Formulary Updates

Published March 17, 2023

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for January 2023. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in January by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Please reference the guide below to navigate this communication:

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

HIGHMARK

Important Drug Safety Updates

TIROSINT®-SOL (levothyroxine sodium) Oral Solution by IBSA Pharma Inc.

On January 31, 2023, IBSA Pharma Inc. voluntarily recalled 27 lots of TIROSINT®-SOL (levothyroxine sodium) Oral Solution to the consumer level. This voluntary recall has been initiated because these lots may be subpotent. The company's analyses show a slight decrease below 95.0% of its labeled amount in levothyroxine sodium (T4) for some lots.

Patients being treated for hypothyroidism (underactive thyroid), who receive subpotent TIROSINT®-SOL, may experience signs and symptoms of hypothyroidism (underactive thyroid) which may include, fatigue, increased sensitivity to cold, constipation, dry skin, puffy face, hair loss, slow heart rate, depression, swelling of the thyroid gland and/or unexplained weight gain or difficulty losing weight. Over- or under-treatment with TIROSINT® SOL may have negative effects on growth and development, cardiovascular function, bone metabolism, reproductive function, cognitive function, emotional state, gastrointestinal function, and glucose and lipid metabolism. Any patients — including those who might be pregnant, newborn infants, or elderly patients — should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. To date, IBSA Pharma Inc. has not received any reports of adverse events that have been determined to be related to this voluntary recall.

Highmark Formulary Update – January 2023

SECTION I. Highmark Commercial and Healthcare Reform Formularies

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

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

- Highmark Comprehensive Formulary
- Highmark Healthcare Reform Comprehensive Formulary

Highmark is happy to inform you that Table 1 includes products that have been added to the formulary. Adding products to the formulary may mean lower copays or coinsurance rates for members. By adding products to the formulary, Highmark hopes to promote adherence to medication protocols and improve the overall health of our members.

Table 1. Products Added

All products added to the formulary effective February 2023, unless otherwise noted.

Brand Name	Generic Name	Comments
Dexcom G7 Receiver	blood glucose meter, continuous	Type 1, Type 2, and gestational diabetes in patients 2 years and older
Dexcom G7 Sensors	blood glucose sensor	Type 1, Type 2, and gestational diabetes in patients 2 years and older
Genotropin	somatropin	Treatment of adults and pediatrics with growth failure
Mifepristone 200 mg tablet**	Mifepristone 200 mg tablet	Medical termination of intrauterine pregnancy through 70 days of gestation
Rotarix* (rotovirus vaccine, live)	Rotarix (rotovirus vaccine, live)	Prevention of rotavirus gastroenteritis

Coverage may be contingent upon plan benefits.

*Commercial Comprehensive Formulary Only

**Effective date to be determined

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Ezetimibe-atorvastatin	Ezetimibe-atorvastatin	atorvastatin calcium, rosuvastatin calcium, ezetimibe
Idacio*	adalimumab-aacf	Humira
Jylamvo oral solution*	methotrexate	methotrexate sodium tablet

Brand Name	Generic Name	Preferred Alternatives
Mifeprex 200 mg tablet*	mifepristone	Mifepristone 200 mg tablet
Tascenso ODT 0.5 mg	fingolimod lauryl sulfate	fingolimod
Krazati	adagrasib	Prescriber discretion
Olpruva*	sodium phenylbutyrate	Prescriber discretion
Rezlidhia	olutasidenib	Prescriber discretion
Sunlenca tablets	lenacapavir	Prescriber discretion
Rotarix***	rotovirus vaccine, live	Prescriber discretion

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
**Physicians may request coverage of these products using the Prescription Drug Medication Request Form.
*** HCR comprehensive formulary only

Table 3. Additions to the Specialty Tier Copay Option

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

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

Brand Name	Generic Name
Idacio	adalimumab-aacf
Jylamvo oral solution	methotrexate
Krazati	adagrasib
Olpruva	sodium phenylbutyrate
Tascenso ODT 0.5 mg	fingolimod lauryl sulfate
Rezlidhia	olutasidenib

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 February 2023, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Mifepristone 200 mg tablet*	Mifepristone 200 mg tablet	1	Medical termination of intrauterine pregnancy through 70 days of gestation
Dexcom G7 Receiver	blood glucose meter, continuous	3	Type 1, Type 2, and gestational diabetes in patients 2 years and older
Dexcom G7 Sensors	blood glucose sensor	3	Type 1, Type 2, and gestational diabetes in patients 2 years and older

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Genotropin	somatropin	4	Treatment of adults and pediatrics with growth failure
Rotarix (rotovirus vaccine, live)	Rotarix (rotovirus vaccine, live)	3	Prevention of rotavirus gastroenteritis
Items listed below were not added to the formulary			
Ezetimibe-atorvastatin	Ezetimibe-atorvastatin	NF	Atorvastatin Calcium, Rosuvastatin Calcium, Ezetimibe
Idacio*	adalimumab-aacf	NF	Humira
Jylamvo oral solution*	methotrexate	NF	methotrexate sodium tablet
Mifeprex 200 mg tablet*	mifepristone	NF	Mifepristone 200 mg tablet
Olpruva*	sodium phenylbutyrate	NF	sodium phenylbutyrate tablets
Tascenso ODT 0.5 mg	fingolimod lauryl sulfate	NF	fingolimod
Krazati	adagrasib	NF	Prescriber discretion
Rezlidhia	olutasidenib	NF	Tibsovo
Sunlenca tablets	lenacapavir	NF	Prescriber discretion

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

C. Changes to the Highmark Core Formulary

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

Table 1. Formulary Updates
All formulary changes effective February 2023, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Mifepristone 200 mg tablet*	Mifepristone 200 mg tablet	1	Medical termination of intrauterine pregnancy through 70 days of gestation
Dexcom G7 Receiver	blood glucose meter, continuous	3	Type 1, Type 2, and gestational diabetes in patients 2 years and older
Dexcom G7 Sensors	blood glucose sensor	3	Type 1, Type 2, and gestational diabetes in patients 2 years and older
Rotarix (rotovirus vaccine, live)	Rotarix (rotovirus vaccine, live)	3	Prevention of rotavirus gastroenteritis
Genotropin	somatropin	4	Treatment of adults and pediatrics with growth failure
Items listed below were not added to the formulary			

