Formulary Updates

Published February 11, 2022
Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for October 2021. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in October 2021 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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C. Changes to the Highmark Healthcare Reform Essential 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

Firvanq® (Vancomycin Hydrochloride for Oral Solution) by Azurity Pharmaceuticals, Inc.: Recall – Mix Up of Diluent

On September 8th, 2021, Azurity Pharmaceuticals, Inc. recalled the above product. The affected product was recalled due to some products in the affected lot were found to incorrectly contain a First Omeprazole (FIRST-PPI) diluent instead of the Firvanq diluent bottle.

Vancomycin may not be completely solubilized in the FIRST-PPI diluent which could lead to doses above or below those recommended in the label. There is reasonable probability that the administration of inappropriate doses of oral vancomycin may lead to persistent diarrhea associated with dehydration and electrolyte abnormalities, recurrence of Clostridium difficile (C. difficile) infection, its progression to severe colitis, colon perforation requiring colectomy, and potentially death. Elderly and immunocompromised patients are especially vulnerable to the complications of C. difficile infection. To date, Azurity has not received any reports of adverse events related to this recall.

Ruzurgi® (amifampridine) 10 mg Tablets by Jacobus Pharmaceutical Company Inc.: Recall – Contamination

On September 13th, 2021, Jacobus Pharmaceutical Company Inc. recalled the above product. The affected product was recalled due to yeast, mold, and aerobic bacterial contamination.

Oral products heavily contaminated with yeast, mold, and aerobic bacteria may result in serious and life-threatening infections. The use of the defective product in patients with underlying immunosuppressive conditions such as Lambert Eaton Syndrome (LEMS) increases the concern for serious infections.

CHANTIX® (Varenicline) by Pfizer: Recall – N-nitroso-varenicline

On September 16th, 2021, Pfizer expanded their recall of the above product. The affected product was recalled due to the presence of a nitrosamine, N-nitroso-varenicline, at or above the FDA interim acceptable intake limit.

Long-term ingestion of N-nitroso-varenicline may be associated with a theoretical potential increased cancer risk in humans, but there is no immediate risk to patients taking this medication. The health benefits of stopping smoking outweigh the theoretical potential cancer risk from the nitrosamine impurity in varenicline.

GLUCAGON® Emergency Kit by Eli Lilly and Company: Recall – Loss of Potency

On September 26th, 2021, Eli Lilly and Company recalled the above product. The affected product was recalled due to a product complaint reporting that the vial of Glucagon was in liquid form instead of the powder form.

Severe hypoglycemia in patients with diabetes, if not reversed, can potentially cause adverse health consequences ranging from transient, minor complaints to neurological damage, seizures, and even death if not promptly treated. Associated with the one product complaint, it was reported to Lilly that the involved patient experienced lack of drug effect and reported subsequent seizures.

Lidocaine HCl Topical Solution 4% by Teligent Pharma, Inc.: Recall – Superpotency

On October 12th, 2021, Teligent Pharma Inc. recalled the above product. The affected products were recalled because the firms testing has found it to be super potent based on an Out of Specification (OOS) result obtained at the 18-month stability timepoint.

Use of the super potent product would result in a higher than intended lidocaine dose. An increased lidocaine dose could lead to the development of local anesthetic systemic toxicity depending on the duration of the treatment and the specific patient. Local anesthetic systemic toxicity can result in central nervous system reactions including excitation and/or depression and more serious signs of cardiovascular toxicity, such as bradycardia, hypotension, and even cardiovascular collapse can present very quickly. If local anesthetic systemic toxicity is not recognized and treated quickly, severe morbidity and even death can result. Adults and the elderly who are more likely to use this product as well as children of lower body weight are more likely to experience local anesthetic systemic toxicity if a higher than intended lidocaine concentration is administered. To date, Teligent Pharma, Inc. has not received any reports of adverse events related to this recall.

Irbesartan Tablets and Irbesartan and Hydrochlorothiazide Tablets by Lupin Pharmaceuticals, Inc.: Recall – Potential Presence of N-nitrosoirbesartan Impurity

On October 14th, 2021, Lupin Pharmaceuticals Inc. recalled the above product. The affected product was recalled because analysis revealed that certain tested API batches (but not finished product batches) were above the specification limit for the impurity, N-nitrosoirbesartan.

N-nitrosoirbesartan impurity is a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests.

From October 8, 2018 (the earliest date of shipment from the manufacturing site of any of the affected batches), to September 30, 2021, Lupin received 4 reports of illness from Irbesartan and 0 reports from Irbesartan and Hydrochlorothiazide.

Highmark Formulary Update – October 2021

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 November 2021 unless otherwise noted.

Brand Name	Generic Name	Comments
Comirnaty	COVID-19 vaccine	COVID-19 Prevention
TicoVac*	Tick Borne Encephalitis Vaccine	Tick Borne Encephalitis
Vaxneuvance	pneumococcal 15-valent conjugate vaccine	Prevention of pneumococcal disease

*Commercial Comprehensive only

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Kerendia	finerenone	Invokana
Loreev XR	lorazepam ER	lorazepam tablet; clonazepam tablet; diazepam tablet
Rezurock	belumosudil	prednisone tablet; methylprednisolone tablet; tacrolimus capsule
Skytrofa	lonapegsomatropin-tcgd	Norditropin Flexpro
Trudhesa nasal spray	dihydroergotamine mesylate nasal spray	sumatriptan spray, non-aerosol (ea); dihydroergotamine mesylate aerosol, spray with pump (ml); sumatriptan succinate tablet
Twyneo*	tretinoin/benzoyl peroxide	Tretinoin cream (gram); tretinoin microsphere; adapalene gel (gram)

Brand Name	Generic Name	Preferred Alternatives
Bylvay	odevixibat	Provider Discretion
Welireg	belzutifan	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
Rezurock	belumosudil
Skytrofa	lonapegsomatropin-tcgd
Bylvay	odevixibat
Welireg	belzutifan

B. Changes to the Highmark Healthcare Reform Progressive Formulary

Note: The Progressive Formulary does not apply to Highmark Delaware 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 members. For your convenience, you may search the following formularies here.

Table 1. Formulary Updates

All products added to the formulary effective October 2021 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below are Preferred products			
No changes at this time.			
Items listed below are Non-Preferred products			
Kerendia	finerenone	3 - Nonpreferred Brand	Invokana
Loreev XR	lorazepam ER	3 - Nonpreferred Brand	lorazepam tablet; clonazepam tablet; diazepam tablet
Trudhesa nasal spray	dihydroergotamine mesylate nasal spray	3 - Nonpreferred Brand	Provider DiscretionN/A (Sunsetting Progressive)
Twyneo	tretinoin/benzoyl peroxide	3 - Nonpreferred Brand	Provider DiscretionN/A (Sunsetting Progressive)

Rezurock	belumosudil	4 - Nonpreferred Specialty	prednisone tablet; methylprednisolone tablet; tacrolimus capsule
Skytrofa	lonapegsomatropin-tcgd	4 - Nonpreferred Specialty	Norditropin Flexpro, Genotropin, Humatrope
Comirnaty	COVID-19 vaccine	3 - Nonpreferred Brand	Provider Discretion
TicoVac	Tick Borne Encephalitis Vaccine	3 - Nonpreferred Brand	Provider Discretion
Vaxneuvance	pneumococcal 15-valent conjugate vaccine	3 - Nonpreferred Brand	Provider Discretion
Bylvay Oral Pellets	odevixibat Oral Pellets	4 - Nonpreferred Specialty	Provider Discretion
Welireg	belzutifan	4 - Nonpreferred Specialty	Provider Discretion

Coverage may be contingent upon plan benefits.
Formulary options: **Tier 1:** Formulary Generic drugs; **Tier 2:** Formulary Brand drugs; **Tier 3:** Non-Formulary Generic drugs, Non-Formulary Brand drugs, Formulary Specialty drugs; **Tier 4:** Non-Formulary Specialty drugs.
*Effective date to be determined.

