Formulary Updates

Published January 2025

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for December 2024. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in December by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Please reference the guide below to navigate this communication:

As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (PRC). Once on the PRC, go to **Policies & Programs** > **Formulary** and then scroll down to find the formulary you're looking for.

Important Drug Safety Updates

DRUG NAME by MANUFACTURER: Recall – Reason for recall
(The above bolded statement should be a hyperlink that takes user directly to FDA alert).

Endo Expands Voluntary Recall of Clonazepam Orally Disintegrating Tablets, USP (C-IV) Due to Potential Product Carton Strength Mislabeling

On Nov. 18, 2024, Endo, Inc. (OTCQX: NDOI) ("Endo") announced today that one of its operating subsidiaries, Endo USA, Inc., is expanding its previously announced voluntary recall of Clonazepam Orally Disintegrating Tablets, USP (C-IV) due to potential product carton strength mislabeling.

Children and adults who inadvertently consume a higher dose of clonazepam could be at increased risk for the adverse events of significant sedation, confusion, dizziness, diminished reflexes, ataxia, and hypotonia. There is reasonable probability for significant, possibly life-threatening, respiratory depression especially for patients with concomitant pulmonary disease, patients who have prescribed dosing near maximal dosing, and patients also taking other medications that could cause additional respiratory depression. To date, Endo has not received any reports of adverse events associated with this product recall.

Serious liver injury being observed in patients without cirrhosis taking Ocaliva (obeticholic acid) to treat primary biliary cholangitis

The U.S. Food and Drug administration (FDA) released a Drug Safety Communication warning of increased risks of serious liver injury, including liver transplant and death, with the use of Ocaliva (obeticholic acid) in patients who did not have cirrhosis of the liver. The FDA previously identified the risk of serious liver injury in patients with advanced cirrhosis and in 2021 restricted the use in these patients. The FDA advises healthcare professionals to carefully assess patients' liver health before prescribing Ocaliva, closely monitor liver function during treatment, and promptly discontinue the drug if signs of liver injury appear. Healthcare professionals should explain the signs and symptoms of worsening liver injury to patients and instruct patients to contact their healthcare professional if they develop signs and symptoms of worsening liver injury.

Highmark Formulary Update – December 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 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 December 2024, unless otherwise noted.

Brand Name	Generic Name	Comments
Ebglyss	lebrikizumab-lbkz	Moderate-to-severe atopic dermatitis

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Aqneursa	levacetylleucine	Prescriber Discretion
Cobenfy	xanomeline and trospium chloride	aripiprazole tablet, quetiapine fumarate tablet
Cobenfy starter pack	xanomeline and trospium chloride	aripiprazole tablet, quetiapine fumarate tablet
Hympavzi	marstacimab-hncq	Prescriber Discretion
Imuldosa 45 mg/0.5 mL*	ustekinumab-srlf	Stelara syringe (mL) 45mg/0.5mL; Stelara vial (mL) 45mg/0.5mL
Imuldosa 90 mg/mL*	ustekinumab-srlf	Stelara syringe (mL) 90 mg/mL
Itovebi 3 mg, 9 mg	inavolisib	Prescriber Discretion
Miplyffa	arimoclomol	Prescriber Discretion
Orlynvah*	sulopenem etzadroxil and probenecid	Prescriber Discretion

Brand Name	Generic Name	Preferred Alternatives
Otulfi 45 mg/0.5 mL*	ustekinumab-aauz	Stelara syringe (mL) 45mg/0.5mL; Stelara vial (mL) 45mg/0.5mL
Otulfi 90mg/mL*	ustekinumab-aauz	Stelara syringe (mL) 90 mg/mL
Undecatrex	testosterone undecanoate	testosterone gel in metered-dose pump 20.25/1.25; testosterone gel in packet (gram) 50 mg (1%); testosterone cypionate vial (ml)
Vyalev	foscarbidopa and foslevodopa	carbidopa/levodopa, carbidopa-levodopa er, pramipexole di-hcl

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. To access this form for your region, go to the Provider Resource Center and choose your region from the top right. Select **Resources & Education > Forms > Pharmacy Prior Authorization Forms and then scroll down to the **Prescription Drug Medication Request Form**.

Table 3. Additions to the Specialty Tier Copay Option

Note: The specialty tier does not apply to Highmark Delaware Healthcare Reform members; see Highmark Delaware's online Provider Resource Center and access the Pharmacy Program/Formularies link for details on the formularies and formulary options that apply to Highmark Delaware Healthcare Reform members. Once on the page, click on Heathcare Reform, which is under the "Line of Business" header.

