years of age or older, has a diagnosis of depressive episodes associated with bipolar I or bipolar II disorder, and has experienced therapeutic failure, contraindication, or intolerance to either a generic quetiapine product or generic aripiprazole tablets.
Atypical Antipsychotics - Healthcare Reform	TBD	Policy revised for Caplyta (lumateperone) to require therapeutic failure, contraindication, or intolerance to either a generic quetiapine product or adjunctive

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		olanzapine and fluoxetine therapy for a diagnosis of bipolar disorder. Policy revised for Rexulti (brexpiprazole) to allow use in adults and pediatric patients 13 years of age and older for a diagnosis of schizophrenia.
Dartisla ODT (glycopyrrolate) – Commercial and Healthcare Reform	TBD	New policy created for Dartisla ODT (glycopyrrolate) for use in members 18 years of age or older as an adjunct treatment of peptic ulcer disease after trial and failure to generic glycopyrrolate 2 mg tablets.
Dyanavel XR (amphetamine) - Commercial and Healthcare Reform	TBD	New policy created for Dyanavel XR (amphetamine) to require the member is 6 years of age or older, has a diagnosis of attention deficit hyperactivity disorder (ADHD), and has experienced therapeutic failure, contraindication, or intolerance to two of the following generic products: amphetamine/dextroamphetamine extended-release, methylphenidate HCl extended-release, dexmethylphenidate HCl extended-release, or dextroamphetamine extended-release. Reauthorization criteria requiring prescriber attestation that the member has experienced positive clinical response to therapy.
Evekeo (amphetamine sulfate) – Commercial and Healthcare Reform	02/07/2022	Policy for Evekeo (amphetamine sulfate) revised to require baseline cataplexy episodes for a diagnosis of narcolepsy with cataplexy. Amphetamine/Dextroamphetamine was removed from alternatives for narcolepsy. Reauthorization criteria revised to include prescriber attestation that the member experienced a decrease in cataplexy episodes with narcolepsy compared to baseline.
Methotrexate Injections - Healthcare Reform	02/15/2022	This policy was termination and combined with policy J-0876 Methotrexate Injections - Commercial.
Non-Preferred Benign Prostatic Hyperplasia Therapy – Commercial and Healthcare Reform	TBD	Policy revised to add Entadfi (finasteride/tadalafil) that member is initiating therapy for signs and symptoms of benign prostatic hyperplasia (BPH), tried and failed a preferred generic alpha-1 blocker and finasteride and tadalafil available separately and taken together. If the member is using Cialis (tadalafil) with Proscar (finasteride), the member is initiating treatment for BPH. Reauthorization for Entadfi (finasteride/tadalafil) or Cialis (tadalafil) with Proscar (finasteride) added to ask that member had a positive response to previous therapy and is re-initiating treatment and authorization duration is 6

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		months. Reauthorization for all other BPH drugs changed documentation to attestation.
Non-Preferred Topiramate Products – Commercial and Healthcare Reform	TBD	Policy revised to include Eprontia (topiramate) oral solution. For diagnosis of migraine, the member must be 12 years of age or older, have a diagnosis of migraine, must be unable to swallow pills or food, and have experienced therapeutic failure, contraindication, or intolerance to two plan-preferred generic migraine preventive therapies. For diagnosis of seizures, the member must be 2 years of age or older, have a diagnosis of partial onset seizures, primary generalized tonic-clonic seizures, or adjunctive treatment of Lennox-Gastaut syndrome, must be unable to swallow pills or food, and have experienced therapeutic failure, contraindication, or intolerance to two plan-preferred generic anti-epileptic drugs. Reauthorization criteria of prescriber attestation of positive clinical response to therapy.
Topical Corticosteroids - Commercial and Healthcare Reform	02/16/2022	Policy revised to add as targets: Desrx 0.05% (desonide) gel, Topicort 0.05% (desoximetasone) cream and ointment; remove as targets: Locoid Lipocream 0.1% (hydrocortisone butyrate) lotion, amcinonide 0.01% ointment, brand Clodan 0.05% (clobetasol propionate) shampoo, generic desoximetasone 0.25% ointment. Generic hydrocortisone butyrate 0.1% solution added as a qualifier agent for low to medium potency topical corticosteroids. Healthcare Reform policy combined with Commercial.
Topical Corticosteroids - Healthcare Reform	01/25/2022	Policy terminated and criteria and revisions combined into J-0872.