C. Changes to the Highmark Healthcare Reform Essential Formulary

The Essential Formulary is a closed formulary for select Healthcare Reform (HCR) plans. A list of drugs included on the Essential Formulary, listed by therapeutic class, is available at here.

Table 1. Formulary Updates
All formulary changes effective November 2021 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Comirnaty	COVID-19 vaccine	3 - Nonpreferred Brand	COVID-19 Prevention
TicoVac	Tick Borne Encephalitis Vaccine	3 - Nonpreferred Brand	Tick Borne Encephalitis
Vaxneuvance	pneumococcal 15-valent conjugate vaccine	3 - Nonpreferred Brand	Prevention of pneumococcal disease
Items listed below were not added to the formulary			
Kerendia	finerenone	NF	Invokana
Loreev XR	lorazepam ER	NF	lorazepam tablet; clonazepam tablet; diazepam tablet
Rezurock	belumosudil	NF	prednisone tablet; methylprednisolone tablet; tacrolimus capsule
Skytrofa	lonapegsomatropin-tcgd	NF	norditropin flexpro

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Trudhesa nasal spray	dihydroergotamine mesylate nasal spray	NF	sumatriptan succinate tablet; zolmitriptan tablet
Twyneo*	tretinoin/benzoyl peroxide	NF	tretinoin cream (gram); tretinoin gel (gram); adapalene-benzoyl peroxide
Bylvay	odevixibat	NF	Provider Discretion
Welireg	belzutifan	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 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 November 2021 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Comirnaty	COVID-19 vaccine	3	COVID-19 Prevention
TicoVac	Tick Borne Encephalitis Vaccine	3	Tick Borne Encephalitis
Vaxneuvance	pneumococcal 15-valent conjugate vaccine	3	Prevention of pneumococcal disease
Items listed below were not added to the formulary			
Kerendia	finerenone	NF	Invokana
Loreev XR	lorazepam ER	NF	lorazepam tablet; clonazepam tablet; diazepam tablet
Rezurock	belumosudil	NF	prednisone tablet; methylprednisolone tablet; tacrolimus capsule
Skytrofa	lonapegsomatropin-tcgd	NF	Norditropin flexpro
Trudhesa nasal spray	dihydroergotamine mesylate nasal spray	NF	sumatriptan spray, non-aerosol (ea); sumatriptan succinate tablet
Twyneo*	tretinoin/benzoyl peroxide	NF	tretinoin gel (gram); adapalene-benzoyl peroxide; adapalene gel (gram)
Bylvay	odevixibat	NF	Provider Discretion
Welireg	belzutifan	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.

E. 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)			
Kerendia	finerenone	2	CKD associated with Type 2 DM
Vaxneuvance	pneumococcal 15-valent conjugate vaccine	2	Prevention of pneumococcal disease
TicoVac	Tick Borne Encephalitis Vaccine	2	Tick Borne Encephalitis
Items listed below were added to the formulary (Non-Preferred)			
Bylvay	odevixibat	3	Provider Discretion
Rezurock	belumosudil	3	prednisone tablet; methylprednisolone tablet; tacrolimus capsule
Trudhesa nasal spray	dihydroergotamine mesylate nasal spray	3	sumatriptan spray, non-aerosol (ea); dihydroergotamine mesylate aerosol, spray with pump (ml); sumatriptan succinate tablet
Welireg	belzutifan	3	Provider Discretion
Skytrofa*	onapegsomatropin-tcgd	3	Norditropin Flexpro, Genotropin
Twyneo*	tretinoin/benzoyl peroxide	3	tretinoin cream (gram); tretinoin microsphere; adapalene gel (gram)
Comirnaty*	COVID-19 vaccine	3	Provider Discretion
Items listed below were not added to the formulary			
Loreev XR	lorazepam ER	NF	lorazepam tablet; clonazepam tablet; diazepam tablet

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
Bylvay	odevixibat
Rezurock	belumosudil
Welireg	belzutifan
Skytrofa	lonapegsomatropin-tcgd

F. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Androgen Receptor Inhibitors - Commercial and Healthcare Reform	10/14/2021	Policy for Nubeqa (darolutamide), Erleada (apalutamide), and Xtandi (enzalutamide) updated to require the member to be 18 years of age or older.
Arakoda and Krintafel (tafenoquine) - Commercial and Healthcare Reform	10/14/2021	Policy revised for Krintafel (tafenoquine) to require use in combination with chloroquine or hydroxychloroquine.
BTK Inhibitors – Commercial and Healthcare Reform	10/14/2021	Policy revised for Brukinsa (zanubrutinib) to add criteria for members 18 years of age and older with Waldenström's macroglobulinemia; and for Brukinsa (zanubrutinib) to add criteria for members 18 years of age or older with a diagnosis of relapsed or refractory marginal zone lymphoma after receipt of at least one previous anti-CD20 (Cluster of Differentiation 20)-based regimen.
Bylvay (odevixibat) – Commercial and Healthcare Reform	10/15/2021	New policy for Bylvay (odevixibat) requiring age of 3 months or older, diagnosis of progressive familial intrahepatic cholestasis type 1 or 2 confirmed by genetic testing, diagnosis of pruritis, elevated serum bile acids above the laboratory reference range, not exclusively on liquid food, and does not have cirrhosis, portal hypertension, or history of hepatic decompensation. Reauthorization requiring improvement in pruritis, decrease in serum bile acids from baseline, and attestation that the member has not progressed to cirrhosis, portal hypertension, or hepatic decompensation. Initial authorization of 6 months and reauthorization duration of 12 months.
CGRP Inhibitors – Commercial and Healthcare Reform	10/15/2021	Policy revised to update language for concomitant use of two chemically distinct calcitonin gene-related peptide inhibitors to require prescriber attestation that benefits outweigh risks. Ubrelvy (ubrogepant) criteria updated to require age of 18 years or older.
Chronic Inflammatory Diseases - Commercial and Healthcare Reform	10/15/2021	Policy criteria for plaque psoriasis revised to require therapeutic failure to phototherapy or systemic therapy, or contraindication to both phototherapy and systemic therapy. Stelara (ustekinumab) quantity limit exception created