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

Brand Name	Generic Name
Aqneursa	levacetylleucine
Ebglyss	lebrikizumab-lbkz
Hympavzi	marstacimab-hncq
Imuldosa 45 mg/0.5 mL, 90 mg/mL	ustekinumab-srlf
Itovebi 3 mg, 9 mg	inavolisib
Miplyffa	arimoclomol
Otulfi 45 mg/0.5 mL, 90mg/mL	ustekinumab-aauz
Vyalev	foscarbidopa and foslevodopa

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 December 2024, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Ebglyss	lebrikizumab-lbkz	4	Moderate-to-severe atopic dermatitis
Items listed below were not added to the formulary			
Aqneursa	levacetylleucine	NF	Prescriber Discretion
Cobenfy	xanomeline and trospium chloride	NF	aripiprazole tablet, quetiapine fumarate tablet
Cobenfy starter pack	xanomeline and trospium chloride	NF	aripiprazole tablet, quetiapine fumarate tablet
Hympavzi	marstacimab-hncq	NF	Prescriber Discretion
Imuldosa 45 mg/0.5 mL*	ustekinumab-srlf	NF	Stelara syringe (mL) 45mg/0.5mL; Stelara vial (mL) 45mg/0.5mL
Imuldosa 90 mg/mL*	ustekinumab-srlf	NF	Stelara syringe (mL) 90 mg/mL
Itovebi 3 mg, 9 mg	inavolisib	NF	Prescriber Discretion
Miplyffa	arimoclomol	NF	Prescriber Discretion
Orlynvah*	sulopenem etzadroxil and probenecid	NF	Prescriber Discretion
Otulfi 45 mg/0.5 mL*	ustekinumab-aauz	NF	Stelara syringe (mL) 45mg/0.5mL; Stelara vial (mL) 45mg/0.5mL
Otulfi 90mg/mL*	ustekinumab-aauz	NF	Stelara syringe (mL) 90 mg/mL
Undecatrex	testosterone undecanoate	NF	testosterone gel in packet (gram) 50 mg (1%); testosterone cypionate vial (ml)
Vyalev	foscarbidopa and foslevodopa	NF	carbidopa/levodopa tablet, carbidopa-levodopa er, pramipexole di-hcl

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

C. Changes to the Highmark Core Formulary

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

Table 1. Formulary Updates
All formulary changes effective December 2024 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Ebglyss	lebrikizumab-lbkz	4	Moderate-to-severe atopic dermatitis
Items listed below were not added to the formulary			
Aqneursa	levacetylleucine	NF	Prescriber Discretion
Cobenfy	xanomeline and trospium chloride	NF	aripiprazole tablet, quetiapine fumarate tablet

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Cobenfy starter pack	xanomeline and trospium chloride	NF	aripiprazole tablet, quetiapine fumarate tablet
Hympavzi	marstacimab-hncq	NF	Prescriber Discretion
Imuldosa 45 mg/0.5 mL*	ustekinumab-srlf	NF	Stelara syringe (mL) 45mg/0.5mL; Stelara vial (mL) 45mg/0.5mL
Imuldosa 90 mg/mL*	ustekinumab-srlf	NF	Stelara syringe (mL) 90 mg/mL
Itovebi 3 mg, 9 mg	inavolisib	NF	Prescriber Discretion
Miplyffa	arimoclomol	NF	Prescriber Discretion
Orlynvah*	sulopenem etzadroxil and probenecid	NF	Prescriber Discretion
Otulfi 45 mg/0.5 mL*	ustekinumab-aauz	NF	Stelara syringe (mL) 45mg/0.5mL; Stelara vial (mL) 45mg/0.5mL
Otulfi 90mg/mL*	ustekinumab-aauz	NF	Stelara syringe (mL) 90 mg/mL
Undecatrex	testosterone undecanoate	NF	testosterone gel in metered-dose pump 20.25/1.25; testosterone gel in packet (gram) 50 mg (1%); testosterone cypionate vial (ml)
Vyalev	foscarbidopa and foslevodopa	NF	carbidopa/levodopa, carbidopa-levodopa er, pramipexole di-hcl

