Formulary Updates

Published September 22, 2022

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

Please reference the guide below to navigate this communication:

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B. Changes to the Highmark Healthcare Reform Essential Formulary
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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

Magnesium Citrate Saline Laxative Oral Solution Expansion 1 by VI-Jon, LLC: Recall – Microbial Contamination

On July 25, 2022, Vi-Jon expanded their July 14, 2022, recall of the above product to include more flavors of the product. The recall was due to the presence of *Gluconacetobacter liquefaciens,* which was identified during a third-party microbial test.

Immunocompromised patients may be at increased risk for invasive infections caused by *Gluconacetobacter* liquefaciens leading to serious, life-threatening adverse health consequences. To date, Vi-Jon, LLC is aware of three reports of serious adverse reactions potentially related to this recall. Vi-Jon, LLC is in the process of investigating these reports.

Magnesium Citrate Saline Laxative Oral Solution Expansion 2 by VI-Jon, LLC: Recall – Microbial Contamination

On August 4, 2022, Vi-Jon expanded their recall of the above product for a second time, to include more NDCs. The recall was due to the presence of *Gluconacetobacter liquefaciens,* which was identified during a third-party microbial test.

Immunocompromised patients may be at increased risk for invasive infections caused by *Gluconacetobacter* liquefaciens leading to serious, life-threatening adverse health consequences. To date, Vi-Jon, LLC is aware of three reports of serious adverse reactions potentially related to this recall. Vi-Jon, LLC is in the process of investigating these reports.

Highmark Formulary Update – August 2022

SECTION I. Highmark Commercial and Healthcare Reform Formularies

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

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

- Highmark Comprehensive Formulary
- Highmark Healthcare Reform Comprehensive Formulary

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

Table 1. Products Added

All products added to the formulary effective September 2022, unless otherwise noted.

Brand Name	Generic Name	Comments
Mounjaro	tirzepatide	Type 2 Diabetes Mellitus
Priorix*	Measles, Mumps, and Rubella Vaccine, Live	Prevention of measles, mumps, and rubella in individuals 12 months of age and older.

*For Commercial Comprehensive only

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
drospirenone chewable tablets*	drospirenone chewable tablets	norethindrone acetate tablet 0.35 mg, camila, errin
Fylnetra*	pegfilgrastim-pbbk	Neulasta Syringe (ML), Neupogen
Radicava ORS	edaravone oral solution	riluzole
Tyvaso DPI	treprostinil	sildenafil citrate tablet 20 mg, ambrisentan
venlafaxine besylate ER	venlafaxine besylate ER	venlafaxine oral capsule extended release
Vtama	tapinarof	calcipotriene cream (gram); betamethasone dipropionate cream (gram); triamcinolone acetonide ointment (gram) 0.5 %
Pheburane*	sodium phenylbutyrate	Prescriber Discretion

Brand Name	Generic Name	Preferred Alternatives
Priorix***	Measles, Mumps, and Rubella 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.
***For HCR Comprehensive only; this drug is covered on the Commercial Comprehensive plan.

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
Fylnetra	pegfilgrastim-pbbk
Pheburane	sodium phenylbutyrate
Radicava ORS	edaravone oral solution
Tyvaso DPI	treprostinil
Vtama	tapinarof

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 September 2022, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Mounjaro	tirzepatide	3	Type 2 Diabetes Mellitus
Priorix	Measles, Mumps, and Rubella Vaccine, Live	3	Measles, Mumps, and Rubella Vaccine, Live
Items listed below were not added to the formulary			
Fylnetra*	pegfilgrastim-pbbk	NF	Zarxio
Pheburane*	sodium phenylbutyrate	NF	sodium phenylbutyrate tablets
Radicava ORS	edaravone oral solution	NF	riluzole
Tyvaso DPI	treprostinil	NF	sildenafil citrate tablet 20 mg, ambrisentan
Vtama	tapinarof	NF	calcipotriene cream (gram); betamethasone dipropionate; triamcinolone acetonide ointment (gram) 0.5 %

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
drospirenone chewable tablets*	drospirenone chewable tablets	NF	norethindrone acetate tablet 0.35 mg, camila, errin
venlafaxine besylate ER	venlafaxine besylate ER	NF	venlafaxine oral capsule extended release

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.

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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 September 2022 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Mounjaro	tirzepatide	3	Type 2 Diabetes Mellitus
Priorix	Measles, Mumps, and Rubella Vaccine, Live	3	Prevention of measles, mumps, and rubella in individuals 12 months of age and older.
Items listed below were not added to the formulary			
drospirenone chewable tablets*	drospirenone chewable tablets	NF	norethindrone acetate tablet 0.35 mg, camila, errin
Fylnetra*	pegfilgrastim-pbbk	NF	Nivestym
Pheburane*	sodium phenylbutyrate	NF	sodium phenylbutyrate tablets
Radicava ORS	edaravone oral solution	NF	riluzole
Tyvaso DPI	treprostinil	NF	sildenafil citrate tablet 20 mg, ambrisentan
venlafaxine besylate ER	venlafaxine besylate ER	NF	venlafaxine oral capsule extended release
Vtama	tapinarof	NF	calcipotriene cream (gram); betamethasone dipropionate cream (gram); triamcinolone acetonide ointment (gram) 0.5 %