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Ezetimibe-atorvastatin	Ezetimibe-atorvastatin	NF	Atorvastatin Calcium, Rosuvastatin Calcium, Ezetimibe
Idacio*	adalimumab-aacf	NF	Humira
Jylamvo oral solution*	methotrexate	NF	methotrexate sodium tablet
Mifeprex 200 mg tablet*	mifepristone	NF	Mifepristone 200 mg tablet
Olpruva*	sodium phenylbutyrate	NF	sodium phenylbutyrate tablets
Rezlidhia	olutasidenib	NF	Tibsovo
Tascenso ODT 0.5 mg	fingolimod lauryl sulfate	NF	fingolimod
Krazati	adagrasib	NF	Prescriber discretion
Sunlenca tablets	lenacapavir	NF	Prescriber discretion

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

D. Changes to the Highmark National Select Formulary

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

Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (Preferred)			
Ezetimibe-atorvastatin	Ezetimibe-atorvastatin	1	Reduction of cholesterol
Dexcom G7 Receiver	blood glucose meter, continuous	2	Type 1, Type 2, and gestational diabetes in patients 2 years and older
Dexcom G7 Sensors	blood glucose sensor	2	Type 1, Type 2, and gestational diabetes in patients 2 years and older
Mifepristone 200 mg tablet*	Mifepristone 200 mg tablet	1	Medical termination of intrauterine pregnancy through 70 days of gestation
Items listed below were added to the formulary (Non-Preferred)			
Idacio*	adalimumab-aacf	3	Humira
Jylamvo oral solution*	methotrexate	3	methotrexate sodium tablet
Krazati	adagrasib	3	Prescriber discretion

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Mifeprex 200 mg tablet	mifepristone	3	mifepristone
Olpruva*	sodium phenylbutyrate	3	Prescriber discretion
Rezlidhia	olutasidenib	3	Prescriber discretion
Rotarix	rotovirus vaccine, live	3	Prescriber discretion
Sunlenca tablets	lenacapavir	3	Prescriber discretion
Items listed below were not added to the formulary			
Rezlidhia	olutasidenib	NF	Tibsovo
Tascenso ODT 0.5 mg	fingolimod lauryl sulfate	NF	fingolimod

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
Idacio	adalimumab-aacf
Jylamvo oral solution	methotrexate
Krazati	adagrasib
Olpruva	sodium phenylbutyrate
Rezlidhia	olutasidenib
Tascenso ODT 0.5 mg	fingolimod lauryl sulfate

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Adalimumab BIOSIMILARS – Commercial and Healthcare Reform	TBD	Policy revised for adalimumab biosimilars to add new biosimilar Idacio (adalimumab-aacf) to policy criteria to mirror current criteria for Humira (adalimumab). Clarified that induction therapy authorization should match quantity limitation tables for respective drug and diagnosis.
Adbry (tralokinumab-ldrm) – Commercial and Healthcare Reform	02/03/2023	Policy revised for Adbry (tralokinumab-ldrm) for reauthorization to also require the member to meet one of the following: Adbry is requested at a dosing interval of every 4 weeks; prescriber attestation that the member has not achieved clear or almost clear skin; prescriber attestation

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		that an every 4-week dosing interval would not be appropriate. Quantity limitations for maintenance therapy revised to two (2) or four (4) 150 mg syringes every four (4) weeks.
Anti-Obesity – Commercial and Healthcare Reform	02/03/2023	Policy revised to add initiation and maintenance criteria for Wegovy's (semaglutide) new pediatric patient indication; and update Saxenda (liraglutide) and Wegovy continuation and maintenance criteria for dose optimization. Wegovy adolescent initiation (0 to < 5 months of previous therapy) and maintenance (≥5 months of previous therapy) requiring age 12 years of age or older, use for chronic weight management, baseline/current age, height, weight, and body mass index (BMI), baseline BMI corresponding to 95th percentile or greater for age and sex based on the CDC criteria, use in combination with reduced calorie diet and exercise, and attestation of no use with another glucagon-like peptide-1 receptor agonist (GLP-1 RA)/GLP-1RA combination product. For Wegovy adolescent maintenance only, requiring ≥5% BMI reduction from baseline, maintenance of BMI reduction from baseline, and requested dose of 1.7 mg or 2.4 mg weekly or attestation of titration goal to 1.7 mg weekly. Existing Saxenda adolescent maintenance criteria updated to require ≥1% BMI reduction from baseline, maintenance of BMI reduction from baseline, and requested dose of 2.4 mg or 3 mg daily. Authorization duration for adolescent initiation of 5 months and adolescent maintenance of 12 months. Existing adult continuation criteria updated requiring requested dose of 3 mg daily for Saxenda, and 2.4 mg weekly or attestation of titration goal to 2.4 mg weekly for Wegovy. Existing adult maintenance criteria updated requiring requested dose of 3 mg daily for Saxenda and 2.4 mg weekly for Wegovy.
Austedo (deutetrabenazine) – Commercial and Healthcare Reform	02/03/2023	Policy revised for Austedo (deutetrabenazine) for initial authorization of tardive dyskinesia (TD) to require prescriber attestation that the member continues to experience symptoms of TD despite dose reduction/tapering/discontinuation of the offending medication(s), or that dose