Formulary options: **Tier 1:** Generic drugs; **Tier 2:** Generic 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)			
Ebglyss	lebrikizumab-lbkz	2	Moderate-to-severe atopic dermatitis
Items listed below were added to the formulary (Non-Preferred)			
Aqneursa*	levacetylleucine	3	Prescriber Discretion
Hympavzi*	marstacimab-hncq	3	Prescriber Discretion
Imuldosa 45 mg/0.5 mL*	ustekinumab-srlf	3	Stelara syringe (mL) 45mg/0.5mL; Stelara vial (mL) 45mg/0.5mL
Imuldosa 90 mg/mL*	ustekinumab-srlf	3	Stelara syringe (mL) 90 mg/mL

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Itovebi 3 mg, 9 mg*	inavolisib	3	Prescriber Discretion
Miplyffa*	arimoclomol	3	Prescriber Discretion
Orlynvah*	sulopenem etzadroxil and probenecid	3	Prescriber Discretion
Otulfi 45 mg/0.5 mL*	ustekinumab-aauz	3	Stelara syringe (mL) 45mg/0.5mL; Stelara vial (mL) 45mg/0.5mL
Otulfi 90mg/mL*	ustekinumab-aauz	3	Stelara syringe (mL) 90 mg/mL
Vyalev*	foscarbidopa and foslevodopa	3	carbidopa/levodopa, carbidopa-levodopa er, pramipexole di-hcl
Items listed below were not added to the formulary			
Cobenfy	xanomeline and trospium chloride	NF	aripiprazole tablet, quetiapine fumarate tablet
Cobenfy starter pack	xanomeline and trospium chloride	NF	aripiprazole tablet, quetiapine fumarate tablet
Undecatrex	testosterone undecanoate	NF	testosterone gel in metered-dose pump 20.25/1.25; testosterone gel in packet (gram) 50 mg (1%); testosterone cypionate vial (ml)

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
Aqneursa	levacetylleucine
Ebglyss	Lebrikizumab-Lbkz
Hympavzi	marstacimab-hncq
Imuldosa	ustekinumab-srlf
Itovebi	inavolisib
Miplyffa	arimoclomol
Otulfi	ustekinumab-aauz
Vyalev	foscarbidopa and foslevodopa

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Alkindi Sprinkle (hydrocortisone) – Commercial and Healthcare Reform	12/20/2024	Policy revised to remove criteria of prescriber attestation of dose being titrated at least every 4 months for members ≤ 1 years old.
Anabolic Steroids – Commercial and Healthcare Reform	TERMED 12/19/2024	Policy terminated.
Anti-Obesity – Commercial and Healthcare Reform	10/28/2024	Policy revised to remove additional authorization duration for discontinuation of Contrave (bupropion/naltrexone).
Anti-Obesity – Administrative Services Only (ASO) Commercial	10/28/2024	Policy revised to remove additional authorization duration for discontinuation of Contrave (bupropion/naltrexone).
Anti-Obesity – Fully Insured Commercial and Healthcare Reform	12/20/2024	Policy revised to remove additional authorization duration for discontinuation of Contrave (bupropion/naltrexone).
BCR-ABL Kinase Inhibitors – Commercial and Healthcare Reform	01/01/2025	Policy revised for brand Sprycel (dasatinib) to require therapeutic failure or intolerance to generic dasatinib for initial and reauthorization; and to remove step through generic imatinib for newly diagnosed chronic myeloid leukemia in the chronic phase, newlydiagnosed acute lymphoblastic leukemia (ALL) in pediatrics, and ALL in adults. Policy revised for Scemblix (asciminib) to require age and diagnosis based on expanded FDA-approved indications.
CDK Inhibitors – Commercial and Healthcare Reform	12/20/2024	Policy revised for Kisqali (ribociclib) and Kisqali Femara Co-Pack (ribociclib; letrozole) to require age and diagnosis based on FDA-approved expanded indication for stage II and III early breast cancer. Policy revised for Ibrance (palbociclib) to require a diagnosis of endocrine-resistant, hormone receptor-positive, human epidermal growth factor receptor-negative, locally

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		advanced or metastatic breast cancer; the member is 18 years of age or older; disease is PIK3CA-mutated as detected by an FDA-approved test; the member is using Ibrance (palbociclib) in combination with Itovebi (inavolisib) and fulvestrant; and the member has experienced recurrence on or after completing adjuvant endocrine therapy.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	01/01/2025	Policy revised to move Simlandi (adalimumab-ryvk) to preferred adalimumab product and adalimumab-ryvk to non-preferred. Adalimumab-adbm [00597] labeler is preferred and adalimumab-adbm [82009] labeler is non-preferred for Commercial Comprehensive and HCR Comprehensive.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	12/20/2024	Policy revised for Cimzia (certolizumab) to add new indication for polyarticular juvenile idiopathic arthritis (pJIA) to require diagnosis and age based on FDA-approved indication, prescribed by or in consultation with a rheumatologist, therapeutic failure or intolerance to at least one nonbiological DMARD, or all are contraindicated or initial biologic therapy is needed due to involvement of high-risk joints, high disease activity, and/or member is judged by their physician to be at high risk of disabling joint damage and therapeutic failure or intolerance to at least two step 1 or 2 agents for pJIA. Policy revised for Bimzelx (bimekizumab-bkzx) to add new indications of psoriatic arthritis (PsA), non-radiographic