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		allowing for every 4 week dosing for Crohn's Disease if clinical documentation provided that the member is a partial responder or non-responder to every 8 week dosing.
Chronic Inflammatory Diseases - Commercial National Select Formulary	10/15/2021	Policy criteria for plaque psoriasis revised to require therapeutic failure to phototherapy or systemic therapy, or contraindication to both phototherapy and systemic therapy. Stelara (ustekinumab) quantity limit exception created allowing for every 4 week dosing for Crohn's Disease if clinical documentation provided that the member is a partial responder or non-responder to every 8 week dosing.
Cystic Fibrosis Inhaled Medications - Commercial and Healthcare Reform	10/15/2021	Policy revised for Cystic Fibrosis Inhaled Medications to no longer require member to be 6 years of age or older and no longer require documentation confirming the member is not colonized with Burkholderia cepacia complex for Bethkis (tobramycin inhalation solution), Kitabis Pak (tobramycin inhalation solution), Tobi (tobramycin inhalation solution), and Tobi Podhaler (tobramycin inhalation powder). Policy also revised to no longer require member to be 7 years of age or older and no longer require documentation confirming the member is not colonized with Burkholderia cepacia complex for Cayston (aztreonam inhalation solution).
Cystic Fibrosis Inhaled Medications - Commercial NSF	10/15/2021	Policy revised for Cystic Fibrosis Inhaled Medications to no longer require member to be 6 years of age or older and no longer require documentation confirming the member is not colonized with Burkholderia cepacia complex for Bethkis (tobramycin inhalation solution), Kitabis Pak (tobramycin inhalation solution), Tobi (tobramycin inhalation solution), Tobi Podhaler (tobramycin inhalation powder), and tobramycin inhalation solution. Policy also revised to no longer require member to be 7 years of age or older and no longer require documentation confirming the member is not colonized with Burkholderia cepacia complex for Cayston (aztreonam inhalation solution).
Diacomit (stiripentol) - Commercial and Healthcare Reform	10/15/2021	Policy revised for Diacomit (stiripentol) to add additional reauthorization criteria requiring the member to use Diacomit (stiripentol) in combination with clobazam.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Diclofenac Containing Products - Commercial and Healthcare Reform	10/15/2021	Criteria for Zipsor (diclofenac potassium) revised to include use in pediatric patients 12 years of age and older, as per FDA-approved label change.
Dificid (fidaxomicin) - Commercial and Healthcare Reform	10/15/2021	Policy revised for Dificid (fidaxomicin) to remove step through vancomycin and to require confirmation of Clostridium difficile diagnosis with 3 or more unexplained and new-onset loose bowel movements in < 24 hours and one of the following: a positive nucleic acid amplification test (NAAT) or polymerase chain reaction (PCR) result for C. difficile, a positive glutamate dehydrogenase (GDH) test result, a positive enzyme immunoassay (EIA) for C. difficile toxin, or a positive stool culture for C. difficile.
Drizalma Sprinkle (duloxetine) - Commercial and Healthcare Reform	10/15/2021	Criteria added for a diagnosis of fibromyalgia, a new FDA-approved indication: Member must be 18 years of age or older, member must have a documented diagnosis of fibromyalgia, there is clinical documentation (i.e., chart notes) of the fibromyalgia diagnosis including all of the following: widespread bilateral pain above and below the waist, pain of at least 3 months duration, and at least one of the following five fibromyalgia symptoms: cognitive impairment, fatigue, sleep disturbance, neurological symptoms, exercise intolerance. In addition, the member has an inability to swallow capsules/tablets.
Evzio (naloxone) Step Therapy – Commercial and Healthcare Reform	10/15/2021	Policy terminated- Evzio is no longer on the market.
Fertility - New York Commercial and Healthcare Reform	10/11/2021	Policy revised for Fertility to add requirement that a member has experienced therapeutic failure or intolerance to plan-preferred Endometrin (progesterone) in order to obtain Crinone (progesterone).
Human Growth Hormone - Commercial and Healthcare Reform	10/17/2021	Policy revised to add Sogroya (somapacitan-beco) to require member is an adult and meets one (1) of the following: 1) has multiple pituitary growth hormone deficiencies, 2) has central nervous system irradiation, or 3) has reconfirmation of growth hormone deficiency in adulthood defined as all of the following: growth velocity of < 2 cm/year, epiphyseal fusion has occurred (bone age > 14 years for females and > 16 years for males), has not used growth

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		hormone for at least 1 month, and has the following response to all of the following standard growth hormone stimulation tests A) arginine or macimorelin and B) insulin or glucagon. Reauthorization attesting positive response. Policy revised to add Skytrofa (lonapegsomatropin-tcgd) that member has pituitary growth hormone deficiency, growth velocity at least 2 standard deviations below the age-appropriate mean or a height at least 2.25 standard deviations below the age-appropriate mean, subnormal response to two (2) standard growth hormone stimulation tests, and if female, bone age ≤ 14 years or if male, bone age ≤ 16 years. Or the member is a neonate has a condition indicating growth hormone deficiency and growth hormone level < 10 ng/mL. Reauthorization of growth velocity of at least 2 cm/year (if less than 2 cm/year meets adults approval criteria) and bone age. As non-preferred growth hormone products the member has tried and failed all preferred products.
Human Growth Hormone - Commercial and Healthcare Reform	10/17/2021	Policy revised for growth hormone to remove "contraindication" in all step therapy through all preferred growth hormone products as all products are somatropin. Removed step therapy criteria in children with Noonan Syndrome as Norditropin is a preferred product. For human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS)-wasting removed that other causes of weight loss have been ruled out. For short bowel syndrome defined it as < 200 cm of functional small bowel and for reauthorization asked that member continues to be dependent on parenteral or intravenous nutrition support. Added that Humatrope (somatropin) and Zomacton (somatropin) are exempt from preferred product requirements when used for children with short stature homeobox-containing gene (SHOX) for Commercial National Select Formulary. Reauthorization duration for Zorbtive (somatropin) changed from 12 months to 3 months.
Human Growth Hormone - Delaware Commercial and Healthcare Reform	10/17/2021	Policy revised to add Sogroya (somapacitan-beco) to require member is an adult and meets one (1) of the following: 1) has multiple pituitary