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)			
Mounjaro	tirzepatide	2	Type 2 Diabetes Mellitus
Priorix	Measles, Mumps, and Rubella Vaccine, Live	2	Prevention of measles, mumps, and rubella in individuals 12 months of age and older.
Radicava ORS	edaravone oral solution	2	
Items listed below were added to the formulary (Non-Preferred)			
drospirenone chewable tablets*	drospirenone chewable tablets	3	norethindrone acetate tablet 0.35 mg, camila, errin
Pheburane*	sodium phenylbutyrate	3	sodium phenylbutyrate
Fylnetra*	pegfilgrastim-pbbk	3	Fulphila, Ziextenzo
Tyvaso DPI*	treprostinil	3	sildenafil citrate tablet 20 mg, ambrisentan
Vtama*	tapinarof	3	calcipotriene cream (gram); betamethasone dipropionate cream (gram); triamcinolone acetonide ointment (gram) 0.5 %
Items listed below were not added to the formulary			
venlafaxine besylate ER	venlafaxine besylate ER	NF	venlafaxine oral capsule extended release

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
Fylnetra	pegfilgrastim-pbbk
Pheburane	sodium phenylbutyrate
Radicava ORS	edaravone oral solution
Tyvaso DPI	treprostinil
Vtama	tapinarof

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
ALK-Targeting Kinase Inhibitors – Commercial and Healthcare Reform	08/11/2022	Policy revised for Xalkori (crizotinib) requiring age and diagnosis based on FDA-approved expanded indication.
Anti-Angiogenesis and VEGF Kinase Inhibitors – Commercial and Healthcare Reform	08/11/2022	Policy revised for brand Nexavar (sorafenib) to require therapeutic failure or intolerance to generic sorafenib and to specify criteria for advanced renal cell carcinoma; reauthorization criteria revised for Nexavar (sorafenib) to require documentation that the AB-rated generic is ineffective or not tolerated.
Anti-Obesity – Commercial and Healthcare Reform	08/12/2022	Policy revised for Saxenda (liraglutide) and Wegovy (semaglutide) to update that they are not used concurrently with any glucagon-like pepetide-1 receptor agonist combinations. Policy revised for Saxenda (liraglutide) in use in pediatrics to change initiation duration to 5 months. Policy revised for Qsymia (phentermine and topiramate extended-release) to require diagnosis based on new FDA-approved indication for use in pediatrics for chronic weight management, baseline and current age, height, weight, and body mass index, and will be used with diet and exercise. Reauthorization added for maintenance that member has experienced at least 5% weight loss from baseline and has maintained weight loss from baseline.
Apomorphine Products – Commercial and Healthcare Reform	08/16/2022	Policy revised to require a step through generic apomorphine hydrochloride injection for brand Apokyn (apomorphine hydrochloride) for initial and reauthorization.
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Commercial and Healthcare Reform	08/16/2022	Policy revised for Tafinlar (dabrafenib) and Mekinist (trametinib) requiring age and diagnosis based on FDA-approved expanded indication.
Brexafemme (ibrexafungerp) – Commercial and Healthcare Reform	08/09/2022	Policy revised to require that the member has experienced less than 3 episodes of vulvovaginal candidiasis in the last year and to allow trial or contraindication to a non-fluconazole oral or topical azole regimen for members with non-albicans Candida.
Chelating Agents – Commercial and Healthcare Reform	08/16/2022	Policy revised for Ferriprox (deferiprone) to require age, trial and failure to generic deferiprone tablets, Reauthorization revised for Exjade (deferasirox) and Jadenu (deferasirox) to include trial and failure to generic deferasirox tablets.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		Reauthorization criteria revised for Ferriprox (deferiprone) to include trial and failure to generic deferasirox tablets and generic deferiprone tablets.
Chemotherapy Induced Nausea and Vomiting (CINV) – Commercial	08/09/2022	Policy revised to add criteria for Anzemet (dolasetron) to require use in members 2 years of age or older for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy; and if the member is 4 years of age or older, the member has experienced therapeutic failure or intolerance to generic ondansetron.
Chemotherapy Induced Nausea and Vomiting (CINV) – Healthcare Reform	08/09/2022	Policy revised to add criteria for Anzemet (dolasetron) to require use in members 2 years of age or older for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy; and if the member is 4 years of age or older, the member has experienced therapeutic failure or intolerance to generic ondansetron.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	08/16/2022	Policy revised for Olumiant (baricitinib) for alopecia areata requiring age, diagnosis based on FDA-approved indication, trial/failure to systemic therapy (e.g., corticosteroid, methotrexate, cyclosporine) or high potency topical corticosteroid, or contraindication to all.
Chronic Inflammatory Diseases – Commercial National Select Formulary	08/10/2022	Policy revised for Olumiant (baricitinib) for alopecia areata requiring age, diagnosis based on FDA-approved indication, trial/failure to systemic therapy (e.g., corticosteroid, methotrexate, cyclosporine) or high potency topical corticosteroid, or contraindication to all.
Diacomit (stiripentol) – Commercial and Healthcare Reform	08/09/2022	Policy revised to included expanded age indication. For patients 6 months to 2 years of age weighing at least 7 kilograms, the member requires therapeutic failure, contraindication, or intolerance to clobazam and continues to use in combination with clobazam.
Dojolvi (triheptanoin) – Commercial and Healthcare Reform	08/17/2022	Policy revised for Dojolvi (triheptanoin) to require attestation that the member has experienced trial/failure/contraindication to commercially available medium chain triglyceride (MCT) products or has experienced at least one significant clinical manifestation of long-chain fatty acid oxidation disorders, and attestation that the