*For Commercial and Healthcare Reform policies, an exception to some or all the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.
**All effective dates are tentative and subject to delay pending internal review or approval.
Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria.

3. Formulary Program

No changes at this time.

4. Quantity Level Limit (QLL) Programs*

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

Table 1. Quantity Level Limits – Quantity per Duration for Commercial and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Adbry (tralokinumab-ldrm)	4 syringes (150 mg/mL) per 28 days	12 syringes (150 mg/mL) per 84 days
Besremi (ropeginterferon alfa-2b-njft)	2 syringes (2mL) per 28 days	6 syringes (6 mL) per 84 days
Livtencity (maribavir)	224 tablets per 365 days	224 tablets per 365 days
molnupiravir	40 capsules per 365 days	40 capsules per 365 days
mRNA COVID-19 Vaccines	4 doses per 720 days	4 doses per 720 days
Paxlovid (nirmatrelvir tablets; ritonavir tablets)	30 tablets (1 carton of 5 blister cards) per 365 days	30 tablets (1 carton of 5 blister cards) per 365 days
PreHevbrio (hepatitis B vaccine (recombinant))	4 units per 720 days	4 units per 720 days
Rapid OTC COVID Antigen Tests	8 tests per 30 days	8 tests per 30 days
Xarelto (rivaroxaban) oral suspension	4 bottles (620 mL) per 30 days	12 bottles (1,860 mL) per 90 days
Yusimry (adalimumab-aqvh)	2 syringes per 28 days	6 syringes per 84 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
Xaciato (clindamycin phosphate) 2% vaginal gel	1 tube (25 g) per dispensing event	1 tube (25 g) 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
Dartisla ODT (glycopyrrolate)	4 tablets per day
diclofenac sodum 25 mg tablet	3 tablets per day
Dyanavel XR (amphetamine) ER tablets	1 tablet per day
Eprontia (topiramate) oral solution	16 mL per day
Lofena (disclofenac sodium) 25 mg tablet	3 tablets per day
Lyvispah (baclofen) 5 mg oral granules	16 packets per day
Lyvispah (baclofen) 10 mg oral granules	8 packets per day
Lyvispah (baclofen) 20 mg oral granules	4 packets per day
Oxbryta (voxelotor) tablets for oral suspension	3 tablets per day
Recorlev (levoketoconazole)	8 tablets per day
Tarpeyo (budesonide)	4 capsules per day

Drug Name	Daily Limit
Voxzogo (vosoritide)	1 vial package per day
Entadfi (finasteride/tadalafil)	1 capsule per day
Rinvoq (upadacitinib) 30 mg tablet	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.

Brand Name	Generic Name	Comments
PreHevbrio	hepatitis B vaccine (recombinant)	Prevention of hepatitis B

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

Brand Name	Generic Name	Preferred Alternatives
Dartisla ODT	glycopyrrolate	glycopyrrolate 2 mg tablets
Dyanavel XR	amphetamine ER tablets	dextroamphetamine-amphetamine capsule,extended release 24hr; methylphenidate HCl tablet extended release
Entadfi	finasteride/tadalafil	finasteride 5 mg, dutasteride, tamsulosin
Eprontia oral solution	topiramate oral solution	gabapentin, valproic acid (as sodium salt), carbamazepine
Leqvio	inclisiran	ezetimibe, atorvastatin, Repatha SureClick
Lyvispah oral granules	baclofen oral granules	baclofen 10 mg tablet, baclofen 20 mg tablet
Rezvoglar	insulin glargine-aglr	Basaglar, Lantus
Xaciato 2% vaginal gel	clindamycin phosphate 2% vaginal gel	clindamycin phosphate cream with applicator, metronidazole gel with applicator (gram)

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.

