Formulary Updates

Published March 2024

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for January 2024. 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:

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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 Availity or our website). Click the **PHARMACY PROGRAM/FORMULARIES** link from the menu on the left.

Important Drug Safety Updates

Azurity Pharmaceuticals Inc, Zenzedi® (dextroamphetamine sulfate tablets, USP) 30 mg

On January 24, 2024, Azurity Pharmaceuticals, Inc. began voluntarily recalling one (1) lot (F230169A) of Zenzedi® CII (dextroamphetamine sulfate tablets, USP) 30 mg to the consumer level. The product is being recalled due to a report from a pharmacist in Nebraska who opened a bottle of Zenzedi® 30 mg tablets and found tablets of Carbinoxamine Maleate, an antihistamine drug.

Patients who take carbinoxamine instead of Zenzedi® will experience undertreatment of their symptoms, which may result in functional impairment and an increased risk of accidents or injury. Patients who unknowingly consume carbinoxamine could experience adverse events which include, but are not limited to, drowsiness, sleepiness, central nervous system (CNS) depression, increased eye pressure, enlarged prostate urinary obstruction, and thyroid disorder. For patients with Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy (sleep disorder), there is a reasonable probability that accidents or injuries that occur due to the sedating effects of carbinoxamine, could lead to ongoing disability or death in severe cases, particularly if individuals who use it (unaware that they have not received Zenzedi®) engage in activities requiring significant focus and alertness (e.g., driving, operating heavy machinery).

Highmark Formulary Update – January 2024

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 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 March 2024, unless otherwise noted.

Brand Name	Generic Name	Comments
Ixchiq**	chikungunya vaccine, live	Chikungunya virus prevention

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
**Commercial Comprehensive only

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Augtyro	repotrectinib	Xalkori
Fabhalta	iptacopan	Prescriber discretion
Filsuvez*	birch triterpenes	Prescriber discretion
Fruzaqla	fruquintinib	Prescriber discretion
Iwilfin	eflornithine	Prescriber discretion
Ixchiq***	chikungunya vaccine, live	Prescriber discretion
Ogsiveo	nirogacestat	Prescriber discretion
Truqap	capivasertib	anastrozole tablet, letrozole tablet
Wainua	eplontersen	Prescriber discretion
Zituvio	sitagliptin	Tradjenta, Januvia

Brand Name	Generic Name	Preferred Alternatives
Zoryve topical foam	roflumilast	hydrocortisone cream (gram) 2.5%; ciclopirox shampoo; Ketoconazole cream (gram)

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.
***Healthcare Reform Comprehensive 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
Augtyro	repotrectinib
Fabhalta	iptacopan
Filsuvez	birch triterpenes
Fruzaqla	fruquintinib
Iwilfin	eflornithine
Ogsiveo	nirogacestat
Truqap	capivasertib
Wainua	eplontersen
Zoryve topical foam	roflumilast

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 March 2024, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Ixchiq	chikungunya vaccine, live	3	Chikungunya virus prevention
Items listed below were not added to the formulary			
Augtyro	repotrectinib	NF	Prescriber discretion
Fabhalta	iptacopan	NF	Prescriber discretion
Filsuvez*	birch triterpenes	NF	Prescriber discretion

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Fruzaqla	fruquintinib	NF	Prescriber discretion
Iwilfin	eflornithine	NF	Prescriber discretion
Ogsiveo	nirogacestat	NF	Prescriber discretion
Truqap	capivasertib	NF	anastrozole tablet, letrozole tablet
Wainua	eplontersen	NF	Prescriber discretion
Zituvio	sitagliptin	NF	Tradjenta, Januvia
Zoryve topical foam	roflumilast	NF	hydrocortisone cream (gram) 2.5%; ciclopirox shampoo; Ketoconazole cream (gram)

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 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 March 2024, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Ixchiq	chikungunya vaccine, live	3	Chikungunya virus prevention
Items listed below were not added to the formulary			
Augtyro	repotrectinib	NF	Xalkori
Fabhalta	iptacopan	NF	Prescriber discretion
Filsuvez*	birch triterpenes	NF	Prescriber discretion
Fruzaqla	fruquintinib	NF	Prescriber discretion
Iwilfin	eflornithine	NF	Prescriber discretion
Ogsiveo	nirogacestat	NF	Prescriber discretion
Truqap	capivasertib	NF	anastrozole tablet, letrozole tablet
Wainua	eplontersen	NF	Prescriber discretion
Zituvio tablets	sitagliptin	NF	Tradjenta,Januvia
Zoryve topical foam	roflumilast	NF	hydrocortisone cream (gram) 2.5%; Ciclopirox shampoo; Ketoconazole cream (gram)