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		growth hormone deficiencies, 2) has central nervous system irradiation, or 3) has reconfirmation of growth hormone deficiency in adulthood defined as all of the following: growth velocity of < 2 cm/year, epiphyseal fusion has occurred (bone age > 14 years for females and > 16 years for males), has not used growth hormone for at least 1 month, and has the following response to all of the following standard growth hormone stimulation tests A) arginine or macimorelin and B) insulin or glucagon. Reauthorization attesting positive response. Policy revised to add Skytrofa (lonapegsomatropin-tcgd) that member has pituitary growth hormone deficiency, growth velocity at least 2 standard deviations below the age-appropriate mean or a height at least 2.25 standard deviations below the age-appropriate mean, subnormal response to two (2) standard growth hormone stimulation tests, and if female, bone age ≤ 14 years or if male, bone age ≤ 16 years. Or the member is a neonate has a condition indicating growth hormone deficiency and growth hormone level < 10 ng/mL. Reauthorization of growth velocity of at least 2 cm/year (if less than 2 cm/year meets adults approval criteria) and bone age. As non-preferred growth hormone products the member has tried and failed all preferred products.
Human Growth Hormone - Delaware Commercial and Healthcare Reform	10/17/2021	Policy revised for growth hormone to remove "contraindication" in all step therapy through all preferred growth hormone products as all products are somatropin. Removed step therapy criteria in children with Noonan Syndrome as Norditropin is a preferred product. For human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS)-wasting removed that other causes of weight loss have been ruled out. For short bowel syndrome defined it as < 200 cm of functional small bowel and for reauthorization asked that member continues to be dependent on parenteral or intravenous nutrition support. For small for gestational age (SGA) added that member has failed to catch up by 2 years of age. Added that Humatrope (somatropin) and Zomacton (somatropin) are

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		exempt from preferred product requirements when used for children with short stature homeobox-containing gene (SHOX) for Commercial National Select Formulary. Reauthorization duration for Zorbtive (somatropin) changed from 12 months to 3 months.
Interleukin (IL)-5 Antagonists - Commercial and Healthcare Reform	10/17/2021	Policy revised for Nucala (mepolizumab) and Fasenra (benralizumab) to allow for a diagnosis of asthma evidenced by a prebronchodilator forced expiratory volume in 1 second (FEV1) below 90% in adolescents. New indication for Nucala (mepolizumab) added for chronic rhinosinusitis with nasal polyps (CRSwNP) requiring the member is 18 years of age or older, have a diagnosis of CRSwNP, baseline bilateral nasal polyp score ≥ 5, documentation of baseline nasal congestion score, and try and fail a generic intranasal corticosteroid. Reauthorization for the prescriber to submit attestation that the member has a decrease in their nasal polyp score or in the nasal congestion/obstruction severity score.
Kuvan (sapropterin dihydrochloride) - Commercial and Healthcare Reform	10/17/2021	Policy revised for Kuvan (sapropterin dihydrochloride) to add requirement that member is one (1) month of age or older and remove reauthorization criteria requiring member to step through the generic formulation if trying to access the brand formulation.
Market Watch Programs – Delaware	10/17/2021	Policy revised to add Ibuprofen-famotidine, hydroxychloroquine (100 MG, 300 MG & 400 MG), Loreev XR, and Thalitone to the High Cost Low Value table. Evzio was also removed since off the market.
Market Watch Programs – PA, NY, and WV	10/19/2021	Policy revised to add Ibuprofen-famotidine, hydroxychloroquine (100 MG, 300 MG & 400 MG), Loreev XR, and Thalitone to the High Cost Low Value table. Evzio was also removed since off the market.
Nascobal (cyanocobalamin) - Healthcare Reform	10/29/2021	Policy terminated; combined into policy J-0761 Nascobal (cyanocobalamin) - Commercial and Healthcare Reform.
Natpara (parathyroid hormone) - Commercial and Healthcare Reform	10/19/2021	Policy revised to include concomitant use of or contraindication to calcium or vitamin D supplementation in reauthorization criteria.
New York - Chemotherapy Override	10/11/2021	A new policy was created to allow for override of prior authorization for cancer chemotherapy as

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Exception - Commercial and Healthcare Reform		per New York Consolidated Laws, Insurance Law-ISC 3221, section (12)(A). The following criteria must be met for an override: The requested product is an FDA-approved federal legend product, the drug must be classified as a cancer chemotherapy medication, the chemotherapy drug in question for the specific type of cancer for which it has been prescribed is recognized in one of the following compendia: 1. American Hospital Formulary Service-Drug Information (AHFS-DI) 2. National Comprehensive Cancer Networks (NCCN) Drugs and Biologics Compendiu, 3. IBM Micromedex DRUGDEX 4. Elsevier Gold Standard's Clinical Pharmacology 5. Other authoritative compendia as identified by the Federal Secretary of Health and Human Service or the Center for Medicare and Medicaid Services (CMS) 6. Recommended by a review article or editorial comment in a major peer reviewed professional journal.
Non-Preferred Basal Insulins - Commercial and Healthcare Reform	11/24/2021	Policy created for Semglee (insulin glargine-yfgn) to require diagnosis of type 2 diabetes, trial and failure of metformin or using with metformin, and trial and failure through the following: Basaglar (insulin glargine), Lantus (insulin glargine), Levemir (insulin detemir), Toujeo (insulin glargine), and Tresiba (insulin degludec). Reauthorization attesting continued use needed.
Non-Preferred Dipeptidyl Peptidase IV (DPP-IV) Inhibitors and Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Commercial and Healthcare Reform	10/13/2021	Policy created to include Qtern (dapagliflozin/saxagliptin) and Steglujan (ertugliflozin/sitagliptin). Policy revised for Qtern (dapagliflozin/saxagliptin) to try and fail canagliflozin- and empagliflozin-containing products.
Non-Preferred Dipeptidyl Peptidase IV Inhibitors (DPP-IV) – Commercial and Healthcare Reform	10/13/2021	Policy revised to remove combination products Qtern (dapagliflozin/saxagliptin) and Steglujan (ertugliflozin/sitagliptin) to include in J-1108 Non-Preferred Dipeptidyl Peptidase IV Inhibitors and Sodium-Glucose Co-Transporter 2 Inhibitors – Commercial and Healthcare Reform. Clarified that member has tried and failed metformin or using Nesina (alogliptin), Onglyza (saxagliptin), or Oseni (alogliptin/pioglitazone) in addition to a metformin-containing product.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Noxafil (posaconazole) - Commercial and Healthcare Reform	10/19/2021	Policy revised for Noxafil (posaconazole) delayed-release tablets and oral suspension to request one of the following: the member is a hematopoietic stem cell transplant (HSCT) recipient with graft versus host disease (GVHD) or the member is expected to have prolonged neutropenia from chemotherapy due to a hematologic malignancy. Criteria added that if the request is for Noxafil (posaconazole) delayed-release tablets, the member is 2 years of age or older and weighs > 40 kg. Double step therapy through clotrimazole, fluconazole, itraconazole, and voriconazole removed. If the request is for Noxafil oral suspension, the provider should attest that the member is unable to swallow tablets. Criteria added for Noxafil (posaconazole) delayed-release tablets for the treatment of invasive aspergillosis infection treatment to require all of the following: the member is 13 years of age or older, the member has a diagnosis of invasive aspergillosis, the member has experienced therapeutic failure, contraindication, or intolerance to generic voriconazole, and if the request is for brand Noxafil (posaconazole) delayed-release tablets, the member has experienced therapeutic failure or intolerance to the generic posaconazole tablets. Age requirement of 13 years of age or older added to Noxafil (posaconazole) oral suspension for treatment of oropharyngeal candidiasis and aspergillosis or candidiasis prophylaxis.
Noxafil (posaconazole) - Commercial and Healthcare Reform	10/19/2021	Policy revised for Noxafil (posaconazole) PowderMix for delayed-release oral suspension to require the member be 2 years of age or older.
NTRK Inhibitors - Commercial and Healthcare Reform	10/19/2021	Policy revised for Vitrakvi (larotrectinib) to require an FDA-approved test for the corresponding genetic abnormality.
Orilissa (elagolix) - Commercial and Healthcare Reform	10/21/2021	Policy revised for Orilissa (elagolix) to add requirements that the total cumulative duration of therapy with Orilissa (all strengths) does not exceed 24 months and the total cumulative duration of therapy with Orilissa 200 mg does not exceed 6 months. For reauthorization, added requirement the total cumulative duration of therapy with Orilissa 200 mg does not exceed 6 months.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Provigil (modafinil) and Nuvigil (armodafinil) - Commercial and Healthcare Reform	10/21/2021	Policy revised for Provigil (modafinil) and Nuvigil (armodafinil) to add criteria for indication of Idiopathic Hypersomnia (IH) for Provigil. In order to obtain Provigil (modafinil) for IH, member must be 18 years of age or older; member must have diagnosis of IH; member must not have diagnosis of cataplexy; prescriber must provide polysomnography and/or MSLT substantiating at least 2 SOREMPs, prescriber must provide MSLT demonstrating a mean sleep latency of 8 minutes or less, OR polysomnography demonstrating total 24-hour sleep time of at least 660 minutes (11 hours) OR wrist actigraphy demonstrating at least 660 minutes (11 hours) of sleep per 24 hours averaged across at least 7 days of monitoring; prescriber must provide baseline data of either EDS via the Epworth Sleepiness Scale (ESS) or Maintenance of Wakefulness Test (MWT); and member has experienced therapeutic failure or intolerance to generic modafinil if requesting brand Provigil. For reauthorization, prescriber attests the member experienced a decrease in daytime sleepiness as proven by improvement on the (ESS) or (MWT) compared to baseline.
Provigil (modafinil) and Nuvigil (armodafinil) - Commercial and Healthcare Reform (Delaware Only)	10/21/2021	Policy revised for Provigil (modafinil) and Nuvigil (armodafinil) to add criteria for indication of Idiopathic Hypersomnia (IH) for Provigil. In order to obtain Provigil (modafinil) for IH, member must be 18 years of age or older; member must have diagnosis of IH; member must not have diagnosis of cataplexy; prescriber must provide polysomnography and/or MSLT substantiating at least 2 SOREMPs, prescriber must provide MSLT demonstrating a mean sleep latency of 8 minutes or less, OR polysomnography demonstrating total 24-hour sleep time of at least 660 minutes (11 hours) OR wrist actigraphy demonstrating at least 660 minutes (11 hours) of sleep per 24 hours averaged across at least 7 days of monitoring; prescriber must provide baseline data of either EDS via the Epworth Sleepiness Scale (ESS) or Maintenance of Wakefulness Test (MWT); and member has experienced therapeutic failure or intolerance to generic modafinil if requesting brand Provigil. For reauthorization, prescriber attests the member experienced a decrease in