Brand Name	Generic Name	Comments
PreHevbrio	hepatitis B vaccine (recombinant)	Prevention of hepatitis B

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

Brand Name	Generic Name	Preferred Alternatives
Eprontia oral solution	topiramate oral solution	gabapentin, valproic acid (as sodium salt), carbamazepine

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

Brand Name	Generic Name	Preferred Alternatives
Dartisla ODT	glycopyrrolate	glycopyrrolate 2 mg tablets
Dyanavel XR	(amphetamine) ER tablets	dextroamphetamine-amphetamine capsule,extended release 24hr; methylphenidate HCl tablet extended release
Entadfi	finasteride/tadalafil	finasteride 5 mg, tamsulosin, tadalafil 5 mg
Leqvio	inclisiran	ezetimibe, atorvastatin, Repatha SureClick
Lyvispah oral granules	baclofen oral granules	baclofen 10 mg tablet, baclofen 20 mg tablet
Rezvoglar	insulin glargine-aglr	Basaglar, Lantus
Tarpeyo	budesonide	methylprednisolone tablet, prednisone tablet
Xaciato 2% vaginal gel	clindamycin phosphate 2% vaginal gel	clindamycin phosphate cream with applicator, metronidazole gel with applicator (gram)
Voxzogo	vosoritide	Provider Discretion

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

C. Additions to the Specialty Tier

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

Brand Name	Generic Name
Adbry	tralokinumab-ldrm

Apretude	cabotegravir
Besremi	ropeginterferon alfa-2b-njft
Fyarro	sirolimus
Livtencity	maribavir
Oxbryta tablets for oral suspension	voxelotor tablets for oral suspension
Recorlev	levoketoconazole
Tezspire	tezepelumab-ekko
Vyvgart	efgartigimod alfa
Xarelto oral suspension	rivaroxaban oral suspension
Yusimry	adalimumab-aqvh
Voxzogo*	vosoritide
Tarpeyo*	budesonide

*Product was added to Specialty Tier for Incentive Formulary but not added to Venture Formulary or Performance Formulary.

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Adalimumab BIOSIMILARS - Medicare	TBD	Policy revised for adalimumab biosimilars to add new biosimilar Yusimry (adalimumab-aqhy) to policy criteria. Criteria for juvenile idiopathic arthritis updated to require the member is 4 years of age or older for Abrilada, Amjevita, Hadlima, Hulio, or Hyrimoz; or 2 years of age or older for Cyltezo or Yusimry. Criteria for Crohn's disease updated to require the member is 18 years of age or older for Abrilada, Amjevita, Hadlima, Hulio, or Hyrimoz; or 6 years of age or older for Cyltezo or Yusimry.
Adbry (tralokinumab-ldrm) - Medicare	02/02/2022	New policy created for Adbry (tralokinumab-ldrm) to require a diagnosis of moderate-to-severe 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 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

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		topical therapies are contraindicated due to damaged skin; Reauthorization of positive clinical response to therapy. Initial authorization duration of 6 months, and reauthorization duration of 12 months.
Adbry (tralokinumab-ldrm) - Medicare	02/25/2022	Policy revised for Adbry (tralokinumab-ldrm) to require the member has experienced therapeutic failure, contraindication, or intolerance to Dupixent (dupilumab) and Rinvoq (upadacitinib).
Atypical Antipsychotics – Medicare	02/03/2022	Policy revised for Caplyta (lumateperone) to require that the member is 18 years of age or older, has a diagnosis of depressive episodes associated with bipolar I or bipolar II disorder, and has experienced therapeutic failure, contraindication, or intolerance to one (1) other formulary generic antipsychotic.
CDK Inhibitors – Medicare	02/01/2022	Policy revised for Kisqali (ribociclib) in adult patients (criteria were removed which required the member to be pre/post-menopausal, except when Kisqali (ribociclib) is used in combination with fulvestrant following disease progression on endocrine therapy in postmenopausal women or in men). Policy revised for Kisqali Femara Co-Pack (ribociclib; letrozole) for use in adult patients (criteria were removed which required the member to be a pre/post-menopausal woman).
Chronic Inflammatory Diseases - Medicare	02/03/2022	Policy criteria revised for Cosentyx (secukinumab) to lower age requirement to 2 years of age or older for a diagnosis of psoriatic arthritis (PsA). New indication added for enthesitis-related arthritis (ERA) for the member to be 4 years of age or older, have a diagnosis of ERA, and experience therapeutic failure or intolerance to 1 non-biologic disease modifying anti-rheumatic drug (DMARD). Quantity limitations updated to allow induction therapy of 5 pens/prefilled syringes (150mg/mL or 75 mg/mL) within the first 4 weeks of therapy and maintenance therapy of one pen/prefilled syringe (150mg/mL or 75 mg/mL). Criteria revised for Orencia (abatacept) intravenous (IV) for a new indication of acute graft vs. host disease (aGVHD) to require the member is 2 years of age or older, using for