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		product will not be used concomitantly with another MCT product (added to initial and reauthorization).
Dupixent (dupilumab) – Commercial and Healthcare Reform	08/16/2022	Policy revised for Dupixent (dupilumab) to update age for atopic dermatitis to 6 months and older. Added new indication of eosinophilic esophagitis (EoE) requiring age, diagnosis based on FDA-approved indication supported by esophageal eosinophil count greater than or equal to 15 eos/hpf, history of two or more episodes of dysphagia per week, trial/failure/contraindication to high-dose proton pump inhibitor therapy. Reauthorization for EoE to require histological remission or reduced severity or frequency of dysphagia.
EGFR-Targeting Kinase Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised for Iressa (gefitinib) to require for brand Iressa that the member has experienced therapeutic failure or intolerance to generic gefitinib. Reauthorization criteria revised to require for brand Iressa documentation that the member has experienced therapeutic failure or intolerance to the AB-rated generic.
Empaveli (pegcetacoplan) – Commercial and Healthcare Reform	08/09/2022	Policy revised for Empaveli (pegcetacoplan) to require attestation that Empaveli will not be used in combination with another complement inhibitor (e.g., Soliris [eculizumab] or Ultomiris [ravulizumab]) unless initially cross titrating from Soliris or Ultomiris. Reauthorization revised to require attestation that Empaveli will not be used in combination with another complement inhibitor. Initial authorization duration revised to 6 months.
Evrysdi (risdiplam) – Commercial and Healthcare Reform	08/09/2022	Policy revised for Evrysdi (risdiplam) to remove age requirement of 2 months of age or older due to expanded indication.
Gimoti (metoclopramide) nasal spray – Commercial and Healthcare Reform	08/09/2022	Policy revised for Gimoti (metoclopramide) to allow step through metoclopramide orally disintegrating tablets (ODT) in addition to oral tablets or oral solution, or that the member is not a candidate for oral dosage forms.
Gonadotropin-Releasing Hormone (GnRH) Agonists – Commercial and Healthcare Reform	08/09/2022	Policy revised for Lupron Depot (leuprolide acetate for depot suspension) and Lupron Depot-Ped (leuprolide acetate for depot suspension) to allow coverage for diagnosis of gender dysphoria and if member is 15 years of age or younger the drug is prescribed by a clinician competent in the

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		evaluation and induction of pubertal development. Policy revised for Lupron Depot-Ped (leuprolide acetate for depot suspension) to decrease age for central precocious puberty (CPP) and for reauthorization add normalization of estradiol level or normalization of testosterone level. Policy revised to add reauthorization criteria that prescriber attests that the member has experienced a positive response to therapy and member requires continued therapy.
Imcivree (setmelanotide) – Commercial and Healthcare Reform	08/17/2022	Policy revised for Imcivree (setmelanotide) to require diagnosis for new FDA-approved indication Bardet-Biedl syndrome, baseline and current age, height, weight, and body mass index. Reauthorization added for continuation that member has experienced at least 5% weight loss from baseline and for maintenance member has maintained weight loss from baseline.
Interferons – Commercial and Healthcare Reform	08/17/2022	Policy revised for Besremi (ropeginterferon alfa-2b-njft) to require documentation of disease risk; for intermediate or high-risk polycythemia vera, trial/failure/contraindication to Pegasys (peginterferon alpha-2a) is required; polycythemia vera approvable indication for Pegasys.
Lonsurf (trifluridine-tipiracil) – Commercial and Healthcare Reform	08/17/2022	Policy revised for Lonsurf (trifluridine/tipiracil) to require anti-EGFR (epidermal growth factor receptor) therapy if disease is left-sided only.
Market Watch Programs – Delaware	09/01/2022	Policy revised to add metformin hydrochloride 625 mg tablet and trial/failure to metformin hydrochloride IR (generic Glucophage). Policy revised to remove Aspruzyo Sprinkle (ranolazine). Policy revised to add meloxicam suspension to require trial/failure to generic ibuprofen oral suspension.
Market Watch Programs – New York, Pennsylvania and West Virginia	09/01/2022	Policy revised to add metformin hydrochloride 625 mg tablet and trial/failure to metformin hydrochloride IR (generic Glucophage). Policy revised to remove Aspruzyo Sprinkle (ranolazine). Policy revised to add meloxicam suspension to require trial/failure to generic ibuprofen oral suspension.
Natpara (parathyroid hormone) – Commercial and Healthcare Reform	08/17/2022	Policy revised for Natpara (parathyroid hormone) to update initial authorization duration from 12 months to 6 months. The member will continue to use Natpara (parathyroid hormone) as adjunct to