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		reduction/tapering/discontinuation of the offending medication(s) would not be appropriate. Quantity level limits revised to require that the member is not receiving any concomitant strong CYP2D6 inhibitors.
Brexafemme (ibrexafungerp) – Commercial and Healthcare Reform	02/03/2023	Policy revised for Brexafemme (ibrexafungerp) for new indication of recurrent vulvovaginal candidiasis (RVVC) requiring member to have a diagnosis of RVVC, the member has experienced ≥ 3 episodes of vulvovaginal candidiasis in less than one year and the member has experienced therapeutic failure, contraindication, or intolerance to a six-month maintenance course of oral fluconazole.
Camzyos – Commercial and Healthcare Reform	02/03/2023	Reauthorization criteria for Camzyos (mavacamten) revised to remove requirement for pVO2 improvement. The prescriber attests that the member has experienced a positive clinical response to therapy defined as meeting one (1) of the following criteria: 1.) Reduction in NYHA class or 2.) No NYHA class worsening. The criterion requiring prescriber attestation that the member will not be taking concomitant disopyramide, ranolazine, or a combination of beta blockers and calcium channel blockers remains in place.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	02/03/2023	Policy revised to clarify that induction therapy authorization should match quantity limitation tables for respective drug and diagnosis.
Chronic Inflammatory Diseases – Commercial National Select Formulary	02/03/2023	Policy revised to clarify that induction therapy authorization should match quantity limitation tables for respective drug and diagnosis.
Diclofenac sodium 3% gel and Carac (fluorouracil 0.5%) cream – Commercial and Healthcare Reform	02/03/2023	Policy revised to remove reference to brand name Solaraze (diclofenac sodium); this product is no longer commercially available. The criteria remain in place for the generic formulation, diclofenac sodium 3%. In both the initial authorization and reauthorization sections, the criterion requiring therapeutic failure or intolerance to generic diclofenac sodium 3% gel for coverage of brand Solaraze was removed.
Egaten (triclabendazole) – Commercial and Healthcare Reform	TBD	Policy revised for Egaten (triclabendazole) to require prescribers requesting any quantity over 2000 mg to submit documentation of patient's weight.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Fingolimod – Commercial and Healthcare Reform	02/03/2023	Policy revised to remove requirement from Tascenso ODT (fingolimod) 0.25 mg to experience therapeutic failure or intolerance to plan-preferred generic fingolimod capsules or have an inability to swallow capsules. Criteria for new dosage strength of Tascenso ODT (fingolimod) 0.5 mg added to policy. Requires diagnosis based on FDA approved indication, age, weight, and either therapeutic failure or intolerance to plan-preferred fingolimod capsules, or inability to swallow capsules. Reauthorization for Tascenso ODT 0.25 mg requires a therapeutic response to therapy, and verification of age and weight. Reauthorization for Tascenso ODT 0.5 mg requires a therapeutic response to therapy and a continued inability to swallow capsules.
Gaucher Disease – Commercial and Healthcare Reform	02/03/2023	Policy revised to add Zavesca (miglustat) and to remove documentation and require confirmation of diagnosis by one (1) of the following: deficiency in glucocerebrosidase activity in peripheral leukocytes or genetic testing confirms mutant alleles.
Gonadotropin-releasing Hormone (GnrH) Agonists – Commercial and Healthcare Reform	02/03/2023	Policy revised to add leuprolide acetate depot and require FDA-approved diagnosis.
Hepatitis C Oral Agents – Commercial and Healthcare Reform	02/03/2023	Policy revised to add Zepatier (elbasvir-grazoprevir) x 12 weeks for genotype 1a with compensation as a preferred product for treatment naive patients. The Viekira Pak (ombitasvir-paritaprevir-ritonavir) was deleted from all treatment regimens and for limitations of coverage, it was added that based on the lack of evidence and guideline support, requests for Viekira Pak (ombitasvir-paritaprevir-ritonavir) will not be authorized. For treatment-naïve adults, Epclusa (sofosbuvir-velpatasvir) plus ribavirin x 12 weeks for patients with baseline NS5A Y93H for velpatasvir for genotype 3 with compensation was moved to non-preferred. For treatment experienced adults, interferon or interferon + first generation protease inhibitors

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		were deleted as a prior treatment regimen for all genotypes. An asterisk (*) was also added to the treatment-experienced adult table to clarify this. For all previous liver transplant patients who were direct acting antiviral (DAA) experienced, ribavirin was added as an option to Vosevi (sofosbuvir-velpatasvir-voxilaprevir) treatment. Criteria was added to the pediatric treatment-naïve section for if the request is for Mavyret (glecaprevir-pibrentasvir) for 16 weeks of therapy, the member meets all of the following: the member has HCV genotype 3 and the member is interferon-experienced. For treatment-naive pediatric patients, Harvoni (ledipasvir-sofosbuvir) was added with ribavirin x 12 weeks for genotype 1 patients as preferred with decompensated cirrhosis. For treatment-experienced pediatrics and genotypes 1-6 and for patients without cirrhosis and compensated cirrhosis, NS3/4A protease inhibitors but no NS5A inhibitor was added with Mavyret (glecaprevir-pibrentasvir) x 12 weeks as non-preferred and NS5A protease inhibitor but no NS5A inhibitor with Mavyret (glecaprevir-pibrentasvir) x 16 weeks as non-preferred. For treatment-experienced pediatrics with an interferon-based regimen with or without ribavirin and/or sofosbuvir, Epclusa (sofosbuvir-velpatasvir) x 12 weeks was added as preferred. For treatment experienced pediatrics, interferon-based regimen +/- ribavirin and sofosbuvir: simeprevir, boceprevir or telaprevir were deleted. An asterisk (*) was also added to the treatment experienced pediatric section to clarify these patients are to have no exposure to NS34A or NS5A protease inhibitors. For treatment experienced kidney transplant patients with compensated liver disease and DAA experience, ribavirin was added as an option x 12 weeks.
Hepatitis C Oral Agents – Commercial Core	02/03/2023	Policy revised to add Zepatier (elbasvir-grazoprevir) x 12 weeks for genotype 1a with compensation as a non-preferred product for treatment naive patients. Zepatier (elbasvir-grazoprevir) x 12 weeks was added for genotype