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		aGVHD prophylaxis, undergoing hematopoietic stem cell transplantation from a matched or 1 allele-mismatched unrelated donor, and using in combination with a calcineurin inhibitor and methotrexate. Criteria revised for Otezla (apremilast) to remove disease severity requirement from plaque psoriasis diagnosis from expanded indication. Criteria revised for Rinvoq (upadacitinib) to require the member has trialed at least 1 tumor necrosis factor (TNF) blocker for rheumatoid arthritis (RA). New indication added for PsA requiring diagnosis of PsA and the member has trialed at least 1 TNF blocker. Olumiant (baricitinib) criteria revised to add that at least one TNF blocker is trialed along with 2 preferred biologics for RA. Xeljanz (tofacitinib) criteria revised for new indication of ankylosing spondylitis (AS) requiring the member is 18 years or older, diagnosis of AS, trialed at least 1 nonsteroidal anti-inflammatory drug (NSAID), and added the member has trialed at least 1 TNF blocker for all indications.
Chronic Inflammatory Diseases - Medicare	02/25/2022	Policy revised for Rinvoq (upadacitinib) 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; and therapeutic failure or intolerance to 1 systemic therapy, or all are contraindicated. Skyrizi (risankizumab) added as Step 1 Preferred Agent

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		for Psoriatic Arthritis (PsA) requiring the member is 18 years or older and has a diagnosis of PsA.
Cialis (tadalafil) and Entadfi (finasteride/tadalafil) – Medicare	TBD	Policy revised to add Entadfi (finasteride/tadalafil) that member is initiating therapy for signs and symptoms of benign prostatic hyperplasia (BPH), tried and failed finasteride and tadalafil available separately and taken together. Reauthorization for Entadfi (finasteride/tadalafil) added to ask that member is re-initiating treatment and authorization duration is 6 months.
Dartisla ODT (glycopyrrolate) – Medicare	02/05/2022	New policy created for Dartisla ODT (glycopyrrolate) for use in members as an adjunct treatment of peptic ulcer disease after trial and failure to generic glycopyrrolate tablets.
Darzalex (daratumumab) and Darzalex Faspro (daratumumab and hyaluronidase-fihj) – Medicare	02/05/2022	Policy revised for Darzalex Faspro (daratumumab and hyaluronidase) to add criteria for use in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant; and to add criteria for use in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.
Direct Oral Anticoagulants (DOACs) – Medicare	TBD	Policy created for Pradaxa (dabigatran etexilate) oral pellets that member is 11 years of age or younger, diagnosis of venous thromboembolic events (VTE), and if member is 8 years of age or older the member has an inability to swallow Pradaxa capsules. Policy created for Xarelto (rivaroxaban) oral suspension that member is 17 years of age or younger, diagnosis of VTE or thromboprophylaxis in those with congenital heart disease after the Fontan procedure, and for VTE if member is ≥ 30 kg or for thromboprophylaxis if the member is ≥ 50 kg the member has an inability to swallow Xarelto tablets. For reauthorization of both drugs, member is 11 years of age or younger for Pradaxa (dabigatran etexilate) oral pellets or 17 years of age or younger for Xarelto (rivaroxaban) oral suspension and continues to have an inability to swallow.
Elyxyb (celecoxib) - Medicare	02/05/2022	New policy for Elyxyb (celecoxib) requiring diagnosis of migraine and therapeutic failure or