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		axial spondyloarthritis (nr-axSpA) and ankylosing spondylitis (AS) to require diagnosis and age based on FDA-approved indication, prescribed in by or in consultation with a specialist, therapeutic failure or intolerance to at least two step 1 or 2 agents for requested indication, spinal or axial PsA require therapeutic failure or intolerance to one nonsteroidal anti-inflammatory drug or all are contraindicated, PsA without spinal or axial disease requires therapeutic failure or intolerance to one non-biological DMARD or all are contraindicated and enthesitis and/or dactylitis associated PsA require therapeutic failure or intolerance to one nonsteroidal anti-inflammatory drug or local glucocorticoid injection or all are contraindicated. Criteria revised for Sotyktu (deucravacitinib) to update from a triple step to a double step.
Chronic Inflammatory Diseases – Commercial National Select Formulary	01/01/2025	Policy revised to move Simlandi (adalimumab-ryvk) to preferred adalimumab product, Adalimumab-adbm [00597] labeler is preferred and adalimumab-adbm [82009] labeler is non-preferred.
Chronic Inflammatory Diseases – Commercial National Select Formulary	12/20/2024	Policy revised for Cimzia (certolizumab) to add new indication for polyarticular juvenile idiopathic arthritis (pJIA) to require diagnosis and age based on FDA-approved indication, prescribed by or in consultation with a rheumatologist, therapeutic failure or intolerance to at least one nonbiological DMARD, or all are contraindicated or initial

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		biologic therapy is needed due to involvement of high-risk joints, high-disease activity, and/or member is judged by their physician to be at high risk of disabling joint damage and therapeutic failure or intolerance to at least two step 1 or 2 agents for pJIA. Policy revised for Bimzelx (bimekizumab-bkzx) to add new indications of psoriatic arthritis (PsA), non-radiographic axial spondyloarthritis (nr-axSpA) and ankylosing spondylitis (AS) to require diagnosis and age based on FDA-approved indication, prescribed in by or in consultation with a specialist, therapeutic failure or intolerance to at least two step 1 or 2 agents for requested indication, spinal or axial PsA require therapeutic failure or intolerance to one nonsteroidal anti-inflammatory drug or all are contraindicated, PsA without spinal or axial disease requires therapeutic failure or intolerance to one non-biological DMARD or all are contraindicated and enthesitis and/or dactylitis associated PsA require therapeutic failure or intolerance to one nonsteroidal anti-inflammatory drug or local glucocorticoid injection or all are contraindicated. Criteria revised for Omvoh (mirikizumab-mrkz) moved to a step 1 preferred agent.
Clotting Factor Products – Commercial and Healthcare Reform	TBD	Policy revised to add Hympavzi (marstacimab-hncq) as a target requiring FDA-approved age and indication, documentation of severe disease, and previous use of a factor replacement therapy. Reauthorization

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		requires disease stability, improvement, or delayed disease progression. Additional quantities allowed for induction dosing and for members at least 50 kg who have been on therapy for at least six months and experienced at least 2 breakthrough bleeds.
Dupixent (dupilumab) – Commercial and Healthcare Reform	10/31/2024	Policy revised to remove the prebronchodilator forced expiratory volume in 1 second (FEV1) below 80% in adults, prebronchodilator FEV1 below 90% in adolescents, and FEV1 reversibility of at least 12% and 200 milliliters after albuterol (salbutamol) administration for asthma. Policy revised to include chronic obstructive pulmonary disease (COPD) with an initial authorization requiring all of the following: the member is 18 years of age and older, a diagnosis of COPD (ICD: 10: J41-J44), a post-bronchodilator FEV1 ≤ 80% predicted, a blood eosinophil count of ≥ 300 cells/mcL, a modified Medical Research Council dyspnea scale score of ≥ 2, the member meets one of the following criteria: an exacerbation history of at least two (2) moderate exacerbations resulting treatment with systemic corticosteroids and/or antibiotics in the previous year, one (1) severe exacerbation resulting in hospitalization or observation in the emergency department for over 24 hours in the previous year, or GOLD group E and the member has inadequate symptom control despite regular treatment for at least 3 months with triple therapy consisting of a long-acting muscarinic