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		1b and 4 without or with compensated cirrhosis as a treatment option for treatment naïve. The Viekira Pak (ombitasvir-paritaprevir-ritonavir) was deleted from all treatment regimens and for limitations of coverage, it was added that based on the lack of evidence and guideline support, requests for Viekira Pak (ombitasvir-paritaprevir-ritonavir) will not be authorized. Epclusa (sofosbuvir-velpatasvir) AG + ribavirin x 12 weeks for patients with baseline NS5A Y93H for velpatasvir changed from preferred to non-preferred for genotype 3 without cirrhosis for treatment naive patients. For treatment-experienced adults, interferon or interferon + first generation protease inhibitors were deleted as a prior treatment regimen for all genotypes. An asterisk (*) was also added to the treatment experienced adult table to clarify this. For all previous liver transplant patients who were direct acting antiviral (DAA) experienced, ribavirin was added as an option to Vosevi (sofosbuvir-velpatasvir-voxilaprevir) treatment. Criteria was added to the pediatric treatment-naïve section for if the request is for Mavyret (glecaprevir-pibrentasvir) for 16 weeks of therapy, the member meets all of the following: the member has HCV genotype 3 and the member is interferon-experienced. For treatment-naive pediatric patients, Harvoni (ledipasvir-sofosbuvir) AG was added with ribavirin x 12 weeks for genotype 1 patients with decompensated cirrhosis and Harvoni (ledipasvir-sofosbuvir) plus ribavirin x 12 weeks for non-preferred products. For treatment-experienced pediatrics and genotypes 1-6 and for patients without cirrhosis and compensated cirrhosis, NS3/4A protease inhibitors but no NS5A inhibitor was added with Mavyret (glecaprevir-pibrentasvir) x 12 weeks and NS5A protease inhibitor but no NS5A inhibitor with Mavyret (glecaprevir-pibrentasvir) x 16 weeks. For treatment experienced pediatrics, interferon-based regimen +/- ribavirin and sofosbuvir:

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		simeprevir, boceprevir or telaprevir were deleted. An asterisk (*) was also added to the treatment-experienced pediatric section to clarify these patients are to have no exposure to NS34A or NS5A protease inhibitors. For treatment-experienced kidney transplant patients with compensated liver disease and DAA experience, ribavirin was added as an option x 12 weeks. An additional approval criteria was added to each section for if the request is for the brand Epclusa (sofosbuvir-velpatasvir) or Harvoni (ledipasvir-sofosbuvir) product, the member has experienced therapeutic failure or intolerance to the authorized generic product.
Hepatitis C Oral Agents – Commercial National Select	02/03/2023	Policy revised to add Zepatier (elbasvir-grazoprevir) x 12 weeks for genotype 1a with compensation as a preferred product for treatment naive patients. The Viekira Pak was deleted from all treatment regimens and for limitations of coverage, it was added that based on the lack of evidence and guideline support, requests for Viekira Pak (ombitasvir-paritaprevir-ritonavir) will not be authorized. For treatment experienced adults, interferon or interferon + first generation protease inhibitors were deleted as a prior treatment regimen for all genotypes. An asterisk (*) was also added to the treatment experienced adult table to clarify this. For all previous liver transplant patients who were direct acting antiviral (DAA) experienced, ribavirin was added as an option to Vosevi (sofosbuvir-velpatasvir-voxilaprevir) treatment. Criteria was added to the pediatric treatment-naïve section for if the request is for Mavyret (glecaprevir-pibrentasvir) for 16 weeks of therapy, the member meets all of the following: the member has HCV genotype 3 and the member is interferon-experienced. For treatment naive pediatric patients, Harvoni (ledipasvir-sofosbuvir) was added with ribavirin x 12 weeks for genotype 1 patients as preferred with decompensated cirrhosis and Harvoni AG plus ribavirin x 12 weeks for non-preferred products.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		For treatment experienced pediatrics and genotypes 1-6 and for patients without cirrhosis and compensated cirrhosis, NS3/4A protease inhibitors but no NS5a inhibitor was added with Mavyret (glecaprevir-pibrentasvir) x 12 weeks as non-preferred and NS5A protease inhibitor but no NS5A inhibitor with Mavyret (glecaprevir-pibrentasvir) x 16 weeks as non-preferred. For treatment-experienced pediatrics with an interferon-based regimen with or without ribavirin and/or sofosbuvir, Epclusa (sofosbuvir-velpatasvir) x 12 weeks was added as preferred, and Epclusa (sofosbuvir-velpatasvir) AG x 12 weeks was added as non-preferred. For treatment experienced pediatrics, interferon-based regimen +/- ribavirin and sofosbuvir: simeprevir, boceprevir or telaprevir were deleted. An asterisk (*) was also added to the treatment experienced pediatric section to clarify these patients are to have no exposure to NS34A or NS5A protease inhibitors. For treatment experienced kidney transplant patients with compensated liver disease and DAA experience, ribavirin was added as an option x 12 weeks.
Hereditary Angioedema – Commercial and Healthcare Reform	02/03/2023	Policy revised to add requirement for medication prescribed by or in consultation with an allergist, immunologist, or a provider who specializes in the treatment of hereditary angioedema.
Hetlioz (tasimelteon) and Hetlioz LQ (tasimelteon) – Commercial and Healthcare Reform	TBD	Policy revised to add generic tasimelteon to the policy matching the requirements for brand Hetlioz (tasimelteon). Policy revised for Hetlioz (tasimelteon) capsules to require step through generic tasimelteon capsules for initial authorization and reauthorization for the treatment of Non-24-hour Sleep-Wake Disorder in adults.
Human Growth Hormone – Commercial and Healthcare Reform	01/28/2023	Policy revised to add Genotropin (somatropin) as a preferred product for all Commercial and Healthcare Reform formularies (excluding Commercial National Select Formulary). Policy revised to add Omnitrope (somatropin) as a preferred product for Commercial National Select Formulary only.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Human Growth Hormone – Delaware Commercial and Healthcare Reform	01/28/2023	Policy revised to add Genotropin (somatropin) as a preferred product for all Commercial and Healthcare Reform formularies (excluding Commercial National Select Formulary). Policy revised to add Omnitrope (somatropin) as a preferred product for Commercial National Select Formulary only.
IDH1 Inhibitors – Commercial and Healthcare Reform	02/03/2023	Policy revised for Rezlidhia (olutasidenib) to require age, diagnosis based on FDA-approved expanded indication, supported by FDA-approved test. Policy revised for Tibsovo (ivosidenib) to require monotherapy or in combination with azacitidine for newly-diagnosed acute myeloid leukemia (AML) based on FDA label.
Ingrezza (valbenazine) – Commercial and Healthcare Reform	02/03/2023	Policy revised for Ingrezza (valbenazine) for initial authorization of tardive dyskinesia (TD) to require prescriber attestation that the member continues to experience symptoms of TD despite dose reduction/tapering/discontinuation of the offending medication(s) or that dose reduction/tapering/discontinuation of the offending medication(s) would not be appropriate.
KRAS G12C Inhibitors – Commercial and Healthcare Reform	02/03/2023	Policy revised for Krazati (adagrasib) to require age, diagnosis based on FDA-approved indication, as supported by FDA-approved test.
Luxturna (voretigene neparvovec-rzyl) – Commercial and Healthcare Reform	02/03/2023	Policy revised for Luxturna (voretigene neparvovec-rzyl) to updated age from 3 years to 12 months of age or older.
Market Watch Programs – Delaware	02/20/2023	Policy revised to add Relexxii and generic methylphenidate ER 45 mg and 63 mg tablets to require trial/failure to amphetamine/dextroamphetamine ER, dexmethylphenidate HCl ER, dextroamphetamine ER, and methylphenidate ER 36 mg and 54 mg. Policy revised to add ezetimibe-atorvastatin to require trial/failure of atorvastatin + ezetimibe and rosuvastatin + ezetimibe.
Market Watch Programs – NY, PA, and WV	02/20/2023	Policy revised to add Relexxii and generic methylphenidate ER 45 mg and 63 mg tablets to require trial/failure to amphetamine/dextroamphetamine ER, dexmethylphenidate HCl ER, dextroamphetamine ER, and methylphenidate ER 36 mg and 54 mg. Policy revised to add ezetimibe-atorvastatin to