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)			
Fabhalta	iptacopan	2	Treatment of paroxysmal nocturnal hemoglobinuria (PNH)
Iwilfin	eflornithine	2	Treatment of high-risk neuroblastoma
Items listed below were added to the formulary (Non-Preferred)			
Augtyro*	repotrectinib	3	Xalkori
Filsuvez*	birch triterpenes	3	Prescriber discretion
Ixchiq*	chikungunya vaccine, live	3	Prescriber discretion
Ogsiveo*	nirogacestat	3	Prescriber discretion
Truqap*	capivasertib	3	anastrozole tablet, letrozole tablet
Wainua*	eplontersen	3	Prescriber discretion
Zoryve topical foam	roflumilast	3	Hydrocortisone cream (gram) 2.5%; ciclopirox shampoo; Ketoconazole cream (gram)
Items listed below were not added to the formulary			
Fruzaqla	fruquintinib	NF	Lonsurf
Zituvio	sitagliptin	NF	Januvia, saxagliptin

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
Augtyro	repotrectinib
Fabhalta	iptacopan
Filsuvez	birch triterpenes
Fruzaqla	fruquintinib
Iwilfin	eflornithine
Ogsiveo	nirogacestat
Truqap	capivasertib
Wainua	eplontersen
Zoryve topical foam	roflumilast

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Adbry (tralokinumab-ldrm) – Commercial and Healthcare Reform	02/16/2024	Policy revised for Adbry (tralokinumab-ldrm) for FDA-approved age of 12 years and older, requiring FDA-approved dosing regimen, and quantity limitations updated for expanded age population.
Androgen Receptor Inhibitors – Commercial and Healthcare Reform	02/16/2024	Policy revised for Xtandi (enzalutamide) to require age and diagnosis based on expanded FDA-approved indication.
Anti-Angiogenesis and VEGF Kinase Inhibitors – Commercial and Healthcare Reform	02/16/2024	Policy revised to add Fruzaqla (fruquintinib) to require age and FDA-approved diagnosis. Policy revised for Votrient (pazopanib) to require therapeutic failure or intolerance to generic pazopanib if the request is for brand Votrient for initial and reauthorization.
Anti-Obesity – Commercial and Healthcare Reform	12/15/2023	Policy revised to update authorization duration for Zepbound from 5 to 6 months to align with Wegovy. Initiation for Zepbound updated to 0 - <6 mo; continuation updated to 6 - <12 mo.
Anti-Obesity – Commercial and Healthcare Reform	01/20/2024	Policy revised for anti-obesity medications to allow for attestation of active participation for at least 3 months in (initiation) or using in combination with (continuation and maintenance) a lifestyle modification program that encourages reduced calorie diet and increased physical activity.
BTK Inhibitors – Commercial and Healthcare Reform	02/16/2024	Policy revised to include new indication for Jaypirca (pirtobrutinib) to require diagnosis, the member to be 18 or older, and for the member to have tried at least 1 BTK inhibitor and 1 BCL-2 inhibitor.
Cresemba (isavuconazonium sulfate) capsules – Commercial and Healthcare Reform	02/16/2024	Policy revised for Cresemba (isavuconazonium sulfate) for expanded indication to allow approval for adults and pediatric patients 6 years of age and older who weigh at least 16 kilograms.
Dupixent (dupilumab) – Commercial and Healthcare Reform	TBD	Reauthorization criteria revised for Dupixent (dupilumab) for prurigo nodularis allowing the member has experienced a reduction in the number of nodules or lesions from baseline. Quantity limitations table updated to reflect FDA-approved dosing regimens. Initial authorization criteria revised for Dupixent (dupilumab) for asthma requiring the member meets one of the following: ≥ 2 asthma