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		daytime sleepiness as proven by improvement on the (ESS) or (MWT) compared to baseline.
Qbrexza (glycopyrronium) Cloth 2.4% - Commercial and Healthcare Reform	10/21/2021	Policy revised for Qbrexza (glycopyrronium) to require trial and failure of at least 1 aluminum chloride 20% product. Limitations of coverage revised to remove anticholinergic contraindications (moved to prescribing considerations).
Rezurock (belumosudil) - Commercial and Healthcare Reform	10/21/2021	New policy created for Rezurock (belumosudil) requiring member to be at least 12 years of age, diagnosis of chronic graft-versus-host disease (cGVHD), and therapeutic failure, contraindication, or intolerance to two (2) lines of systemic therapy. Reauthorization attesting member has experienced positive clinical response to therapy. Quantity limit allowing for additional quantities of Rezurock (belumosudil) up to two (2) tablets per day when a member is taking a strong CYP3A inducer or the member is taking a proton pump inhibitor (PPI) and meets one (1) of the following: experienced therapeutic failure, contraindication, or intolerance to a histamine-2 receptor antagonist (H2RA) or the member has a diagnosis (e.g. Helicobacter pylori) where treatment with a PPI is necessary. Authorization duration of 12 months.
Targretin (bexarotene) - Commercial and Healthcare Reform	10/21/2021	Policy for Targretin (bexarotene) revised to require the member to be 18 years of age or older. Policy also revised to specify failure on generic oral bexarotene when the request is for Targretin oral capsules.
Tibsovo (ivosidenib) – Commercial and Healthcare Reform	10/22/2021	Policy revised for Tibsovo (ivosidenib) to add criteria for members 18 years of age or older with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.
Valchlor (mechlorethamine) - Commercial and Healthcare Reform	10/22/2021	Policy revised for Valchlor (mechlorethamine) for use in members 18 years of age or older.
Welireg (belzutifan) – Commercial and Healthcare Reform	10/22/2021	Policy created for Welireg (belzutifan) to require 18 years of age or older, diagnosis of von Hippel Lindau (VHL) syndrome associated with renal cell carcinoma, central nervous system

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		hemangioblastoma, or pancreatic neuroendocrine tumor, not requiring immediate surgery. Reauthorization attesting disease improvement or delayed disease progression. Authorization duration for 12 months.
Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates)	11/01/2021	Policy revised for Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates) to add criteria for new indication of Idiopathic Hypersomnia (IH) for Xywav. In order to obtain Xywav (calcium, magnesium, potassium, and sodium oxybates) for IH, member must be 18 years of age or older; member must have diagnosis of IH; member must not have diagnosis of cataplexy; prescriber must provide polysomnography and/or MSLT substantiating at least 2 SOREMPs, prescriber must provide MSLT demonstrating a mean sleep latency of 8 minutes or less OR polysomnography demonstrating total 24-hour sleep time of at least 660 minutes (11 hours) OR wrist actigraphy demonstrating at least 660 minutes (11 hours) of sleep per 24 hours averaged across at least 7 days of monitoring; prescriber must provide baseline data of either EDS via the Epworth Sleepiness Scale (ESS) or Maintenance of Wakefulness Test (MWT); and member has experienced therapeutic failure, contraindication, or intolerance to both plan-preferred generic modafinil and a generic plan-preferred CNS stimulant (e.g. methylphenidate, amphetamine salts). For Narcolepsy, removed criteria regarding hypocretin 1 deficiency and now require members ≥ 18 years of age to experience therapeutic failure, contraindication, or intolerance to both plan-preferred generic modafinil and a generic plan-preferred CNS stimulant (e.g. methylphenidate, amphetamine salts) and members < 18 years of age to experience therapeutic failure, contraindication, or intolerance to either plan-preferred generic modafinil or a generic plan-preferred CNS stimulant (e.g. methylphenidate, amphetamine salts).
Zolinza (vorinostat) - Commercial and Healthcare Reform	10/22/2021	Policy revised for Zolinza (vorinostat) for use in members 18 years of age or older.