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		require trial/failure of atorvastatin + ezetimibe and rosuvastatin + ezetimibe.
Noxafil (posaconazole) – Commercial and Healthcare Reform	02/03/2023	Policy revised for Noxafil (posaconazole) PowderMix for delayed-release oral suspension to require the member to be 2 years or age or older, weighs ≤ 40 kg, and if the member is 13 years or age or older, the member has experienced therapeutic failure or intolerance to plan preferred Noxafil oral suspension.
Parathyroid Hormone Analogs – Commercial and Healthcare Reform	02/03/2023	Policy revised for Tymlos (abaloparatide) to remove the requirement that the member is a postmenopausal female based on expanded indication. Policy revised for Forteo (teriparatide) to require step through Tymlos (abaloparatide) if the member is a male at high risk for fracture.
Parathyroid Hormone Analogs – Commercial National Select Formulary	02/03/2023	Policy revised for Tymlos (abaloparatide) to remove the requirement that the member is a postmenopausal female based on expanded indication.
PARP Inhibitors – Commercial and Healthcare Reform	02/03/2023	Policy revised for Rubraca (rucaparib) to require age; diagnosis based on FDA-approved indication; and, as applicable, supported by FDA-approved test. Policy revised for Zejula (niraparib) to require diagnosis based on FDA-approved indication; requirement removed for an FDA-approved test.
Pretomanid – Commercial and Healthcare Reform	02/03/2023	Updated policy for pretomanid for the member to have experienced therapeutic failure, contraindication, or intolerance to either isoniazid or a rifamycin antibiotic (rifampin, rifabutin, or rifapentine). Policy revised for updated authorization criteria of 9 months.
Recorlev (levoketoconazole) – Commercial and Healthcare Reform	02/03/2023	Policy revised for Recorlev (levoketoconazole) to add it is not approved for the treatment of fungal infections to the limitations of coverage. Removed documentation of endogenous Cushing's syndrome from initial authorization criteria.
Relyvrio (sodium phenylbutyrate and taurorsodiol) – Commercial and Healthcare Reform	02/03/2023	Policy revised to specify that diagnosis of sporadic or familial amyotrophic lateral sclerosis (ALS) is supported by the following: progressive motor neuron symptoms, signs of ALS in limb(s) or body segment(s), and the absence of evidence of other disease states or factors that could explain the clinical signs or symptoms.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Sunosi (solriamfetol) – Commercial and Healthcare Reform	02/03/2023	Policy revised for Sunosi (solriamfetol). Narcolepsy reauthorization revised to remove narcolepsy with cataplexy criterion. Authorization criteria for Obstructive Sleep Apnea (OSA)/Hypopnea Syndrome revised to eliminate apnea/hypopnea index and signs/symptoms of OSA and replaced with member is experiencing persistent daytime sleepiness despite adequate OSA treatment and the prescriber attests that alternative causes of daytime sleepiness have been excluded.
Testosterone (Androgens) – Commercial and Healthcare Reform	02/03/2023	Policy revised for testosterone products to remove requirement of at least one specific, non-sexual symptom of low testosterone, and to allow for symptoms of low testosterone in general.
Thiola and Thiola EC (tiopronin) – Commercial and Healthcare Reform	02/03/2023	Policy revised for Thiola (tiopronin) to update reauthorization criteria to require attestation of reduction in urine cystine concentration from baseline.
Topiramate ER – Commercial and Healthcare Reform	02/03/2023	Policy revised for Eprontia (topiramate) for initial authorization of seizures to add option for current member stability on Eprontia.
Urea Cycle Disorder Medications – Commercial and Healthcare Reform	TBD	Policy revised to include Olpruva (sodium phenylbutyrate) requiring diagnosis based on FDA-approved indication, and trial/failure to generic sodium phenylbutyrate.
Voxzogo (Vosoritide) – Commercial and Healthcare Reform	02/03/2023	Policy revised for Voxzogo (vosoritide) to require age between 5 and 17 years old.
Xeloda (capecitabine) – Commercial and Healthcare Reform	02/03/2023	Policy revised for Xeloda (capecitabine) to require age, diagnosis, and genetic status, when applicable, based on FDA-approved indications; existing step through generic capecitabine is maintained.
Xolair (omalizumab) – Commercial and Healthcare Reform	TBD	Policy revised for Xolair (omalizumab) for reauthorization of chronic spontaneous urticaria (CSU) to also require the member to meet one of the following: Xolair is requested at a dose of 150 mg every 4 weeks; prescriber attestation that the member has had one (1) or more CSU attacks in the last 6 months; prescriber attestation that a dose of 150 mg every 4 weeks would not be appropriate. Quantity limitations revised to 1 mL or 2 mL per 21 days.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates) – Commercial and Healthcare Reform	02/03/2023	Policy revised to remove approval of Xyrem (sodium oxybate) for idiopathic hypersomnia (IH). Step through Xyrem removed for approval of Xywav (calcium, magnesium, potassium, and sodium oxybates) for (IH).
Zavesca (miglustat) – Commercial and Healthcare Reform	Term	Terminating to combine with J-0406 Gaucher Disease – Commercial and Healthcare Reform
Zeposia (ozanimod) – Commercial and Healthcare Reform	01/27/2023	Policy revised for Zeposia (ozanimod) to update from double step to single step through Humira (adalimumab) or Stelara (ustekinumab). A trial of an infliximab product (e.g., Remicade, biosimilars) or Simponi subcutaneous also counts towards a trial of Humira. A trial of Entyvio (vedolizumab intravenous) or Stelara intravenous also counts towards a trial of Stelara subcutaneous.
Zokinvy (lonafarnib) – Commercial and Healthcare Reform	02/03/2023	Policy revised for Zokinvy (lonafarnib) to remove documentation for diagnosis.