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months or a history of ≥ 1 asthma exacerbation requiring hospitalization in the previous 12 months and that the member has inadequate symptom control despite regular treatment with medium- or high-dose inhaled corticosteroids (ICS) and at least one additional asthma controller, with or without oral corticosteroids (OCS) and that the member continue treatment with a medium- or high-dose ICS and at least one additional asthma controller, with or without OCS, while using Dupixent.
Empaveli (pegacetacoplan) and Fabhalta (iptacopan) – Commercial and Healthcare Reform	02/16/2024	Policy for Empaveli (pegacetacoplan) revised to include Fabhalta (iptacopan). Initial authorization and reauthorization criteria is identical for the two drugs. Authorization duration revised from 6 months to 1 year. Quantity level limits applies only to Empaveli.
Filsuvez (birch triterpenes) – Commercial and Healthcare Reform	TBD	Policy created for Filsuvez (birch triterpenes) requiring age and FDA-approved diagnosis. Reauthorization requiring positive response of target wound to therapy and attestation that the member requires additional courses of treatment.
Interleukin (IL)-5 Antagonists – Commercial and Healthcare Reform	TBD	Policy revised for Nucala (mepolizumab) and Fasenra (benralizumab) for severe asthma requiring the member meets one of the following: ≥ 2 asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months or a history of ≥ 1 asthma exacerbation requiring hospitalization in the previous 12 months and that the member has inadequate symptom control despite regular treatment with medium- or high-dose inhaled corticosteroids (ICS) and at least one additional asthma controller, with or without oral corticosteroids (OCS) and that the member continue treatment with a medium- or high-dose ICS and at least one additional asthma controller, with or without OCS, while using Nucala (mepolizumab) or Fasenra (benralizumab).

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Iwilfin (eflornithine) – Commercial and Healthcare Reform	02/16/2024	Policy created for Iwilfin (eflornithine) requiring diagnosis of high-risk neuroblastoma and trial/failure of anti-glycolipid disialoganglioside immunotherapy. Reauthorization requiring attestation that disease has not relapsed and total cumulative duration of therapy does not exceed 24 months.
KRAS G12C Inhibitors – Commercial and Healthcare Reform	02/16/2024	Policy revised for Krazati (adagrasib) to allow reauthorization based on disease improvement or delayed disease progression.
Non-Preferred Baclofen Products – Commercial and Healthcare Reform	02/16/2024	Policy revised to add Baclofen Oral Solution (10 mg/5 mL and 5 mg/5 mL) to target medications; criteria for approval remains the same. Lyvispah oral granules is now an obsolete product, removed from the policy.
NTRK and ROS1 Inhibitors – Commercial and Healthcare Reform	02/16/2024	Policy revised to include Augtyro (repotrectinib) to require age of 18 years or older and diagnosis of locally advanced or metastatic ROS1-positive non-small cell lung cancer.
Ogsiveo (nirogacestat) – Commercial and Healthcare Reform	02/16/2024	New policy created for Ogsiveo (nirogacestat) to require the member to be 18 years and older, and have a diagnosis of desmoid tumor with progression within 12 months and that the member requires systemic treatment. Reauthorization to require positive clinical response to therapy.
Parathyroid Hormone Analogs – Commercial and Healthcare Reform	02/16/2024	Policy revised for Forteo (teriparitide) to require step through generic teriparitide.
Recorlev (levoketoconazole) – Commercial and Healthcare Reform	02/16/2024	Policy revised for Recorlev (levoketoconazole) initial authorization to remove ICD-10 E24.1 (Nelson's syndrome) and change to "prescribed by or in consultation with an endocrinologist". Reauthorization changed to require a reduction in 24-hour mean urinary free cortisol levels from baseline and attestation that the member has experienced an improvement in signs and symptoms of Cushing's disease from baseline for reauthorization.
Sunosi (solriamfetol) – Commercial and Healthcare Reform	02/16/2024	Sunosi (solriamfetol) is indicated to improve wakefulness in adult patients with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA). Removed criterion requesting baseline number