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		calcium and vitamin D, and removed contraindication exception to calcium and vitamin D.
Neurogenic Detrusor Overactivity Disorder – Commercial and Healthcare Reform	08/09/2022	Policy revised to include generic oxybutynin ER as an option for trial and failure for approval of Myrbetriq granules or Vesicare LS.
Northera (droxidopa) – Commercial and Healthcare Reform	TBD	Policy revised for Northera (droxidopa) to require therapeutic failure or intolerance to generic droxidopa if the request is for brand Northera (droxidopa) as part of both initial criteria and reauthorization.
Ofev (nintedanib) and Esbriet (pirfenidone) – Commercial and Healthcare Reform	08/17/2022	Policy revised for Esbriet (pirfenidone) initial authorization and reauthorization to require trial/failure of generic prifenidone tablets if the request is for brand Esbriet.
Onpattro (patisiran) – Commercial and Healthcare Reform	08/29/2022	Onpattro must be administered as an intravenous infusion by a healthcare professional and therefore is not covered under the pharmacy benefit. The medication is part of the Global Exclusion list; therefore, the policy is terminated.
Palynziq (pegvaliase-pqpz) – Commercial and Healthcare Reform	08/10/2022	Policy revised for Palynziq (pegvaliase-pqpz) to add that the member is not using Palynziq in combination with Kuvan (sapropterin dihydrochloride) to limitations of coverage.
PARP Kinase Inhibitors – Commercial and Healthcare Reform	08/09/2022	Policy revised for Rubraca (rucaparib) to remove criteria for patients with advanced ovarian cancer who have been treated with two or more chemotherapies following manufacturer withdrawal of this indication.
Pretomanid – Commercial and Healthcare Reform	08/11/2022	Policy revised for pretomanid to require trial/failure/contraindication of isoniazid, rifampin and either a fluoroquinolone or amikacin, kanamycin, or capreomycin for a diagnosis of pre-extensively drug resistant (XDR) tuberculosis (TB) or XDR TB. For a diagnosis of treatment intolerant or nonresponsive multidrug resistant (MDR) TB, requiring trial/failure/contraindication to isoniazid and rifampin. Limitations of coverage revised to add that pretomanid will not be covered for drug-sensitive TB, latent infection due to M. tuberculosis, extra-pulmonary infection due to M. tuberculosis, or MDR TB that is not treatment-intolerant or responsive to standard therapy.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Pulmonary Hypertension – Commercial and Healthcare Reform	08/18/2022	Policy revised to add Tyvaso DPI (treprostinil) to require diagnosis based on FDA-approved indication and supported by results of right heart catheterization. For a diagnosis of pulmonary arterial hypertension, if the member is a new start to therapy, trial/failure/contraindication to sildenafil or ambrisentan. For a diagnosis of pulmonary hypertension associated with interstitial lung disease, the member is a non-smoker or currently engaged in smoking cessation. Reauthorization to require positive clinical response to therapy.
Pylera (bismuth subcitrate potassium, metronidazole, tetracycline) – Commercial and Healthcare Reform	08/09/2022	Policy revised to remove Helidac (bismuth subcitrate/metronidazole/tetracycline) as product is no longer available on the market.
Radicava ORS (edaravone) – Commercial and Healthcare Reform	08/10/2022	New policy for Radicava ORS (edaravone) requiring FDA-approved indication and age, “Definite” or “Probable" amyotrophic lateral sclerosis (ALS) based on the El Escorial revised criteria, ALS Functional Rating Scale-Revised (ALSFRS-R) score ≥ 2 in all items of the ALSFRS-R criteria at the initiation of treatment with Radicava or Radicava ORS, baseline forced vital capacity of at least 80%, not dependent on invasive ventilation or tracheostomy, and ALS disease duration of less than 2 years. Reauthorization requiring stability or improvement in ALS symptoms and not dependent on invasive ventilation or tracheostomy.
Sympazan and Onfi (clobazam) – Commercial and Healthcare Reform	08/18/2022	Policy revised to include a diagnosis of Dravet syndrome.
Synarel (nafarelin) – Commercial and Healthcare Reform	08/17/2022	Policy revised for Synarel (nafarelin acetate) for central precocious puberty (CPP) lowering age to 8 years if female or 9 years if male.
Targretin (bexarotene) – Commercial and Healthcare Reform	08/17/2022	Policy revised for Targretin (bexarotene) topical gel to require for brand Targretin topical gel that the member has experienced therapeutic failure or intolerance to generic topical bexarotene gel; reauthorization criteria revised to require for brand Targretin topical gel documentation that the AB-rated generic is ineffective or not tolerated.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Topical Lidocaine Products – Commercial and Healthcare Reform	TBD	Policy revised for Pliaglis (lidocaine/tetracine) to require in addition to age and FDA-approved indication, member must experience therapeutic failure or intolerance to plan-preferred lidocaine 2.5%/prilocaine 2.5% topical cream before Pliaglis (lidocaine/tetracaine) may be covered.
Urea Cycle Disorder Medications – Commercial and Healthcare Reform	TBD	Policy revised to include Pheburane (sodium phenylbutyrate) requiring diagnosis based on FDA-approved indication, and trial/failure to generic sodium phenylbutyrate.
Uterine Leiomyomas – Commercial and Healthcare Reform	08/17/2022	Policy revised to remove requirement for baseline assessment of bone mineral density.
VEGF and EGFR Kinase Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised for brand Caprelsa (vandetanib) requiring therapeutic failure or intolerance to generic vandetanib; and to require the member is 18 years of age or older. Reauthorization criteria revised for Caprelsa (vandetanib) to require documentation that the AB-rated generic is ineffective or not tolerated.
Viberzi (eluxadoline) – Commercial National Select	08/11/2022	Policy revised for Viberzi (eluxadoline) to remove bile acid sequestrants and selective serotonin reuptake inhibitors as a step therapy options for irritable bowel syndrome with diarrhea (IBS-D). Reauthorization criteria revised to add the member's IBS-D symptoms continue to persist.
Vusion (miconazole nitrate, zinc oxide, white petrolatum) – Commercial and Healthcare Reform	08/18/2022	Policy revised for Vusion (miconazole nitrate 0.25%, zinc oxide 15%, white petrolatum 81.35%) to require trial/failure/contraindication to concomitant use of nystatin cream/ointment and a zinc oxide containing product.
Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) – Commercial and Healthcare Reform	08/09/2022	Policy revised for Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) to require prescriber attestation that the member is not simultaneously using with transthyretin-lowering agents for both initial and reauthorization.