*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
Adhansia XR (methylphenidate hydrochloride) – Commercial	Term	Policy to be terminated; product has been discontinued.
Antiviral Therapy (Sitavig & Denavir) – Commercial	02/03/2023	Policy revised for brand Denavir (penciclovir) to require trial/failure/contraindication to generic penciclovir cream for initial authorization and reauthorization.
Atypical Antipsychotics – Commercial	02/03/2023	Policy revised to add criteria for a new FDA-approved indication for Vraylar (cariprazine): Adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults. The criteria require diagnosis based on FDA-approved indication, age, therapeutic failure, contraindication, or intolerance to one (1) other antidepressant agent in addition to the agent currently being used for the treatment of MDD, and

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		the member has experienced therapeutic failure, contraindication, or intolerance to one (1) of the plan-preferred generic products, quetiapine ER or aripiprazole.
Butalbital Combination Products – Commercial and Healthcare Reform	02/03/2023	Policy revised to remove off-market products Vanatol LQ (butalbital-acetaminophen-caffeine), Vanatol S (butalbital-acetaminophen-caffeine), and Vtol (butalbital-acetaminophen-caffeine).
Dyanavel XR (amphetamine) – Commercial and Healthcare Reform	TBD	Policy revised to add Dyanavel XR (amphetamine) extended-release oral suspension. Criteria remains the same: age and diagnosis based on FDA-approved indication as well as therapeutic failure, contraindication, or intolerance to two of the following generic, plan-preferred products: amphetamine/dextroamphetamine extended-release, methylphenidate HCl extended-release, dexmethylphenidate HCl extended-release, or dextroamphetamine extended-release.
Latuda (lurasidone) – Commercial	02/24/2023	Policy revised for Latuda (lurasidone) to include aripiprazole as a qualifying medication for the schizophrenia criteria. Aripiprazole also added as a qualifier in the automatic approval criteria.
Methotrexate Injections – Commercial and Healthcare Reform	02/03/2023	Policy revised for Rasuvo (methotrexate), Otrexup (methotrexate) and RediTrex (methotrexate) to specifically outline FDA approved indications as policy criteria.
Non-Preferred Combination GLP-1 RA and Basal Insulin Products – Commercial and Healthcare Reform	02/03/2023	Policy revised for Soliqua (insulin glargine and lixisenatide) to clarify that the member has experienced therapeutic failure/contraindication/intolerance to a metformin containing product or is using Soliqua (insulin glargine and lixisenatide) in addition to a metformin-containing product.
Non-Preferred Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) – Commercial and Healthcare Reform	02/03/2023	Policy revised for Bydureon BCise (exenatide extended-release) to require trial/failure/contraindication to Trulicity (dulaglutide) if the member is 10 years of age or older.
Relexxii (methylphenidate hydrochloride) – Commercial and Healthcare Reform	02/24/2023	New policy created for Relexxii (methylphenidate hydrochloride) 45 mg and 63 mg requiring diagnosis of FDA approved indication, age of 6 to 65 years, and therapeutic failure, contraindication, or intolerance to two of the following generic, plan-preferred products: amphetamine/dextroamphetamine extended-

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		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. Authorization duration of 12 months.
Topical Acne Products – Commercial and Healthcare Reform	TBD	Policy revised to add Veltin (clindamycin/tretinoin) to require age, diagnosis of acne vulgaris, and trial/failure to three of the following generic topicals: adapalene, clindamycin or clindamycin/benzoyl peroxide, erythromycin, sulfacetamide, or tretinoin. Reauthorization requiring positive clinical response and acne requires additional courses of treatment. Criteria for Epiduo Forte (adapalene/benzoyl peroxide) revised to require age of 12 years and older.
Topical Corticosteroids – Commercial and Healthcare Reform	02/24/2023	Policy revised to remove products no longer available on the market. Pandel 0.1% (hydrocortisone probutate) cream and Tritocin 0.05% (triamcinolone acetonide) ointment added to policy.

*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
Dexcom G6 Sensors*	3 sensors per 30 days	9 sensors per 90 days
Dexcom G7 Receiver	1 receiver per 365 days	1 receiver per 365 days
Dexcom G7 Sensors	3 sensors per 30 days	9 sensors per 90 days
Idacio (adalimumab-aacf)*	2 syringes or pens every 28 days	6 syringes or pens every 84 days
Linezolid (Zyvox) 600 mg tablet	56 tablets per 180 days	56 tablets per 180 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
Mifeprex (mifepristone) 200 mg tablet*	2 tablets	2 tablets
Sunlenca (lenacapavir) tablets	5 tablets	5 tablets

*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
Ezetimibe-atorvastatin	1 tablet per day
Krazati (adagrasib)	6 tablets per day
Olpruva (sodium phenylbutyrate)*	20 grams per day
Relexxii (methylphenidate)	1 tablet per day
Rezlidhia (olutasidenib)	2 capsules per day
Tascenso ODT (fingolimod lauryl sulfate) 0.5 mg	1 tablet per day

*Effective date to be determined
Members can receive up to the maximum day supply according to their benefits, but the daily limit must not be exceeded for each individual day.