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		of cataplexy episodes in patients with cataplexy associated with narcolepsy.
Tarpeyo (budesonide) – Commercial and Healthcare Reform	02/16/2024	Policy revised to reflect expanded indication and removed "rapid" from disease progression criteria.
Transthyretin-Directed Antisense Oligonucleotides Tegsedi (inotersen) – Commercial and Healthcare Reform	02/16/2024	Policy revised to change policy name to Transthyretin-Directed Antisense Oligonucleotides. Policy revised to add Wainua requiring FDA-approved diagnosis, prescribed by/consultation with neurologist or specialist, complete neurologic examination showing clinical signs and symptoms of disease, prescriber attestations of baseline ambulatory status, scoring used to assess disease severity, and that other gene therapies are not being concomitantly used for same indication. Reauthorization requires member is not on concomitant gene therapy for same indication and attestation of positive response to therapy.
Truqap (capivasertib) – Commercial and Healthcare Reform	02/16/2024	New policy for Truqap (capivasertib) requiring age, FDA-approved diagnosis with appropriate documentation of tumor status and the member to experience disease progression on at least one endocrine-based regimen in the metastatic setting or the member to have experienced recurrence on or within 12 months of completing adjuvant therapy.
Vigabatrin – Commercial and Healthcare Reform	02/16/2024	Policy revised to add Vigpoder (vigabatrin) requiring FDA-labeled diagnosis and age. For refractory complex partial seizures, the member has experienced therapeutic failure or intolerance to at least two (2) alternative generic anticonvulsants. Reauthorization requiring continued FDA approved diagnosis and age and reduction in seizure frequency from baseline.
Vtama (tapinarof) and Zoryve (roflumilast) – Commercial and Healthcare Reform	02/16/2024	Policy revised to add Zoryve (roflumilast) foam requiring age, FDA-approved diagnosis of seborrheic dermatitis (SD), moderate to severe disease, trial/failure to one generic formulary topical corticosteroid or facial/intertriginous involvement, and if the member is 12 years of age or older, trial/failure/contraindication to one generic topical antifungal for SD.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Welireg (belzutifan) – Commercial and Healthcare Reform	02/16/2024	Policy revised for Welireg (belzutifan) to require age and diagnosis based on expanded FDA-approved indication and the member has received prior treatment with a programmed death receptor-1 or programmed death-ligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor.
Xolair (omalizumab) Syringe – Commercial and Healthcare Reform	TBD	Policy revised for Xolair (omalizumab) for moderate to severe persistent asthma to add that the member meets one of the following: pre-bronchodilator forced expiratory volume in 1 second (FEV1) below 80% in adults, pre-bronchodilator FEV1 below 90% in children and adolescents, or FEV1 reversibility of at least 12% and 200 milliliters after albuterol administration; and the member meets one of the following: a history of ≥ 2 asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months or a history of ≥ 1 asthma exacerbation requiring hospitalization in the previous 12 months.

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

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Colony-Stimulating Factors – Commercial and Healthcare Reform	02/16/2024	Policy revised for Rolvedon (eflapegrastim-xnst) to clarify that the member is using for febrile neutropenia prophylaxis.
Dartisla ODT (glycopyrrolate) – Commercial and Healthcare Reform	TBD	Policy revised for Dartisla ODT (glycopyrrolate) 0.85 mg to require the member has experienced therapeutic failure, or intolerance to plan-preferred generic glycopyrrolate 1 mg tablets. Automatic approval criteria revised for Dartisla ODT 0.85 mg to require the member has at least one paid claim for generic glycopyrrolate 1 mg tablets in the member's prescription drug claims history within the previous 365 days.
Evekeo (amphetamine sulfate) – Commercial and Healthcare Reform	02/16/2024	Policy revised to update age to 6 to 17 years for Evekeo ODT (amphetamine orally disintegrating tablet).

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) for Diabetes – Commercial and Healthcare Reform	01/01/2024	Automatic approval criteria revised to remove metformin as a qualifier.
Lidocaine Patches and Topical System – Commercial and Healthcare Reform	02/16/2024	Policy revised to include Dermacinrx Lidocan 5% (lidocaine 5%) patch and Lidocan III 5% (lidocaine 5%) patch to initial and reauthorization for post-herpetic neuralgia and neuropathic pain associated with cancer.
Non-Preferred Dipeptidyl Peptidase IV (DPP-IV) Inhibitors – Commercial and Healthcare Reform	02/16/2024	Policy revised to add Zituvio (sitagliptin) requiring diagnosis, use in combination with a metformin containing product or trial, failure, contraindication to metformin, and trial, failure, contraindication to both a plan-preferred linagliptin and sitagliptin product. Reauthorization approved if the member requires continued therapy.
Non-Preferred Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Commercial and Healthcare Reform	02/16/2024	Policy revised to add dapagliflozin and dapagliflozin/metformin to require diagnosis based on FDA-approved indication. For all indications, trial/failure/contraindication to a brand dapagliflozin- and empagliflozin-containing product; and to a metformin-containing product for type 2 diabetes.
Selenium Sulfide Products – Commercial and Healthcare Reform	02/16/2024	Policy revised to remove SelRx (selenium sulfide) 2.3% shampoo since no longer available on the market.
Topical Corticosteroids – Commercial and Healthcare Reform	02/16/2024	Policy revised for non-preferred topical corticosteroids (TCS) to add desoximetasone 0.25% cream or ointment as a qualifier for high potency TCS criteria.
Topiramate ER – Commercial and Healthcare Reform	TBD	Policy revised to require step through generic topiramate extended release (ER) for brand Qudexy XR (topiramate ER) and Trokendi XR (topiramate ER).
Xeloda (capecitabine) – Commercial and Healthcare Reform	02/16/2024	Policy for Xeloda (capecitabine) revised in locally advanced rectal cancer section to add a criterion requiring a diagnosis of locally advanced rectal cancer.