*For Commercial and Healthcare Reform policies, an exception to some or all the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.
**All effective dates are tentative and subject to delay pending internal review or approval.

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Additional Quantities of Antimalarial Drugs – Commercial and Healthcare Reform	01/01/2023	Policy revised for Coartem (artemether/lumefantrine), Malarone (atovaquone/proguanil hydrochloride), and Qualaquin (quinine sulfate) to include Commercial quantity limit benefits.
Ampyra (dalfampridine) – Commercial and Healthcare Reform	08/10/2022	Policy revised to add option that prescriber attests that the member is not a candidate for disease modifying therapy.
budesonide/formoterol fumarate – Healthcare Reform Essential Formulary	01/01/2023	New policy for budesonide/formoterol fumarate authorized generic requiring diagnosis based on FDA-approved indication and trial/failure/contraindication to Breo Ellipta (fluticasone furoate/vilanterol); generic fluticasone propionate/salmeterol or Wixela Inhub (fluticasone propionate/salmeterol); and Dulera (mometasone furoate/formoterol fumarate), only for a diagnosis of asthma. Reauthorization to require attestation of positive clinical response to therapy.
Buprenorphine (non-opioid dependence use) – Commercial, Healthcare Reform	08/10/2022	Policy criteria revised to allow attestation from the prescriber that the use of a non-steroidal anti-inflammatory drug (NSAID) is inappropriate to treat a patient in place of therapeutic failure or intolerance to one federal legend, generic, plan-preferred NSAID for both Butrans (buprenorphine) and Belbuca (buprenorphine).
Extavia (interferon beta-1b) – Commercial	06/30/2022	Policy terminated as criteria was moved to policy J-1203.
Extavia (interferon beta-1b) – Select Healthcare Reform	06/30/2022	Policy terminated as criteria was moved to policy J-1203.
Lonhala Magnair (glycopyrrolate) – Commercial and Healthcare Reform	08/10/2022	Policy revised for Lonhala Magnair (glycopyrrolate) reauthorization criteria to require one (1) of the following: reduction in (chronic obstructive pulmonary disease) COPD symptoms, improvement in exercise tolerance, delayed disease progression, or reduced number of exacerbations.
Minocycline Immediate-Release – Commercial and Healthcare Reform	08/10/2022	Policy revised to remove treatment of meningitis due to *Neisseria meningitides* as an acceptable diagnosis.
Naprosyn (naproxen) suspension and ketoprofen 25 mg – Commercial National Select Formulary	09/09/2022	Policy revised for Naprosyn (naproxen) suspension to change step therapy to trial/failure to generic ibuprofen oral suspension. Policy revised to add meloxicam suspension to require diagnosis based on FDA-approved indication and trial/failure to

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		generic ibuprofen oral suspension. Reauthorization attesting positive response to therapy.
Non-Preferred Brand and Extended-Release Metformin – Commercial and Healthcare Reform	08/10/2022	Policy revised to add metformin hydrochloride 625 mg tablet to require diagnosis based on FDA-approved indication and trial/failure to metformin hydrochloride IR (generic Glucophage).
Non-Preferred Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) – Commercial and Healthcare Reform	09/09/2022	Policy revised to add Mounjaro (tirzepatide) as a qualifier.
Non-Preferred Nasal Steroids – Commercial and Healthcare Reform	08/10/2022	Policy revised to remove brand Nasonex (mometasone) from policy. Only brand Nasonex was targeted; brand name Nasonex is no longer available, therefore Nasonex/mometasone will no longer be a target.
Non-Preferred Nasal Steroids and Nasal Antihistamine/Steroid Combinations – Commercial and Healthcare Reform	08/10/2022	Policy revised to remove Nasonex (mometasone) from policy. Only brand Nasonex was targeted; brand name Nasonex is no longer available. This policy contains Ryaltris; it will not go into effect until Ryaltris is commercially available.
Non-Preferred NSAIDs - Commercial and Healthcare Reform	09/09/2022	Policy revised for Naprosyn (naproxen) suspension to change step therapy to trial/failure to generic ibuprofen oral suspension. Policy revised to add meloxicam suspension to require diagnosis based on FDA-approved indication and trial/failure to generic ibuprofen oral suspension. Reauthorization attesting positive response to therapy.
Non-Preferred NSAIDs – Commercial and Healthcare Reform	01/01/2023	Policy revised to add Indocin (indomethacin) suspension to require diagnosis based on FDA-approved indication and trial/failure to generic ibuprofen oral suspension. Reauthorization attesting positive response to therapy.
Orphenadrine, Aspirin, Caffeine Combination Products – Commercial and Healthcare Reform	08/10/2022	Policy revised to clarify inclusion of brand and generic Norgesic (orphenadrine citrate, aspirin, and caffeine).
Picato (ingenol mebutate) – Commercial and Healthcare Reform	08/10/2022	Policy terminated as Picato (ingenol mebutate) is no longer available on the market.
Venlafaxine ER – Commercial and Healthcare Reform	09/09/2022	Policy revised to add criteria for venlafaxine besylate extended release (ER) tablets for use in members 18 years of age or older with a diagnosis of either major depressive disorder or generalized