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

SECTION II. Highmark Medicare Part D Formularies

A. Changes to the Highmark Medicare Part D 5-Tier Open Formularies

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

- **Incentive Formulary**
- **Compass Formulary**

Table 1. Preferred Products
Effective immediately pending Centers for Medicare and Medicaid Services (CMS) approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Comments
Rotarix (rotovirus vaccine, live)	Rotarix (rotovirus vaccine, live)	Prevention of rotavirus gastroenteritis

Table 2. Non-Preferred Products

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

Brand Name	Generic Name	Preferred Alternatives
Mifepristone 200 mg tablet	Mifepristone 200 mg tablet	Prescriber discretion
Ezetimibe-atorvastatin	Ezetimibe-atorvastatin	Prescriber discretion
Jylamvo oral solution	methotrexate	Prescriber discretion

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

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

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

Table 1. Preferred Products

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

Brand Name	Generic Name	Comments
Rotarix (rotovirus vaccine, live)	Rotarix (rotovirus vaccine, live)	Prevention of rotavirus gastroenteritis

Table 2. Non-Preferred Products

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

Brand Name	Generic Name	Preferred Alternatives
Mifepristone 200 mg tablet	Mifepristone 200 mg tablet	Prescriber discretion

Table 3. Products Not Added*

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

Brand Name	Generic Name	Preferred Alternatives
Ezetimibe-atorvastatin	Ezetimibe-atorvastatin	atorvastatin, ezetimibe
Jylamvo oral solution	methotrexate	Prescriber discretion

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

C. Additions to the Specialty Tier

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

Brand Name	Generic Name
Elahere	mirvetuximab soravtansine-gynx
Idacio	adalimumab-aacf
Krazati	adagrasib
Lunsumio	mosunetuzumab-axgb
Olpruva	sodium phenylbutyrate
Rebyota	fecal microbiota, live-jslm
Rezlidhia	olutasidenib
Sezaby	phenobarbital sodium for injection
Sunlenca tablets	lenacapavir
Sunlenca vials	lenacapavir
Tascenso ODT 0.5 mg	fingolimod lauryl sulfate
Tzield	teplizumab

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
KRAS G12C Inhibitors – Medicare	02/03/2023	Policy revised for Krazati (adagrasib) to require diagnosis based on FDA-approved indication, supported by FDA-approved test. Policy revised for Lumakras (adagrasib) to remove age requirement.
Livtencity (maribavir) – Medicare	02/03/2023	Policy revised for Livetencity (maribavir) to add additional reauthorization criteria for patients requiring continued antiviral treatment to achieve virologic clearance.
Lunsumio (mosunetuzumab-axgb) – Medicare	02/03/2023	New policy for Lunsumio (mosunetuzumab-axgb) requiring diagnosis of FDA indication.
Methotrexate Injections – Medicare	01/01/2024	Policy revised for Rasuvo (methotrexate), Otrexup (methotrexate) and RediTrex (methotrexate) to specifically outline FDA approved indications as policy criteria.
Ocrevus (ocrelizumab) – Medicare	Term	Terminating to combine with J-1010 Anti-CD20 Multiple Sclerosis Agents – Medicare
Onpattro (patisiran) – Medicare	01/01/2023	Policy revised to add reference to J-0030 to address BvD infusion pump criteria
Panretin gel (alitretinoin) – Medicare	02/03/2023	Policy revised to remove age 18 or older criteria.
Parathyroid Hormone Analogs – Medicare	02/03/2023	Policy revised for Tymlos (abaloparatide) to remove requirement that the member is a postmenopausal female, based on expanded indication.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
PARP Inhibitors – Medicare	02/03/2023	Policy revised for Rubraca (rucaparib) to require diagnosis based on FDA-approved indication. Policy revised for Zejula (niraparib) to require diagnosis based on FDA-approved indication.
Pretomanid – Medicare	02/03/2023	Updated policy for pretomanid for the member to have experienced therapeutic failure, contraindication, or intolerance to either isoniazid or a rifamycin antibiotic (rifampin, rifabutin, or rifapentine). Policy revised for updated authorization criteria of 9 months.
Rebyota (fecal microbiota, live-jslm) – Medicare	02/03/2023	New policy created for Rebyota (fecal microbiota, live-jslm) requiring diagnosis of FDA-approved indication, prescriber attestation that Rebyota will be used for prophylaxis and not treatment of recurrent Clostridioides difficile infection (CDI), and prescriber attestation that the member has completed antibiotic treatment for the most recent recurrent CDI. Reauthorization criteria requiring prescriber attestation that Rebyota will be used for prophylaxis and not treatment of recurrent Clostridioides diificile infection (CDI) and that the member has experienced recurrent CDI episodes after the initial fecal microbiota transplant. Authorization duration of 1 month.
Solaraze (diclofenac sodium 3% topical gel) – Medicare	02/03/2023	Policy revised to remove reference to brand name Solaraze (diclofenac sodium); this product is no longer commercially available. The criteria remain in place for the generic formulation, diclofenac sodium 3%. In both the initial authorization and reauthorization sections, the criterion requiring therapeutic failure or intolerance to generic diclofenac sodium 3% gel for coverage of brand Solaraze was removed.
Tecentriq (atezolizumab) – Medicare	02/03/2023	Policy revised for Tecentriq (atezolizumab) to remove criteria for locally advanced or metastatic urothelial carcinoma following removal of the indication per FDA and addition of criteria for the new indication for treatment of adult and pediatric patients 2 years of age and older with alveolar soft part sarcoma (ASPS) requiring diagnosis of unresectable or metastatic ASPS.
Tzield (teplizumab) – Medicare	02/03/2023	New policy created for Tzield (teplizumab-mzwv) requiring diagnosis of FDA-approved indication and confirmation of Stage 2 Type 1 Diabetes with at least two positive pancreatic islet cell