*For Commercial and Healthcare Reform policies, an exception to some or all the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

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

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Acute Migraine Therapies - Commercial and Healthcare Reform	10/13/2021	Policy revised to add Trudhesa (dihydroergotamine mesylate) Nasal Spray and to require all of the following: a diagnosis of acute migraine headaches with or without aura, attestation that the member requires a non-oral route of administration, and the member has experienced therapeutic failure, contraindication, or intolerance to generic sumatriptan nasal spray.
Additional Antibiotic Quantities - Commercial and Healthcare Reform	10/13/2021	Policy revised for vancomycin and Dificid (fidaxomicin) to require a diagnosis of Clostridium difficile-associated diarrhea, confirmed by both of the following: 3 or more unexplained and new-onset loose bowel movements in less than 24 hours and one of the following: a positive nucleic acid amplification test or polymerase chain reaction result for C. difficile, a positive glutamate dehydrogenase test result, a positive enzyme immunoassay for C. difficile toxin, or a positive stool culture for C. difficile.
Additional Quantities of Ivermectin - Commercial and Healthcare Reform	12/15/2021	New policy created to set quantity limits for Stromectol based on FDA approved indications (strongyloidiasis, onchocerciasis) as well as CDC recommended treatment guidelines. Quantity limits may be exceeded if based on weight (> 300lbs), patient requires greater amount of tablets to achieve dosage guidelines, or patient has a diagnosis of onchocerciasis and requires re-treatment.
Ampyra (dalfampridine) - Commercial and Healthcare Reform	11/01/2021	Policy revised to change criteria from initiation and maintenance to initial authorization and reauthorization. Added criteria that member must concurrently be taking a disease modifying therapy. Removed duplicative reauthorization criteria. Automatic approval criteria removed.
Amrix (cyclobenzaprine) - Commercial and Healthcare Reform	10/14/2021	Policy for Amrix (cyclobenzaprine) revised to add requirement for member to be experiencing mild to moderate pain of acute musculoskeletal disorder(s) to initial authorization criteria.
Ibsrela (tenapanor) - Commercial and Healthcare Reform	11/01/2021	Policy terminated. Ibsrela is not on market.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Kerendia (finerenone) - Commercial and Healthcare Reform	12/15/2021	New policy for Kerendia (finerenone) requiring diagnosis of type 2 diabetes mellitus with chronic kidney disease and concurrent use or contraindication to sodium-glucose cotransporter-2 inhibitors and concurrent use or contraindication to either an angiotensin-converting enzyme inhibitor or an angiotensin receptor blocker.
Leukotriene Modifiers - Healthcare Reform	10/29/2021	Policy terminated; combined into policy J-0019 Leukotriene Modifiers (Accolate, Zyflo) - Commercial and Healthcare Reform.
Non-Preferred Brand and Extended-Release Metformin - Commercial and Healthcare Reform	10/19/2021	Policy revised for brand and generic extended-release (ER) metformin to remove "contraindication" in step therapy as all products and its step therapy are the same molecular ingredient. Step therapy through metformin hydrochloride intermediate release (generic Glucophage) added for Fortamet (metformin hydrochloride extended-release), Glumetza (metformin hydrochloride extended-release), and Riomet ER (metformin hydrochloride). Brand Glucophage (metformin hydrochloride) and brand Glucophage XR (metformin hydrochloride extended-release) removed as targets as off-market and as such Glumetza (metformin hydrochloride extended-release) step through brand Glucophage XR (metformin hydrochloride extended-release) removed. If request is for brand Riomet, the member has experienced therapeutic failure or intolerance to generic metformin oral solution (generic Riomet). Step through generic metformin hydrochloride ER (generic Glucophage XR) for Riomet ER (metformin hydrochloride extended-release suspension) adjusted to if member is 18 years of age or older.
Non-Preferred Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RA) – Commercial and Healthcare Reform	10/19/2021	Policy revised for Non-Preferred Glucagon-Like Peptide-1 Receptor Agonists to remove Bydureon (exenatide extended-release) and Tanzeum (albiglutide) as off market. For Bydureon BCise (exenatide extended-release) if member is 10 to 17 years of age, the member has experienced therapeutic failure or intolerance to Victoza (liraglutide). If the member is 18 years of age or older, the member has tried and failed two (2) of the following: Trulicity (dulaglutide), Victoza (liraglutide), or Ozempic (semaglutide) or Rybelsus (semaglutide).

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Non-preferred Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors - Commercial and Healthcare Reform	10/13/2021	Policy revised to remove Steglujan (ertugliflozin/sitagliptin) to include in J-1108 Non-Preferred Dipeptidyl Peptidase IV Inhibitors and Sodium-Glucose Co-Transporter 2 Inhibitors – Commercial and Healthcare Reform. Policy revised for Farxiga (dapagliflozin) for heart failure without type 2 diabetes, the member has tried and failed Jardiance (empagliflozin).
Ryvent (carbinoxamine) 6 mg - Commercial and Healthcare Reform	12/15/2021	Policy revised for Ryvent (carbinoxamine maleate) 6 mg tablets to require two different generic prescription antihistamine tablets or capsules other than carbinoxamine tablets (Automatic approval criteria updated to remove carbinoxamine 6 mg tablets as a qualifier agent).
Ryvent (carbinoxamine) 6 mg - Healthcare Reform	12/15/2021	Policy terminated as the criteria has been combined into J-0829.
Topical Acne Medications - Healthcare Reform	11/01/2021	Policy terminated as the criteria has been combined into J-0871.
Topical Acne Products - Commercial and Healthcare Reform	11/01/2021	Policy revised for the member to be 9 years of age or older if the request is for Altreno (tretinoin), Aklief (trifarotene), or Amzeeq (minocycline); and 12 years of age or older if the request is for Acanya (benzoyl peroxide/clindamycin), Onexton (benzoyl peroxide/clindamycin), Winlevi (clascoterone), or Ziana (clindamycin/tretinoin). Automatic approval criteria revised to remove clindamycin phosphate/benzoyl peroxide as a qualifier agent.
Topical Acne Products - Commercial and Healthcare Reform	TBD	Policy revised to add Twyneo (tretinoin/benzoyl peroxide) as a target agent requiring the member is 9 years of age or older; has a diagnosis of acne vulgaris and trial and failure of three of the following: adapalene, clindamycin or clindamycin/benzoyl peroxide, erythromycin, sulfacetamide, or tretinoin. Reauthorization to require positive clinical response and additional treatment needed. Authorization duration for 12 months.
Topical Antifungals - Commercial and Healthcare Reform	10/22/2021	Policy revised for Kerydin (tavaborole) to try and fail generic tavaborole 5% solution if the request is for the brand. Reauthorization criteria added for the prescriber to attest that additional topical antifungal therapy is required.
Topical Psoriasis - Healthcare Reform	10/13/2021	Policy terminated as the criteria has been combined into J-0378

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Topical Psoriasis Treatments - Commercial and Healthcare Reform	10/13/2021	Policy revised for topical psorasis treatments to allow for therpeutic failure or intolerance to any one generic formulary high-potency topical corticosteroid. Policy combined with HCR criteria (J-0206)
Xeloda (capecitabine) - Commercial	10/22/2021	Policy revised to include if the member has Dukes' C colon cancer that the member has undergone complete resection of the primary tumor per FDA indication. Policy also revised to include if member has metastatic breast cancer that they may receive Xeloda (capecitabine) if their disease is resistant to paclitaxel and further anthracycline therapy is not indicated per FDA indication.
Zortress (everolimus) - Commercial and Healthcare Reform	11/01/2021	Policy terminated; C2V step did not result in savings.