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		anxiety disorder after the member has received venlafaxine extended-release capsules at a total daily dose meeting or exceeding 75 mg for at least four (4) days; and has experienced therapeutic failure or intolerance to one (1) of the following: venlafaxine ER capsule 37.5 mg, venlafaxine ER capsule 75 mg, venlafaxine ER capsule, 150 mg.
Viibryd (vilazadone) and Trintellix (vortioxetine) – Commercial	08/11/2022	Policy revised to add a criterion restricting use as per FDA approved indication. Viibryd and Trintellix are indicated for the treatment of major depressive disorder (MDD) in adults. New criterion restricts use to members 18 years of age and older. Black box warning for each drug states that pediatric members should not use these medications.
Viibryd (vilazodone) and Trintellix (vortioxetine) – Healthcare Reform	08/11/2022	Policy revised to add a criterion restricting use as per FDA approved indication. Viibryd and Trintellix are indicated for the treatment of major depressive disorder (MDD) in adults. New criterion restricts use to members 18 years of age and older. Black box warning for each drug states that pediatric members should not use these medications.

*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
Freestyle Libre 3 sensor	2 packs per 21 days	6 packs per 63 days
Mounjaro (tirzepatide)	1 carton (4 single-dose pens) per 21 days	3 cartons (12 single-dose pens) per 63 days
Radicava ORS (edaravone) oral solution	One 10-day treatment kit (50 mL) per 28 days	One 10-day treatment kit (50 mL) per 28 days

Radicava ORS (edaravone) oral solution Starter Pack	One starter pack (70 mL) per 720 days	One starter pack (70 mL) per 720 days
Tyvaso DPI (treprostinil) 16 mcg, 32 mcg, 48 mcg, 64 mcg maintenance kits	1 maintenance kit (112 cartridges) per 28 days	3 maintenance kits (336 cartridges) per 84 days
Tyvaso DPI (treprostinil) 32-48 mcg maintenance kit	1 maintenance kit (224 cartridges) per 28 days	3 maintenance kits (672 cartridges) per 84 days
Tyvaso DPI (treprostinil) titration kits (16-32 mcg and 16-32-48 mcg)	1 titration kit per 720 days	1 titration kit per 720 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
Vtama (tapinarof)	1 tube (60 grams) per dispensing event	3 tubes (180 grams) per dispensing event

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

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

Drug Name	Daily Limit
Lyvispah (baclofen) 10 mg	4 packets per day
Lyvispah (baclofen) 5 mg	9 packets per day
metformin hydrochloride 625 mg	4 tablets per day
Olumiant (baricitinib) 4 mg	1 tablet per day
Pheburane (sodium phenylbutyrate)	20 grams per day
venlafaxine besylate ER	2 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 online at:

Incentive Formulary

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

Brand Name	Generic Name	Comments
Mounjaro	tirzepatide	Type 2 Diabetes Mellitus
Priorix	Measles, Mumps, and Rubella Vaccine, Live	Prevention of measles, mumps, and rubella in individuals 12 months of age and older.

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

Brand Name	Generic Name	Preferred Alternatives
drospirenone chewable tablets	drospirenone chewable tablets	norethindrone (contraceptive), Camila, Errin
venlafaxine besylate ER	venlafaxine besylate ER	venlafaxine oral capsule extended release 37.5 mg, venlafaxine oral capsule extended release 75 mg, venlafaxine oral capsule extended release 150 mg

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

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

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

Table 1. Preferred Products
Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Comments
Mounjaro	tirzepatide	Type 2 Diabetes Mellitus

Priorix	Measles, Mumps, and Rubella Vaccine, Live	Prevention of measles, mumps, and rubella in individuals 12 months of age and older.

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

No changes at this time.

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

Brand Name	Generic Name	Preferred Alternatives
drospirenone chewable tablets	drospirenone chewable tablets	norethindrone (contraceptive), Camila, Errin
venlafaxine besylate ER	venlafaxine besylate ER	venlafaxine oral capsule extended release 37.5 mg, venlafaxine oral capsule extended release 75 mg, venlafaxine oral capsule extended release 150 mg
Vtama	tapinarof	calcipotriene 0.005%; fluticasone propionate topical cream 0.05%; betamethasone dipropionate topical cream 0.05%

*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
Amvuttra	vutrisiran
Fylnetra	pegfilgrastim-pbbk
Pheburane	sodium phenylbutyrate
Radicava ORS oral solution	edaravone oral solution
Tyvaso DPI 16 mcg, 32 mcg, 48 mcg, 64 mcg maintenance kits	treprostinil 16 mcg, 32 mcg, 48 mcg, 64 mcg maintenance kits
Vtama*	tapinarof

*For Incentive Formulary only.