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		autoantibody tests and an oral glucose test resulting in dysglycemia without overt hyperglycemia.
Uplizna (inebilizumab-cdon) – Medicare	01/01/2023	Policy revised to add reference to J-0030 to address BvD infusion pump criteria
Vyvgart (efgartigimod alfa-fcab) – Medicare	01/01/2024	Policy revised for Vyvgart (efgartigimod alfa-fcab) authorization duration from 12 months to an initial authorization of 6 months and reauthorization of 12 months.
Zelnorm (tegaserod) – Medicare	Term	Policy terminated since Zelnorm is not eligible for Medicare coverage
KRAS G12C Inhibitors – Medicare	02/03/2023	Policy revised for Krazati (adagrasib) to require diagnosis based on FDA-approved indication, supported by FDA-approved test. Policy revised for Lumakras (adagrasib) to remove age requirement.
Livtencity (maribavir) – Medicare	02/03/2023	Policy revised for Livetencity (maribavir) to add additional reauthorization criteria for patients requiring continued antiviral treatment to achieve virologic clearance.
Lunsumio (mosunetuzumab-axgb) – Medicare	02/03/2023	New policy for Lunsumio (mosunetuzumab-axgb) requiring diagnosis of FDA indication.
Methotrexate Injections – Medicare	01/01/2024	Policy revised for Rasuvo (methotrexate), Otrexup (methotrexate) and RediTrex (methotrexate) to specifically outline FDA approved indications as policy criteria.
Ocrevus (ocrelizumab) – Medicare	Term	Terminating to combine with J-1010 Anti-CD20 Multiple Sclerosis Agents – Medicare
Onpattro (patisiran) – Medicare	01/01/2023	Policy revised to add reference to J-0030 to address BvD infusion pump criteria
Panretin gel (alitretinoin) – Medicare	02/03/2023	Policy revised to remove age 18 or older criteria.
Parathyroid Hormone Analogs – Medicare	02/03/2023	Policy revised for Tymlos (abaloparatide) to remove requirement that the member is a postmenopausal female, based on expanded indication.
PARP Inhibitors – Medicare	02/03/2023	Policy revised for Rubraca (rucaparib) to require diagnosis based on FDA-approved indication. Policy revised for Zejula (niraparib) to require diagnosis based on FDA-approved indication.
Pretomanid – Medicare	02/03/2023	Updated policy for pretomanid for the member to have experienced therapeutic failure, contraindication, or intolerance to either isoniazid or a rifamycin antibiotic (rifampin, rifabutin, or

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		rifapentine). Policy revised for updated authorization criteria of 9 months.
Rebyota (fecal microbiota, live-jslm) – Medicare	02/03/2023	New policy created for Rebyota (fecal microbiota, live-jslm) requiring diagnosis of FDA-approved indication, prescriber attestation that Rebyota will be used for prophylaxis and not treatment of recurrent Clostridioides difficile infection (CDI), and prescriber attestation that the member has completed antibiotic treatment for the most recent recurrent CDI. Reauthorization criteria requiring prescriber attestation that Rebyota will be used for prophylaxis and not treatment of recurrent Clostridioides diificile infection (CDI) and that the member has experienced recurrent CDI episodes after the initial fecal microbiota transplant. Authorization duration of 1 month.
Solaraze (diclofenac sodium 3% topical gel) – Medicare	02/03/2023	Policy revised to remove reference to brand name Solaraze (diclofenac sodium); this product is no longer commercially available. The criteria remain in place for the generic formulation, diclofenac sodium 3%. In both the initial authorization and reauthorization sections, the criterion requiring therapeutic failure or intolerance to generic diclofenac sodium 3% gel for coverage of brand Solaraze was removed.
Tecentriq (atezolizumab) – Medicare	02/03/2023	Policy revised for Tecentriq (atezolizumab) to remove criteria for locally advanced or metastatic urothelial carcinoma following removal of the indication per FDA and addition of criteria for the new indication for treatment of adult and pediatric patients 2 years of age and older with alveolar soft part sarcoma (ASPS) requiring diagnosis of unresectable or metastatic ASPS.
Tzield (teplizumab) – Medicare	02/03/2023	New policy created for Tzield (teplizumab-mzwv) requiring diagnosis of FDA-approved indication and confirmation of Stage 2 Type 1 Diabetes with at least two positive pancreatic islet cell autoantibody tests and an oral glucose test resulting in dysglycemia without overt hyperglycemia.
Uplizna (inebilizumab-cdon) – Medicare	01/01/2023	Policy revised to add reference to J-0030 to address BvD infusion pump criteria
Vyvgart (efgartigimod alfa-fcab) – Medicare	01/01/2024	Policy revised for Vyvgart (efgartigimod alfa-fcab) authorization duration from 12 months to an initial

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		authorization of 6 months and reauthorization of 12 months.

*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	02/03/2023	Policy revised to modify Relexxii (methylphenidate ER) to include all strengths as targets.
Epinephrine Auto-Injectors – Medicare	02/03/2023	Policy revised for Auvi-Q (epinephrine), removed 180 days from the step therapy requirement.
Gonadotropin-releasing Hormone (GnrH) Agonists – Medicare	02/03/2023	Policy revised to add leuprolide acetate depot and require FDA-approved diagnosis.

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)
Briumvi (ublituximab-xiiy)	3 vials every 24 weeks	3 vials every 24 weeks
Dexcom G7 Receiver	1 receiver per 365 days	1 receiver per 365 days
Dexcom G7 Sensors	3 sensors per 30 days	3 sensors per 30 days
Ezetimibe-atorvastatin	1 tablet per day	1 tablet per day
Idacio (adalimumab-aacf)	2 syringes or pens every 28 days	6 syringes or pens every 84 days
Krazati (adagrasib)	6 tablets per day	6 tablets per day
Mifepristone 200 mg tablet	2 tablets per 30 days	2 tablets per 30 days
Olpruva (sodium phenylbutyrate)	20 grams per day	20 grams per day
Rebyota (fecal microbiota, live-jslm)	1 unit per 8 weeks	1 unit per 8 weeks
Relexxii (methylphenidate)	1 tablet per day	1 tablet per day
Rezlidhia (olutasidenib)	2 capsules per day	2 capsules per day
Tascenso ODT (fingolimod lauryl sulfate) 0.5 mg	1 tablet per day	1 tablet per day
Tzield (teplizumab)	14 vials per lifetime	14 vials per lifetime

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