*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
Fruzaqla (fruquintinib) 1 mg capsule	84 capsules per 28 days	252 capsules per 84 days
Fruzaqla (fruquintinib) 5 mg capsule	21 capsules per 28 days	63 capsules per 84 days
Truqap (capivasertib)	64 tablets per 28 days	192 tablets per 84 days
Wainua (eplontersen)	1 single-dose autoinjector (45 mg/0.8 mL) per 30 days	3 single-dose autoinjectors (45 mg/0.8 mL each) per 90 days

*Effective date to be determined.

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

Drug Name	Retail Edit Limit	Mail Edit Limit
Zoryve topical foam (roflumilast)	1 can (60 grams) per dispensing event	3 cans (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
Augtyro (repotrectinib)	8 capsules per day
Fabhalta (iptacopan)	2 capsules per day
Iwilfin (eflornithine)	8 tablets per day
Ogsiveo (nirogacestat)	6 capsules per day

Drug Name	Daily Limit
Zituvio (sitagliptin)	1 tablet per day

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

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

SECTION II. Highmark Medicare Part D Formularies

A. Changes to the Highmark Medicare Part D 5-Tier 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
Ixchiq	chikungunya vaccine, live	Chikungunya virus prevention

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

Brand Name	Generic Name	Preferred Alternatives
Zituvio 100 mg & 50 mg tablets	sitagliptin	Tradjenta (linagliptin), Januvia (sitagliptin)
Zituvio 25 mg tablets	sitagliptin	Tradjenta (linagliptin), Januvia (sitagliptin)
Zoryve topical foam	roflumilast	Hydrocortisone cream; Ketoconazole cream; ciclopirox shampoo

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
Ixchiq	chikungunya vaccine, live	Chikungunya virus prevention

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

Brand Name	Generic Name	Preferred Alternatives
Ryzneuta	efbemalenograstim alfa-vuxw	Neulasta, Fulphila, Ziextenzo
Udenyca OnBody	pegfilgrastim-cbqv	Neulasta, Fulphila, Ziextenzo
Xphozah	tenapanor	sevelamer carbonate tablet; calcium acetate(phosphat bind) capsule
Zituvio 100 mg & 50 mg tablets	sitagliptin	Tradjenta (linagliptin), Januvia (sitagliptin)
Zituvio 25 mg tablets	sitagliptin	Tradjenta (linagliptin), Januvia (sitagliptin)
Zoryve topical foam	roflumilast	hydrocortisone cream; Ketoconazole cream; Ciclopirox shampoo

*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
Adzynma	ADAMTS13, recombinant-krhn
Alyglo	immune globulin intravenous, human-stwk
Augtyro	repotrectinib
Avzivi	bevacizumab-tnjn
Fabhalta	iptacopan
Filsuvez	birch triterpenes
Fruzaqla 1 mg capsule	fruquintinib
Fruzaqla 5 mg capsule	fruquintinib
iDose TR	travoprost intracameral implant
Iwilfin	eflornithine
Ogsiveo	nirogacestat
Truqap	capivasertib
Wainua	eplontersen

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	02/16/2024	Quantity limitations table updated for Adbry (tralokinumab-ldrm) to include expanded age