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		intolerance to two generic non-steroidal anti-inflammatory drugs (NSAIDs).
Eprontia (topiramate) - Medicare	02/05/2022	New policy for Eprontia (topiramate) oral solution. For diagnosis of migraine, the member must have a diagnosis of migraine, must be unable to swallow pills or food, and have experienced therapeutic failure, contraindication, or intolerance to two generic migraine preventive therapies. For diagnosis of seizures, the member must have a diagnosis of partial onset seizures, primary generalized tonic-clonic seizures, or adjunctive treatment of Lennox-Gastaut syndrome, must be unable to swallow pills or food, and have experienced therapeutic failure, contraindication, or intolerance to two generic anti-epileptic drugs.
Hepatitis C Oral Therapy – Medicare	02/05/2022	Policy revised for Zepatier (elbasvir/grazoprevir) to allow use in members 12 years of age or older. Zepatier (elbasvir/grazoprevir) removed as a regimen for treatment-naïve genotype 1a members. Treatment duration for Mavyret (glecaprevir/pibrentasvir) revised to 12 weeks for members who are treatment-naïve, genotype 3, post-liver transplant, with no cirrhosis. In treatment-naive, genotype 1a with no cirrhosis, Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir) + ribavirin (RBV) x 12 weeks removed as a regimen. In treatment-naive, genotype 1a with compensated cirrhosis, Zepatier (elbasvir/grazoprevir) removed as regimen. For all genotypes and treatment-experienced, criteria revised for those who have had prior treatment with interferon or interferon + first generation protease inhibitor. For all genotypes (except for genotype 3), in treatment-experienced members with no prior liver transplant and no cirrhosis or with compensated cirrhosis, Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks and Mavyret (glecaprevir/pibrentasvir) x 16 weeks included as regimens when prior treatment was sofosbuvir/ribavirin +/- interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir; for genotype 3, Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		included as a regimen for prior treatment failure of sofosbuvir/ribavirin +/- interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir (ribavirin added when compensated cirrhosis present); Mavyret (glecaprevir/pibrentasvir) x 16 weeks included as a regimen for prior treatment failure of sofosbuvir/ribavirin +/- interferon. For all genotypes, Mavyret (glecaprevir/pibrentasvir) + sofosbuvir + ribavirin x 24 weeks and Vosevi (sofosbuvir/velpatasvir/voxilaprevir) + ribavirin x 24 weeks included as regimens when prior treatment was sofosbuvir + glecaprevir/pibrentasvir. For genotype 2 and 3, treatment experienced, prior liver transplant, no cirrhosis, and prior treatment with interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon, Harvoni (ledipasvir/ Sofosbuvir) x 12 weeks removed as regimen; Mavyret (glecaprevir/pibrentasvir) x 12 weeks added. For genotype 3, treatment experienced, no prior liver transplant, decompensated cirrhosis, and prior treatment with NS5A inhibitor, Harvoni + ribavirin x 24 weeks removed as regimen.
Interferons - Medicare	02/07/2022	Policy revised to add Besremi (ropeginterferon alfa-2b-njft) for treatment of polycythemia vera in adults. Removed discontinued medication, Pegintron (peginterferon alfa-2b).
Klisyri (tirbanibulin) – Medicare	02/07/2022	Policy revised for Klisyri (tirbanibulin) to reduce to a single step through generic topical imiquimod 5% cream, fluorouracil 5% cream, or fluorouracil solution, or have contraindication to all.
Livtencity (maribavir) - Medicare	02/07/2022	New policy created for Livtencity (maribavir) to require the member is 12 years of age or older weighing at least 35 kg; diagnosis of refractory cytomegalovirus (CMV) infection or disease as evidenced by an antigenemia or polymerase chain reaction (PCR) test; recipient of hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT); and experienced therapeutic failure to ganciclovir, valganciclovir, cidofovir, or foscarnet. Reauthorization criteria to