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Adbry (tralokinumab-ldrm) – Medicare	01/01/2023	Policy revised for Adbry (tralokinumab-ldrm) to remove reauthorization criteria and update initial authorization duration to 12 months.
ALK-Targeting Kinase Inhibitors – Medicare	08/08/2022	Policy revised for Xalkori (crizotinib) requiring diagnosis based on FDA-approved expanded indication.
Amvuttra (vutrisiran) – Medicare	08/09/2022	New policy created to for Amvuttra (vutrisiran) to require diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis in patients 18 years of age and older supported by a mutation in TTR gene confirmed by genetic testing, clinical signs and symptoms of polyneuropathy, a peripheral neuropathy impairment score (NIS) of 5 or greater, and patient is not receiving concomitant TTR-lowering agents or TTR-stabilizing agents. Reauthorization requires an improvement in polyneuropathy from baseline.
Anti-Angiogenesis and VEGF Kinase Inhibitors – Medicare	TBD	Policy revised for brand Nexavar (sorafenib) to require therapeutic failure or intolerance to generic sorafenib.
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Medicare	08/09/2022	Policy revised for Tafinlar (dabrafenib) and Mekinist (trametinib) requiring diagnosis based on FDA-approved expanded indication.
Carac (fluorouracil) Cream – Medicare	01/01/2024	Policy revised to target single-source fluorouracil 0.5% cream requiring age and diagnosis based on FDA-approved indication. For both Carac (fluorouracil) 0.5% cream and fluorouracil 0.5% cream, trial/failure to generic topical fluorouracil solution or fluorouracil 5% cream. If the request is for brand Carac (fluorouracil), trial/failure to fluorouracil 0.5% cream.
Chronic Inflammatory Diseases – Medicare	08/09/2022	Policy revised for Olumiant (baricitinib) for alopecia areata requiring age, diagnosis based on FDA-approved indication, and trial/failure to an intralesional corticosteroid or topical corticosteroid, or contraindication to all. Criteria for Actemra (tocilizumab) intravenous updated for giant cell arteritis (GCA) requiring age, diagnosis based on FDA-approved indication, and trial/failure to one systemic corticosteroid, or all corticosteroids are contraindicated.
Cibinqo (abrocitinib) – Medicare	01/01/2023	Policy revised for Cibinqo (abrocitnib) to remove reauthorization criteria.
Diacomit (stiripentol) – Medicare	08/10/2022	Policy revised to remove age requirement.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Direct Oral Anticoagulants (DOACs) – Medicare	01/01/2023	Policy terminated for future date.
Dojolvi (triheptanoin) – Medicare 2024	01/01/2024	Policy revised for Dojolvi (triheptanoin) to require attestation that Dojolvi will not be used concomitantly with another medium chain triglyceride product. Reauthorization criteria removed.
Dupixent (dupilumab) – Medicare	08/10/2022	Policy revised for Dupixent (dupilumab) for atopic dermatitis to only require topical calcineurin inhibitor therapy if the member is 2 years or older. Added new indication of eosinophilic esophagitis (EoE) requiring diagnosis based on FDA-approved indication supported by esophageal eosinophil count greater than or equal to 15 eos/hpf and clinical symptoms of esophageal dysfunction. Reauthorization for EoE to require histological remission or reduced severity or frequency of clinical symptoms of esophageal dysfunction.
EGFR-Targeting Kinase Inhibitors – Medicare	TBD	Policy revised for Iressa (gefitinib) to require therapeutic failure or intolerance to generic gefitinib.
Empaveli (pegcetacoplan) – Medicare 2023	01/01/2023	Policy revised for Empaveli (pegcetacoplan) to require attestation that Empaveli will not be used in combination with another complement inhibitor (e.g., Soliris [eculizumab] or Ultomiris [ravulizumab]) unless initially cross titrating from Soliris or Ultomiris. Reauthorization revised to require attestation that Empaveli will not be used in combination with another complement inhibitor. Initial authorization duration revised to 6 months.
Ergotamines – Medicare	01/01/2024	Policy revised to add in Cafergot (ergotamine tartrate-caffeine) and Ergomar (ergotamine tartrate) to use for FDA approved indication and trial/failure/contraindication to one generic triptan to abort migraine or one generic prophylactic migraine medication to prevent migraine.
Evrysdi (risdiplam) – Medicare	08/10/2022	Policy revised for Evrysdi (risdiplam) to remove age requirement of 2 months of age or older due to expanded indication.
Gimoti (metoclopramide) nasal spray – Medicare	08/10/2022	Policy revised for Gimoti (metoclopramide) to allow step through metoclopramide orally disintegrating tablets (ODT) in addition to oral

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		tablets or oral solution, or that the member is not a candidate for oral dosage forms.
Immune Globulin – Medicare	08/10/2022	Policy revised for immune globulin products to specify that the member is requesting Immune Globulin intramuscular (IGIM) if using for Hepatitis A prophylaxis or Rubella in pregnancy post-exposure prophylaxis.
Immune Globulin – Medicare	01/01/2024	Policy revised for immune globulin products to remove criteria for inflammatory myopathies since not a medically accepted indication.
Intravitreal Injections – Medicare	08/10/2022	Policy revised to include new indication of Diabetic Macular Edema for Beovu (ranibizumab-nuna).
Lonsurf (trifluridine/tipiracil) – Medicare	08/10/2022	Policy revised for Lonsurf (trifluridine/tipiracil) to require anti-EGFR (epidermal growth factor receptor) therapy if disease is left-sided only.
Natpara (parathyroid hormone) – Medicare	08/10/2022	Policy revised for Natpara (parathyroid hormone) to clarify being used as adjunct therapy.
Non-Preferred Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs) – Medicare	08/05/2022	Policy revised to add criteria for venlafaxine besylate extended release (ER) tablets for use in members with a diagnosis of either major depressive disorder or generalized anxiety disorder after the member has received a venlafaxine extended-release product at a total daily dose meeting or exceeding 75 mg for at least four (4) days
Ofev (nintedanib) and Esbriet (pirfenidone) – Medicare	TBD	Policy revised for Esbriet (pirfenidone) to require trial/failure of generic pirfenidone tablets if the request is for brand Esbriet.
PARP Kinase Inhibitors – Medicare	08/11/2022	Policy revised for Rubraca (rucaparib) to remove criteria for patients with advanced ovarian cancer who have been treated with two or more chemotherapies following manufacturer withdrawal of this indication.
PDGFR Tyrosine Kinase Inhibitors – Medicare	01/01/2023	Policy revised for Ayvakit (avapritinib) to remove age requirement.
Pretomanid – Medicare	08/11/2022	Policy revised for pretomanid to allow for trial/failure/contraindication to amikacin, kanamycin, or capreomycin.
Programmed Death Receptor Therapies – Medicare	08/11/2022	Policy revised for Opdivo (nivolumab) and Keytruda (pembrolizumab) to require diagnosis based on FDA-approved expanded indication.
Pulmonary Hypertension – Medicare	10/05/2022	Policy revised to add Tyvaso DPI (treprostinil) to require diagnosis based on FDA-approved indication and supported by results of right heart