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		population. Clarified that Rinvoq (upadacitinib) step only applies if the member is 18 years of age or older.
Administrative Prior Authorizations for Medicare Part D Plans – Medicare	02/16/2024	Policy revised to add Loqtorzi (toripalimab-tpzi) as a target for BvD infusion pump review and added Alyglo (immune globulin intravenous, human-stwk) as a target for BvD IV immune globulin review.
Adzynma (ADAMTS13, recombinant-krhn) – Medicare	02/16/2024	New policy created for Adzynma (ADAMTS13, recombinant-krhn) requiring diagnosis based on FDA-approved indication. Reauthorization to require a decrease in acute or subacute thrombotic thrombocytopenic purpura (TTP) events from baseline or resolution of events when drug is used.
Amondys 45 (casimersen) – Medicare	02/16/2024	Policy revised for Amondys 45 (casimersen) to remove criteria requiring 6 months of corticosteroids and that the member is ambulatory.
Androgen Receptor Inhibitors – Medicare	02/16/2024	Policy revised for Xtandi (enzalutamide) to require diagnosis based on expanded FDA-approved indication.
Anti-Angiogenesis and VEGF Kinase Inhibitors – Medicare	TBD	Policy revised to add Fruzaqla (fruquintinib) to require FDA-approved diagnosis.
Anti-Angiogenesis and VEGF Kinase Inhibitors – Medicare	02/16/2024	Policy revised for Votrient (pazopanib) to require therapeutic failure or intolerance to generic pazopanib if the request is for brand Votrient.
BTK Inhibitors – Medicare	02/16/2024	Policy revised to include new indication for Jaypirca (pirtobrutinib) to require diagnosis and for the member to have tried at least 1 BTK inhibitor and 1 BCL-2 inhibitor.
Chronic Inflammatory Diseases – Medicare	01/12/2024	Adalimumab-adaz and adalimumab-adbm added as additional preferred adalimumab biosimilars.
Dartisla ODT (glycopyrrolate) 0.85 mg – Medicare	02/16/2024	New policy for Dartisla ODT (glycopyrrolate) 0.85 mg to require a diagnosis of peptic ulcer disease, that it be used as an adjunct to treatment of peptic ulcer disease, and that the member has experienced therapeutic failure, or

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		intolerance to generic glycopyrrolate 1 mg tablets.
Dartisla ODT (glycopyrrolate) 1.7 mg – Medicare	02/01/2024	Policy terminated due to loss of RxCUI for January CMS submission and MedD=N in ESI.
Dibenzyline (phenoxybenzamine) – Medicare	02/16/2024	Policy revised for Dibenzyline (phenoxybenzamine) criteria to remove age requirement of 18 years or older.
Dupixent (dupilumab) – Medicare	02/16/2024	Reauthorization criteria revised for Dupixent (dupilumab) for prurigo nodularis allowing the member has experienced a reduction in the number of nodules or lesions from baseline. Quantity limitations table updated to reflect FDA-approved dosing regimens. Initial authorization criteria revised for Dupixent (dupilumab) for asthma to require the member continue treatment with medium- or high-dose inhaled corticosteroid and at least one additional asthma controller, with or without oral corticosteroids, while using Dupixent (dupilumab).
Dupixent (dupilumab) – Medicare	TBD	Policy revised Dupixent (dupilumab) for asthma to add that the member meet one of the following: a history of ≥ 2 asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months or a history of ≥ 1 asthma exacerbation requiring hospitalization in the previous 12 months and that the member has inadequate symptom control despite regular treatment with medium- or high-dose inhaled corticosteroids and at least one additional asthma controller (e.g., long-acting beta-2 agonist, leukotriene receptor antagonist, or theophylline), with or without oral corticosteroids.
Empaveli (pegacetacoplan) – Medicare	02/16/2024	Policy revised to remove initial authorization and reauthorization duration of approval. The authorization duration was changed to 12 months; administrative changes.
Exondys 51 (eteplirsen) – Medicare	02/16/2024	Policy revised for Exondys 51 (eteplirsen) to remove criteria requiring 6 months of corticosteroids and that the member is ambulatory.
Fabhalta (iptacopan) – Medicare	02/16/2024	New policy for Fabhalta (iptacopan) created to require a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow

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		cytometry; member is experiencing at least one of the following symptoms caused by PNH: hemoglobin < 10.5, elevated lactate dehydrogenase (LDH), history of thromboembolic event, or clinical findings of systemic complications, and only one complement inhibitor is being used for PNH treatment. Reauthorization requires a positive clinical response to therapy.
Filsuvez (birch triterpenes) – Medicare	02/16/2024	Policy created for Filsuvez (birch triterpenes) requiring age and FDA-approved diagnosis. Reauthorization requiring positive response of target wound to therapy and attestation that the member requires additional courses of treatment.
Fleqsuvy (baclofen) and Lyvispah (baclofen) – Medicare Fleqsuvy (baclofen) and Baclofen Oral Solution - Medicare	02/16/2024	Policy revised to add Baclofen Oral Solution 10 mg/5 mL (brand) as a target. The same criteria for Fleqsuvy (baclofen) apply to Baclofen Oral Solution. Lyvispah oral gransules is an obsolete product; removed from the policy.
Interleukin (IL)-5 Antagonists – Medicare	TBD	Policy revised for Nucala (mepolizumab), Fasenra (benralizumab), and Cinqair (reslizumab) for severe asthma requiring the member meets one of the following: ≥ 2 asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months or a history of ≥ 1 asthma exacerbation requiring hospitalization in the previous 12 months and that the member has inadequate symptom control despite regular treatment with medium- or high-dose inhaled corticosteroids (ICS) and at least one additional asthma controller, with or without oral corticosteroids (OCS) and that the member continue treatment with a medium- or high- dose ICS and at least one additional asthma controller, with or without OCS, while using Nucala (mepolizumab) or Fasenra (benralizumab).
Iwilfin (eflornithine) – Medicare	02/16/2024	Policy created for Iwilfin (eflornithine) requiring diagnosis of high-risk neuroblastoma and trial/failure of anti-glycolipid disialoganglioside immunotherapy.
Lotronex (alosetron) – Medicare	TBD	Policy updated to add a step for the member to experience a therapeutic failure or intolerance to generic alosetron if the request is for brand