*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
COVID-19 vaccines	4 doses per 720 days	4 doses per 720 days
Trudhesa (dihydroergotamine mesylate) 0.725 mg nasal spray	12 mL per 30 days	36 mL per 90 days
Vaxneuvance (pneumococcal 15-valent conjugate vaccine)*	0.5 mL per 365 days	0.5 mL per 365 days
Stromectol (ivermectin)	20 tablets per 30 days	20 tablets per 30 days
Stromectol (ivermectin)	40 tablets per 365 days	40 tablets per 365 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

Twyneo (tretinoin/benzoyl peroxide)*	50 grams (1 bottle)	150 grams (3 bottles)

*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
Bylvay (odevixibat) 1200 mcg Oral Capsules	5 capsules per day
Bylvay (odevixibat) 200 mcg Oral Pellets	30 pellets per day
Bylvay (odevixibat) 400 mcg Oral Capsules	15 capsules per day
Bylvay (odevixibat) 600 mcg Oral Pellets	10 pellets per day
Kerendia (finerenone)	1 tablet per day
Loreev XR (lorazepam ER)	4 capsules per day
Qbrexza (glycopyrronium)	1 towelette per day
Rezurock (belumosudil)	1 tablet per day
Welireg (belzutifan)	3 tablets per day

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

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

SECTION II. Highmark Medicare Part D Formularies

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

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

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
TicoVac Vaccine	Tick Borne Encephalitis Vaccine	Tick Borne Encephalitis

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

Brand Name	Generic Name	Preferred Alternatives
Loreev XR	lorazepam ER	lorazepam tablet; clonazepam tablet; diazepam tablet
Trudhesa nasal spray	dihydroergotamine mesylate nasal spray	sumatriptan spray, non-aerosol
Twyneo	tretinoin/benzoyl peroxide	tretinoin topical; tretinoin microspheres topical; adapalene topical

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:

- 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
TicoVac Vaccine	Tick Borne Encephalitis Vaccine	Tick Borne Encephalitis

Table 2. Non-Preferred Products

No changes at this time.

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

Brand Name	Generic Name	Preferred Alternatives
Kerendia	finerenone	Invokana
Loreev XR	lorazepam ER	lorazepam tablet; clonazepam tablet; diazepam tablet
Rezurock	belumosudil	prednisone tablet; methylprednisolone tablet; tacrolimus capsule
Skytrofa	lonapegsomatropin-tcgd	Zomacton, Omnitrope 5 mg/1.5 mL (3.3 mg/mL), Norditropin FlexPro 5 mg/1.5 mL (3.3 mg/mL), Genotropin 5 mg/mL (15 unit/mL), Genotropin MiniQuick 0.2 mg/0.25 mL
Trudhesa nasal spray	dihydroergotamine mesylate nasal spray	sumatriptan spray, non-aerosol; dihydroergotamine spray, non-aerosol
Twyneo	tretinoin/benzoyl peroxide	tretinoin topical; clindamycin-tretinoin topical gel 1.2-0.025 %
Bylvay	odevixibat	Provider Discretion
Nexviazyme	avalglucosidase alfa-ngpt	Provider Discretion
Uptravi	selexipag	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
Invega Hafyera	paliperidone palmitate
Saphnelo	anifolumab-fnia
Welireg	belzutifan
Bylvay*	odevixibat
Kerendia*	finerenone
Nexviazyme*	avalglucosidase alfa-ngpt
Rezurock*	belumosudil
Skytrofa*	lonapegsomatropin-tcgd
Uptravi*	selexipag

*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
Androgen Receptor Inhibitors - Medicare	10/14/2021	Policy for Xtandi (enzalutamide) updated to remove the requirement for the member to be 18 years of age or older.
Benlysta (belimumab) - Medicare	10/22/2021	Policy revised to add Benlysta (belimumab) intravenous (IV) as a target agent and allowing Benlysta (belimumab) IV if the member has a diagnosis of systemic lupus erythematosus (SLE) and is 5 years of age or older.
Blenrep (belantamab mafodotin-blmf) – Medicare	11/01/2021	Policy terminated as coding was never active.
BTK Inhibitors – Medicare	10/14/2021	Policy revised for Brukinsa (zanubrutinib) to add criteria for members 18 years of age and older with Waldenström's macroglobulinemia; and for Brukinsa (zanubrutinib) to add criteria for members 18 years of age or older with a diagnosis of relapsed or refractory marginal zone lymphoma after receipt of at least one previous anti-CD20 (Cluster of Differentiation 20)-based regimen.
Bylvay (odevixibat) – Medicare	10/15/2021	New policy for Bylvay (odevixibat) requiring diagnosis of progressive familial intrahepatic cholestasis confirmed by genetic testing, diagnosis of pruritis, and does not have cirrhosis, portal hypertension, or history of hepatic decompensation. Reauthorization requiring improvement in pruritis and attestation that the member has not progressed to cirrhosis, portal hypertension, or hepatic decompensation. Initial authorization of 6 months and reauthorization of 12 months.
Chronic Inflammatory Diseases - Medicare	01/01/2022	Policy criteria for plaque psoriasis revised to require therapeutic failure to phototherapy or systemic therapy, or contraindication to both phototherapy and systemic therapy.
Darzalex (daratumumab) and Darzalex Faspro (daratumumab and hyaluronidase-fihj) – Medicare	10/15/2021	Policy revised for Darzalex Faspro (daratumumab and hyaluronidase-fihj) to add criteria for use in combination with pomalidomide and dexamethasone for members with multiple myeloma who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Dihydroergotamine Mesylate - Medicare	10/15/2021	Policy revised to add Trudhesa (dihydroergotamine mesylate) Nasal Spray and to require all of the following: a diagnosis of migraine headaches with or without aura, the member requires a non-oral route of administration, and the member has experienced therapeutic failure, contraindication, or intolerance to generic sumatriptan nasal spray.
Drizalma Sprinkle (duloxetine) - Medicare	01/01/2022	Criteria added for a diagnosis of fibromyalgia, a new FDA-approved indication: Member must be 18 years of age or older, member must have a documented diagnosis of fibromyalgia, there is clinical documentation of the fibromyalgia diagnosis including: widespread bilateral pain above and below the waist for at least 3 months duration, and documented fibromyalgia symptoms (cognitive impairment, fatigue, sleep disturbance, neurological symptoms, exercise intolerance). In addition, the member has an inability to swallow capsules/tablets.
Fetzima (levomilnacipran) - Medicare	10/17/2021	Removed automatic approval criteria wording; added justification for step in the background and some prescribing considerations.
High Risk Medications in the Elderly- Medicare	01/01/2022	Background information revised. Addition of non-RxCUI drugs based on High-Risk medication guidelines
Human Growth Hormone - Medicare	01/01/2022	Policy revised to add Skytrofa (lonapegsomatropin-tcgd) for pediatric members that member has pituitary growth hormone deficiency, growth velocity at least 2 standard deviations below the age-appropriate mean or a height at least 2.25 standard deviations below the age-appropriate mean, subnormal response to two (2) standard growth hormone stimulation tests, and if female, bone age ≤ 14 years or if male, bone age ≤ 16 years. Or the member is a neonate has a condition indicating growth hormone deficiency and growth hormone level < 10 ng/mL. Reauthorization of growth velocity of at least 2 cm/year (if less than 2 cm/year meets adults approval criteria) and bone age.
Ibsrela (tenapanor) - Medicare	11/01/2021	Policy terminated asIbsrela is not on market.
Interleukin (IL)-5 Antagonists - Medicare	10/17/2021	Policy revised for Nucala (mepolizumab) to add new indication of chronic rhinosinusitis with nasal