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		catheterization. For a diagnosis of pulmonary hypertension associated with interstitial lung disease, the member is a non-smoker or currently engaged in smoking cessation.
Qualaquin (quinine sulfate) – Medicare	01/01/2023	Policy revised for Qualaquin (quinine sulfate) to align with CDC recommendations.
Radicava (edaravone) – Medicare	08/11/2022	Policy revised to add in Radicava ORS (edaravone) for FDA-approved diagnosis.
Rituximab Products – Medicare	08/11/2022	Policy revised for Riabni (rituximab-arrx) to add expanded indication in moderately-to-severely active rheumatoid arthritis (RA) in combination with methotrexate in adults who have inadequate response to one or more tumor necrosis factor antagonist therapies. Criteria to FDA label and Riabni (rituximab-arrx) added as a preferred biosimilar to step through for Rituxan (rituximab) or Truxima (rituximab-abbs) in RA.
Targretin (bexarotene) – Medicare	TBD	Policy revised for Targretin (bexarotene) topical gel to require for brand Targretin topical gel that the member has experienced therapeutic failure or intolerance to generic topical bexarotene gel.
Tazarotene products – Medicare 2023	01/01/2023	Policy revised to target Arazlo (tazarotene) requiring diagnosis based on FDA-approved indication, trial/failure/contraindication to 1 generic topical tretinoin therapy, trial/failure/contraindication to 1 topical acne medication (e.g., adapalene, clindamycin, erythromycin, sulfacetamide)
Urea Cycle Disorder Medications – Medicare	TBD	Policy revised to include Pheburane (sodium phenylbutyrate) requiring diagnosis based on FDA-approved indication, and trial/failure to generic sodium phenylbutyrate.
VEGF and EGFR Kinase Inhibitors – Medicare	TBD	Policy revised for brand Caprelsa (vandetanib) requiring therapeutic failure or intolerance to generic vandetanib.
Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) – Medicare	01/01/2024	Policy revised for Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) to require that the member is not simultaneously using with transthyretin-lowering agents for both initial and reauthorization.

*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
Consensi (amlodipine/celecoxib) – Medicare	08/18/2022	Policy terminated as Cosensi (amlodipine/celecoxib) is MedD=N
Insomnia Medications – Medicare	01/01/2023	New policy for Belsomra (suvorexant), Dayvigo (lemborexant), and Quviviq (daridorexant) for treatment of insomnia requiring trial of two alternatives: eszopiclone, zaleplon, or zolpidem/zolpidem extended release.
Non-Preferred Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) – Medicare	01/01/2023	Policy revised to add Mounjaro (tirzepatide) based on FDA-approved indication.
Non-Preferred Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) – Medicare	08/08/2022	Policy revised to add Mounjaro (tirzepatide) as a qualifier.
Ursodiol Products – Medicare	01/01/2023	Policy created to require the member to have an FDA approved indication and experience therapeutic failure or intolerance to one of the following: ursodiol 250 mg, ursodiol 300 mg, or ursodiol 500 mg, before one of the following products is covered: Reltone, Urso (brand only), Urso Forte (brand only), ursodiol 200 mg, or ursodiol 400 mg

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)
Amvuttra (vutrisiran)	1 syringe every 90 days	1 syringe every 90 days
Dupixent (dupilumab) 300 mg/2 mL	4 pens/syringes (300 mg/2 mL) per 28 days	12 pens/syringes (300 mg/2 mL) every 84 days
Epsolay (benzoyl peroxide)	30 gm (1 tube) per 28 days	90 gm (3 tubes) per 84 days
metformin hydrochloride 625 mg	4 tablets per day	4 tablets per day
Mounjaro (tirzepatide)	1 carton (4 single-dose pens) per 28 days	3 cartons (12 single-dose pens) per 84 days
Nucala (mepolizumab) 40 mg/0.4 mL	1 syringe every 28 days	3 syringes every 84 days
Olumiant (baricitinib) 4 mg	1 tablet per day	1 tablet per day
Pheburane (sodium phenylbutyrate)	20 grams per day	20 grams per day
Radicava ORS (edaravone) oral solution	One 10-day treatment kit (50 mL) per 28 days	One 10-day treatment kit (50 mL) per 28 days

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Radicava ORS (edaravone) oral solution Starter Pack	Two starter packs (140 mL) per 365 days	Two starter packs (140 mL) per 365 days
Tyvaso DPI (treprostinil) titration kits (16-32 mcg and 16-32-48 mcg)	2 titration kits per 365 days	2 titration kits per 365 days
venlafaxine besylate ER	2 tablets per day	2 tablets per day
Vtama (tapinarof)	1 tube (60 grams) per 30 days	3 tubes (180 grams) per 90 days

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