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		require attestation the member previously experienced a reduction in CMV deoxyribonucleic acid (DNA) level; and experiencing either new onset symptomatic CMV infection or virologic relapse without treatment-emergent maribavir resistance. Authorization duration of 3 months.
Lyvispah (baclofen) - Medicare	TBD	New policy for Lyvispah (baclofen) oral granules to require diagnosis of spasticity, flexor spasms, pain, clonus, or muscular rigidity resulting from multiple sclerosis, spinal cord injury, or other spinal cord diseases, and one of the following: the member has an inability to swallow tablets or has experienced therapeutic failure or intolerance to generic baclofen tablets.
Mechanistic Target of Rapamycin Kinase (mTOR) Inhibitors - Medicare	02/01/2022	Policy renamed to Mechanistic Target of Rapamycin Kinase (mTOR) Inhibitors and revised to add Fyarro (sirolimus protein-bound particles for injectable suspension). The member has a diagnosis of locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor.
Non-Preferred Basal Insulins - Medicare	TBD	Policy revised to require diagnosis of diabetes mellitus (type removed). Policy revised to add Rezvoglar (insulin glargine-aglr) to require diagnosis of diabetes and trial and failure of both Basaglar (insulin glargine) and Lantus (insulin glargine).
Oxbryta (voxelotor) - Medicare	02/09/2022	Policy revised to add Oxbryta (voxelotor) tablets for oral suspension to require the member is 4 years of age and older, has a diagnosis of sickle cell disease (SCD), has experienced therapeutic failure, contraindication, or intolerance to hydroxyurea, and is either 11 years of age or younger or has an inability to swallow tablets. Reauthorization criteria that the member has experienced an improvement in SCD signs, symptoms, or complications. Policy revised for Oxbryta (voxelotor) oral tablets for use in member 4 years of age and older.
PCSK9 Therapies - Medicare	02/09/2022	Policy revised to include new drug Leqvio (inclisiran). For heterozygous familial hypercholesterolemia (HeFH), the member must be 18 years of age or older; have a diagnosis of HeFH supported by genetic confirmation of one mutant allele; or have an untreated low-density lipoprotein (LDL) at least 190 (or 160 before the

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		age of 20) and one physical sign of HeFH and meet one of the following: the World Health Organization (WHO) criteria/Dutch lipid clinical network score greater than 8 points, familial hypercholesterolemia possibility of definite based on the Simon Broome register, or familial hypercholesterolemia possibility of definite on the Make Early Diagnosis to Prevent Early Deaths (MEDPED) tool; have a current LDL level greater than 130 for members 17 years or younger or greater than 100 for members 18 years and older; experienced therapeutic failure to a maximally tolerated statin or is statin intolerant; experienced therapeutic failure or intolerance to Repatha (evolocumab); and will use as adjunct to maximally tolerated statin therapy unless the patient is statin intolerant. Reauthorization criteria for HeFH requiring a reduction in LDL from baseline. For a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), the member must be 18 years of age or older; have a diagnosis of ASCVD substantiated by one of the following: acute coronary syndrome, coronary or other arterial revascularization, history of myocardial infarction, history of stroke, history of transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin, or stable or unstable angina; have a current LDL greater than 70; experienced therapeutic failure to a maximally tolerated statin or is statin intolerant; experienced therapeutic failure or intolerance to Repatha (evolocumab); and will use as adjunct to maximally tolerated statin therapy unless the patient is statin intolerant. Reauthorization criteria for ASCVD requiring a reduction in LDL from baseline. Quantity limit approval criteria for Leqvio (inclisiran) to allow for initiation dosing of 2 syringes in the first 3 months.
PI3K Inhibitors – Medicare	02/09/2022	Policy revised for Copiktra (duvelisib) to remove criteria for adults 18 years of age or older with a diagnosis of follicular lymphoma after no response or intolerance to at least two prior systemic therapies, per the FDA-withdrawn indication.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Programmed Death Receptor Therapies – Medicare	02/10/2022	Policy revised for Keytruda (pembrolizumab) for use as adjuvant treatment in members with renal cell carcinoma who are at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesion; and for members 12 years and older with Stage IIB, IIC, or III melanoma following complete resection.
Recorlev (levoketoconazole) - Medicare	02/10/2022	New policy created for Recorlev (levoketoconazole) to require the member to have a diagnosis of endogenous Cushing's syndrome and the member to not be a candidate for surgery or have experienced therapeutic failure to surgery (i.e., surgery has not been curative). Reauthorization criteria also included to require the member to have achieved a mean urine free cortisol (mUFC) less than the starting baseline value.
Repository Corticotropin Injections – Medicare	02/10/2022	Policy revised to add Purified Cortrophin Gel (repository corticotropin injection). For diagnosis of multiple sclerosis, the member must be experiencing an acute exacerbation, concurrently receiving immunomodulatory therapy, and had trial of two corticosteroids. For rheumatic disorders of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, and ankylosing spondylitis, the member must be using as adjunctive therapy for short term administration or in select cases of rheumatoid arthritis or juvenile rheumatoid arthritis, the member requires low dose maintenance therapy, the member had trial of two corticosteroids, and is concurrently receiving maintenance therapy with an nonsteroidal anti-inflammatory drug (NSAID), disease-modifying antirheumatic drug (DMARD), or biologic. For collagen diseases of systemic lupus erythematosus or systemic dermatomyositis, the member must be using for an exacerbation or in select cases as maintenance therapy, had trial of two corticosteroids, and concurrently receiving maintenance therapy with at least one antimalarial or immunosuppressant. For dermatologic diseases of severe erythema multiforme, stevens Johnson syndrome, and severe psoriasis, the member must have trial of