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		Lotronex (alosetron). Reauthorization criteria updated to require the member has experienced therapeutic failure or intolerance to generic alosetron if the request is for brand Lotronex.
NTRK and ROS1 Inhibitors – Medicare	02/16/2024	Policy revised to include Augtyro (repotrectinib) to require diagnosis of locally advanced or metastatic ROS1-positive, non-small cell lung cancer.
Ogsiveo (nirogacestat) – Medicare	02/16/2024	New policy created for Ogsiveo (nirogacestat) to require the member to have a diagnosis of progressing desmoid tumor and that the member requires systemic treatment.
Parathyroid Hormone Analogs – Medicare	TBD	Policy revised for Tymlos (abaloparatide) and Forteo (teriparitide) to require step through generic teriparitide.
Programmed Death Receptor Therapies – Medicare	02/16/2024	Policy revised to reflect revised FDA indication for urothelial carcinoma. Keytruda (pembrolizumab), in combination with Padcev (enfortumab vedotin), for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma no longer requires that the member is not eligible for cisplatin-containing chemotherapy. Policy revised to add a new FDA-approved indication for Keytruda for cervical cancer. The member must have Internqtional Federation of Gynecology and Obstetrics (FIGO) 2014 Stage III-IVA cervical cancer and the Keytruda must be given in combination with chemoradiotherapy.
Ryvent (Carbinoxamine Products) – Medicare	02/16/2024	Policy revised to clarify generic carbinoxamine 4 mg tablet and 4 mg/5 mL solution are policy targets.
Tarpeyo (budesonide) – Medicare	02/16/2024	Policy revised to reflect expanded indication and removed "rapid" from disease progression criteria.
Transthyretin-Directed Antisense Oligonucleotides Tegsedi (inotersen) – Medicare	02/16/2024	Policy revised to change policy name to Transthyretin-Directed Antisense Oligonucleotides. Policy revised to add Wainua requiring FDA-approved diagnosis, prescriber