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		polyps (CRSwNP) requiring the member is 18 years of age or older, have a diagnosis of CRSwNP, and try and fail an intranasal corticosteroid.
Kerendia (finerenone) - Medicare	10/17/2021	New policy for Kerendia (finerenone) requiring diagnosis of type 2 diabetes mellitus with chronic kidney disease and concurrent use or contraindication to sodium-glucose cotransporter-2 inhibitors.
Monjuvi (tafasitamab-cxix) - Medicare	11/01/2021	Policy terminated as coding was never active.
Nexviazyme (avalglucosidase alfa-ngpt) – Medicare	10/19/2021	New policy created for Nexviazyme (avalglucosidase alfa-ngpt) requiring member to be at least 1 year of age or older with a diagnosis of late onset Pompe disease (LOPD).
Programmed Death Receptor Therapies - Medicare	10/19/2021	Policy revised for Opdivo (nivolumab) to remove criteria as monotherapy for hepatocellular carcinoma (HCC) after sorafenib per the FDA withdrawn indication; for Keytruda (pembrolizumab) to add criteria in combination with lenvatinib for the first-line treatment of adult patients with advanced RCC; for Jemperli (dostarlimab-gxly) to add criteria for members with mismatch repair deficient (dMMR) recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options; and for Opdivo (nivolumab) for the adjuvant treatment of patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection.
Pulmonary Hypertension - Medicare	10/21/2021	Policy revised to add Uptravi (selexipag) intravenous solution to criteria.
Rezurock (belumosudil) - Medicare	10/21/2021	New policy created for Rezurock (belumosudil) requiring member to be at least 12 years of age, diagnosis of chronic graft-versus-host disease (cGVHD), and therapeutic failure, contraindication, or intolerance to two (2) lines of systemic therapy.
Rybelsus (semaglutide) - Medicare	11/01/2021	Policy terminated as policy is not active.
Saphnelo (anifrolumab-fnia) - Medicare	10/21/2021	New policy created for Saphnelo (anifrolumab-fnia) requiring the member is 18 years or older; diagnosis of moderate to severe systemic lupus

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		erythematosus (SLE); positive anti-nuclear antibody (ANA) ≥ 1:80 or anti-double stranded DNA (anti-dsDNA) ≥ 30 IU/mL; trial and failure of two standard of care drug classes (corticosteroids, antimalarials, or immunosuppressives); and continuation of concomitant standard of care during treatment. Reauthorization to require disease stability or improvement; and continuation of standard of care treatment. Authorization duration of 12 months.
Targretin (bexarotene) - Medicare	10/21/2021	Policy revised to add Targretin 1% topical gel to current criteria. No changes to the filed criteria for Targretin 1% topical gel were made, as these were previously filed with CMS.
Tibsovo (ivosidenib) – Medicare	10/22/2021	Policy revised for Tibsovo (ivosidenib) to add criteria for members 18 years of age or older with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.
Trogarzo (ibalizumab-uiyk)- Medicare	11/01/2021	Terminating policy as coding was never active.
Welireg (belzutifan) – Medicare	10/22/2021	Policy created for Welireg (belzutifan) to require 18 years of age or older, diagnosis of von Hippel Lindau (VHL) syndrome associated with renal cell carcinoma, central nervous system hemangioblastoma, or pancreatic neuroendocrine tumor, not requiring immediate surgery. Authorization duration for 12 months.
Wynzora (calcipotriene-betamethasone) - Medicare	11/01/2021	Policy terminated. Wynzora Med D=N
Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates)	01/01/2022	Policy revised for Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates) to add criteria for new indication of Idiopathic Hypersomnia (IH) for Xywav. In order to obtain Xywav (calcium, magnesium, potassium, and sodium oxybates) for IH, member must be 18 years of age or older; member must have diagnosis of IH; member must not have diagnosis of cataplexy; prescriber must provide polysomnography and/or MSLT substantiating at least 2 SOREMPs, prescriber must provide MSLT demonstrating a mean sleep

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		latency of 8 minutes or less OR polysomnography demonstrating total 24-hour sleep time of at least 660 minutes (11 hours) OR wrist actigraphy demonstrating at least 660 minutes (11 hours) of sleep per 24 hours averaged across at least 7 days of monitoring; and prescriber must provide baseline data of either EDS via the Epworth Sleepiness Scale (ESS) or Maintenance of Wakefulness Test (MWT).

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

2. Managed Prescription Drug Coverage (MRxC) Program

No changes at this time.

3. Quantity Level Limit (QLL) Program

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

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Bylvay (odevixibat) 1200 mcg Oral Capsules	5 capsules per day	5 capsules per day
Bylvay (odevixibat) 200 mcg Oral Pellets	30 pellets per day	30 pellets per day
Bylvay (odevixibat) 400 mcg Oral Capsules	15 capsules per day	15 capsules per day
Bylvay (odevixibat) 600 mcg Oral Pellets	10 pellets per day	10 pellets per day
Invega Hafyera (paliperidone palmitate)	1 syringe per 180 days	1 syringe per 180 days
Kerendia (finerenone)	1 tablet per day	1 tablet per day
Loreev XR (lorazepam ER)	4 capsules per day	4 capsules per day
Northera (droxidopa) 100 mg	18 capsules per day (558 capsules per 31 days)	1620 capsules per 90 days
Northera (droxidopa) 200 mg	9 capsules per day (279 capsules per 31 days)	810 capsules per 90 days
Northera (droxidopa) 300 mg	6 capsules per day (186 capsules per 31 days)	540 capsules per 90 days
Rezurock (belumosudil)	2 tablets per day	2 tablets per day
Saphnelo (anifolumab-fnia)	1 vial (2 mL) per 28 days	3 vials (6 mL) per 84 days
Trudhesa (dihydroergotamine mesylate) 0.725 mg nasal spray	12 mL per 28 days	36 mL per 84 days
Welireg (belzutifan)	3 tablets per day	3 tablets per day