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		two corticosteroids, and for psoriasis must be concurrently receiving maintenance therapy with phototherapy, systemic therapy, or a biologic. For allergic states of serum sickness, transfusion due to serum protein reaction, and atopic dermatitis, the member must have trial of two corticosteroids and for atopic dermatitis must be concurrently receiving maintenance therapy with a topical corticosteroid, topical calcineurin inhibitor, topical phosphodiesterase-4 inhibitors, or Dupixent (dupilumab). For ophthalmic diseases of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, allergic conjunctivitis, keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation, the member must have trial of two corticosteroids. For respiratory diseases of symptomatic sarcoidosis, the member must have trial of two corticosteroids. For nephrotic syndrome, the member must have nephrotic syndrome without uremia of the idiopathic type or nephrotic syndrome without uremia due to lupus erythematosus and must be using to induce diuresis or a remission of proteinuria and must have trial of two therapies from different classes (corticosteroids, calcineurin inhibitors, mycophenolate, alkylating-based therapy, angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, or sulfonamide loop diuretics). When used to diagnosis adrenal insufficiency, the member has experienced therapeutic failure, contraindication, or intolerance to cosyntropin. For acute gouty arthritis, the member must be unable to take first line therapies and have trial of two corticosteroids. For pediatric epileptic aphasia, the member must have trial of two corticosteroids. For reauthorization, attestation that the member cannot use corticosteroids, will be using for a new acute exacerbation, and will continue to receive maintenance therapy.
Rituximab Products – Medicare	02/11/2022	Policy revised for Rituxan (rituximab) in combination with chemotherapy for members 6 months of age or older with a diagnosis of previously untreated, advanced stage, CD20-

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL). Expanded indication added for Ruxience (rituximab-pvvr) for a diagnosis of moderately to severely active rheumatoid arthritis (RA), using in combination with methotrexate, an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. For RA, if the request is for Rituxan (rituximab) or Truxima (rituximab-abbs), the member has experienced therapeutic failure or intolerance to Ruxience (rituximab-pvvr).
Tarpeyo (budesonide) - Medicare	02/11/2022	New policy created for Tarpeyo (budesonide) delayed-release capsules requiring a diagnosis of primary immunoglobulin A nephropathy at risk of rapid disease progression and concurrent use, intolerance, or contraindication to at least one angiotensin converting enzyme inhibitor and at least one aldosterone receptor blocker.
Tezspire (tezepelumab-ekko) - Medicare	02/11/2022	New policy created for Tezspire (tezepelumab-ekko) requiring members to be 12 years of age or older, a diagnosis of severe asthma, a member history of 2 or more asthma exacerbations requiring oral or injectable corticosteroid treatment or resulting in hospitalization in the previous 12 months, and inadequate symptom control despite regular treatment with medium or high-dose inhaled corticosteroids (ICS) and at least 1 additional asthma controller (e.g., long-acting beta-2 agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), with or without oral corticosteroids (OCS). Further, members are required to continue treatment with medium or high-dose inhaled corticosteroids (ICS) and at least 1 additional asthma controller (e.g., long-acting beta-2 agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), with or without OCS, while using Tezspire. The member must also meet one (1) of the following criteria: pre-bronchodilator forced expiratory volume in 1 second (FEV1) below 80% in adults, pre-bronchodilator FEV1 below 90% in adolescents, or FEV1 reversibility of at least 12% and 200 milliliters (mL) after albuterol (salbutamol) administration. For reauthorization,