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		attestations of NIS scoring ≥ 10, and that other gene therapies are not being concomitantly used for same indication. Reauthorization requires member experienced improvement in polyneuropathy from baseline.
Truqap (capivasertib) – Medicare	02/16/2024	New policy for Truqap (capivasertib) requiring FDA-approved diagnosis with appropriate documentation of tumor status and the member to experience disease progression on at least one endocrine-based regimen in the metastatic setting or the member to have experienced recurrence on or within 12 months of completing adjuvant therapy.
Tzield (teplizumab) – Medicare	02/16/2024	Policy revised for Tzield (teplizumab-mzwv) to allow for an alternative method of testing for dysglycemia without overt glycemia, if appropriate and an oral glucose tolerance test is not available.
Vigabatrin – Medicare	02/16/2024	Policy revised to add Vigpoder (vigabatrin) requiring FDA labeled diagnosis and age. For refractory complex partial seizures, the member has experienced therapeutic failure or intolerance to at least two (2) alternative treatments.
Vtama (tapinarof) and Zoryve (roflumilast) – Medicare	02/16/2024	Policy revised to add Zoryve (roflumilast) foam requiring FDA-approved diagnosis of seborrheic dermatitis (SD), trial/failure to one generic formulary topical corticosteroid or facial/intertriginous involvement, and if the member is 12 years of age or older, trial/failure/contraindication to one generic topical antifungal for SD.
Vyjuvek (beremagene geperpavec-svdt) – Medicare	TBD	Policy revised for Vyjuvek (beremagene geperpavec-svdt) to add reauthorization requiring positive response of target wound to therapy and attestation that the member requires additional courses of treatment.
Welireg (belzutifan) – Medicare	02/16/2024	Policy revised for Welireg (belzutifan) to require diagnosis based on expanded FDA-approved indication and the member has received prior treatment with a programmed death receptor-1 or programmed death-ligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor. Age requirement removed from Von Hippel Lindau criteria.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Xolair (omalizumab) – Medicare	TBD	Policy revised for Xolair (omalizumab) for moderate to severe persistent asthma to add that the member meets one of the following: pre-bronchodilator forced expiratory volume in 1 second (FEV1) below 80% in adults, pre-bronchodilator FEV1 below 90% in children and adolescents, or FEV1 reversibility of at least 12% and 200 milliliters after albuterol administration; and the member meets one of the following: a history of ≥ 2 asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months or a history of ≥ 1 asthma exacerbation requiring hospitalization in the previous 12 months.
Xphozah (tenapanor) – Medicare	02/16/2024	New policy created for Xphozah (tenapanor) to require the member to have a diagnosis of CKD and is on dialysis and either the member is using Xphozah as add-on therapy for those who have an inadequate response to 2 phosphate binders, one of which is either calcium acetate or sevelamer carbonate tablets or the member has experienced intolerance or contraindication to 2 phosphate binders, one of which is either calcium acetate or sevelamer carbonate tablets.
Zelnorm (tegaserod) – Medicare	02/03/2023	Policy was terminated in February 2023 (currently inactive). MedD = N in ESI.
Zokinvy (lonafarnib) – Medicare	12/22/2023	Policy revised to remove limitations of coverage as not filed.

*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
Colony-Stimulating Factors – Medicare	02/16/2024	Policy revised to add Ryzneuta (efbemalenograstim alfa-vuxw) requiring FDA-approved diagnosis; therapeutic failure or intolerance to two of the following: Neulasta (pegfilgrastim), Fulphila (pegfilgrastim-jmdb), or Ziextenzo (pegfilgrastim-bmez). Policy revised for Fylnetra (pegfilgrastim-pbbk), Nyvepria (pegfilgrastim-apgf), Rolvedon (eflapegrastim-

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		xnst), Stimufend (pegfilgrastim-fpgk), and Udenyca (pegfilgrastim-cbvq) to clarify that the products will be used for the FDA-approved diagnosis. Policy revised to add Udenyca OnBody (pegfilgrastim-cbvq) to require diagnosis based on FDA-approved indication and therapeutic failure/intolerance to two of the following: Neulasta (pegfilgrastim), Fulphila (pegfilgrastim-jmdb), or Ziextenzo (pegfilgrastim-bmez); or to Neulasta (pegfilgrastim) for a diagnosis of Hematopoietic Subsyndrome of Acute Radiation Syndrome.
Intraocular Pressure Reduction Agents – Medicare	02/16/2024	Policy revised to add iDose TR (travoprost intracameral implant) requiring FDA approved diagnosis, trial/failure to generic latanoprost, trial/failure to one generic ophthalmic alternative, attestation specifying the eye in which the implant will be administered and that the specified eye has not previously received a Durysta or iDose TR implant.
Non-Preferred Dipeptidyl Peptidase IV (DPP-IV) Inhibitors – Medicare	02/16/2024	Policy revised to add Zituvio (sitagliptin) requiring diagnosis and trial, failure, contraindication to both a plan-preferred linagliptin and sitagliptin product.

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)
Augtyro (repotrectinib)	8 capsules per day
Fabhalta (iptacopan)	62 capsules per 31 days
Fruzaqla (fruquintinib) 1 mg capsule	84 capsules per 28 days
Fruzaqla (fruquintinib) 5 mg capsule	21 capsules per 28 days
iDose TR (travoprost intracameral implant)	1 intracameral implant per lifetime per eye
Iwilfin (eflornithine)	8 tablets per day
Ogsiveo (nirogacestat)	6 capsules per day
Truqap (capivasertib)	64 tablets per 28 days
Wainua (eplontersen)	1 single-dose autoinjector (45 mg/0.8 mL) per 30 days
Xphozah (tenapanor)	2 tablets per day

Drug Name	Retail Quantity Limit (31 days)
Zituvio (sitagliptin) 100 mg & 50 mg tablets	1 tablet per day
Zituvio (sitagliptin) 25 mg tablets	3 tablets per day
Zoryve topical foam (roflumilast)	1 can (60 grams) per 28 days

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