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		members must meet one (1) of the following criteria: decreased rescue medication or OCS use, decrease in frequency of severe asthma exacerbations, increase in pulmonary function from baseline (e.g., FEV1), or reduction in reported asthma-related symptoms (e.g., asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing).
Thiola and Thiola EC (tiopronin) - Medicare	02/16/2022	Policy for Thiola and Thiola EC (tiopronin) revised to remove age and weight requirement.
Topical Retinoid Therapy - Medicare	02/01/2022	Policy revised to add Twyneo (tretinoin/benzoyl peroxide) as a target agent requiring a diagnosis of acne vulgaris and therapeutic failure, contraindication, or intolerance to two generic topical non-retinoid acne medications.
Voxzogo (vosoritide) - Medicare	02/11/2022	New policy created for Voxzogo (vosoritide) to require the following criteria for coverage: 1. The member is 5 years of age or older; 2. The member has a diagnosis of achondroplasia verified by genetic testing for the FGFR3 gene mutation; 3. The prescriber has provided a baseline annualized growth velocity (AGV); 4. The prescriber attests that the member's epiphyses have not closed. For reauthorization, the following criteria must be met: 1. the member has experienced an increased AGV compared to baseline; 2. the prescriber attests that the member's epiphyses have not closed.
Vyvgart (efgartigimod alfa-fcab) - Medicare	02/11/2022	New policy for Vyvgart (efgartigimod alfa-fcab) requiring diagnosis of generalized myasthenia gravis, anti-acetylcholine receptor (AChR) antibody positive, and therapeutic failure, contraindication, or intolerance to generic pyridostigmine. Reauthorization criteria requiring prescriber attestation of improvement in signs and symptoms or decrease in the number of exacerbations.

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

2. Updates to Step Therapy

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Brand ADHD Step Therapy - Medicare	01/01/2022	Policy revised to add Dyanavel XR (amphetamine) oral tablets to require that the medication is being prescribed for a medically accepted indication. If the member has a diagnosis of ADHD, they have experienced therapeutic failure, contraindication, or intolerance to two of the following generic medications: methylphenidate, dextroamphetamine/amphetamine, atomoxetine, or dexmethylphenidate.

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

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)
Adbry (tralokinumab-ldrm)	4 syringes (150 mg/mL) per 28 days	12 syringes (150 mg/mL) per 84 days
Apretude (cabotegravir)	7 injection kits (21 mL) per 365 days	7 injection kits (21 mL) per 365 days
Besremi (ropeginterferon alfa-2b-njft)	0.72 mL per day	0.72 mL per day
Dartisla ODT (glycopyrrolate)	4 tablets per day	4 tablets per day
Dyanavel XR (amphetamine) ER tablets	1 tablet per day	1 tablet per day
Entadfi (finasteride/tadalafil)	1 capsule per day	1 capsule per day
Eprontia (topiramate) oral solution	16 mL per day	16 mL per day
Leqvio (inclisiran)	1 syringe per 6 months	1 syringe per 6 months
Livtencity (maribavir)	4 tablets per day	4 tablets per day
Lyvispah (baclofen) 5 mg oral granules	16 packets per day	16 packets per day
Lyvispah (baclofen) 10 mg oral granules	8 packets per day	8 packets per day
Lyvispah (baclofen) 20 mg oral granules	4 packets per day	4 packets per day
molnupiravir	360 capsules per 365 days	360 capsules per 365 days
Oxbryta (voxelotor) tablets for oral suspension	8 tablets per day	8 tablets per day
Paxlovid (nirmatrelvir tablets; ritonavir tablets)	270 tablets per 365 days	270 tablets per 365 days
Recorlev (levoketoconazole)	8 tablets per day	8 tablets per day
Rinvoq (upadacitinib) 30 mg tablet	1 tablet per day	1 tablet per day
Tarpeyo (budesonide)	4 capsules per day	4 capsules per day
Tezspire (tezepelumab-ekko)	1 single-dose vial or single dose pre-filled syringe per 28 days	3 single-dose vials or single dose pre-filled syringes per 84 days
Voxzogo (vosoritide)	1 vial package per day	1 vial package per day

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Vyvgart (efgartigimod alfa)	12 vials per 49 days	12 vials per 49 days
Xarelto (rivaroxaban) oral suspension	6 bottles (930 mL) per 31 days	18 bottles (2,790 mL) per 90 days
Yusimry (adalimumab-aqvh)	2 syringes per 28 days	6 syringes per 84 days

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