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (LAMA/LABA/ICS), unless intolerant of, or has contraindications to these agents. Policy updated to include when a benefit, reauthorization of Dupixent (dupilumab) may be approved when one (1) of the following criteria is met: The prescriber attests that the member has experienced a reduction in symptoms of COPD, the prescriber attests that the member has experienced an improvement in exercise tolerance, the prescriber attests that the member has experienced delayed disease progression, or the prescriber attests that the member has experienced a reduction in the number of exacerbations. Criteria for chronic rhinosinusitis with nasal polyposis update to the member 12 years of age and older.
Ebglyss (lebrikizumab-lbkz) – Commercial and Healthcare Reform	12/20/2024	New policy for Ebglyss (lebrikizumab-lbkz) requiring diagnosis, age and weight per FDA-approved indication attested to by specialist, therapeutic failure or intolerance to one generic topical corticosteroid, one generic calcineurin inhibitor or attestation that the member has severe atopic dermatitis where topical therapy is not advisable evidenced by large proportion body surface area or severely damaged skin. If the patient has already had a trial of at least one biologic agent the patient is not required to “step back” and try a

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		non-biologic agent. Reauthorization requires positive clinical response to therapy.
EGFR-Targeting Kinase Inhibitors – Commercial and Healthcare Reform	12/20/2024	Policy revised for Tagrisso (osimertinib) to require age and diagnosis based on expanded FDA-approved indication for locally advanced, unresectable (stage III) non-small cell lung cancer and to require FDA-approved tests for genetic mutations and/or deletions.
Fertility – Commercial and Healthcare Reform – New York	10/30/2024	Policy revised for clomiphene citrate products to allow use with intrauterine insemination (IUI) if the member has the appropriate benefit.
Fertility – Commercial and Healthcare Reform – New York	12/20/2024	Policy revised for Crinone 8% (progesterone) to specify that step through Endometrin (progesterone) is only if the member does not have the National Select Formulary. Endometrin is no longer on shortage.
Fertility – Commercial and Select Healthcare Reform Plans	12/20/2024	Policy revised for Crinone 8% (progesterone) to specify that step through Endometrin (progesterone) is only if the member does not have the National Select Formulary. Endometrin is no longer on shortage.
Fertility – Commercial and Select Healthcare Reform Plans	10/31/2024	Policy revised for clomiphene citrate products to allow use with intrauterine insemination (IUI) if the member has the appropriate benefit.
Fertility – Pennsylvania Healthcare Reform Individual Plans	12/20/2024	Endometrin (progesterone) is no longer on shortage.
Filspari (sparsentan) – Commercial and Healthcare Reform	12/20/2024	Policy revised to define risk of disease progression as proteinuria ≥ 0.5 g/day.
Glucosylceramide Synthase Inhibitors for Gaucher Disease	12/20/2024	Policy revised to add a diagnosis of Niemann-Pick Disease, type C

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
and Niemann-Pick Disease – Commercial and Healthcare Reform		(NPC) to Yargesa and Zavesca (miglustat). For coverage, members must have a molecularly confirmed diagnosis of NPC, the prescriber must attest that the member is experiencing neurological symptoms from NPC, and miglustat will be given in combination with Miplyffa (arimoclomol). If the request is for brand Zavesca, the member has experienced therapeutic failure or intolerance to generic miglustat. Reauthorization requires that the member has experienced positive clinical response to therapy and continues to take Miplyffa along with the miglustat. Quantity limits added for Yargesa and Zavesca (miglustat) to allow larger quantities of medication per day to achieve recommended doses for NPC.
Interleukin (IL)-5 Antagonists – Commercial and Healthcare Reform	12/20/2024	Policy revised to remove the prebronchodilator forced expiratory volume in 1 second (FEV1) below 80% in adults, prebronchodilator FEV1 below 90% in adolescents, and FEV1 reversibility of at least 12% and 200 milliliters after albuterol (salbutamol) administration for the diagnosis of severe asthma for Nucala (mepolizumab) and Fasenra (benralizumab). Policy revised to include Fasenra's expanded indication of Eosinophilic Granulomatosis with Polyangiitis (EGPA). When a benefit coverage of Fasenra may be approved for EGPA when all of the following criteria are met: the member is 18 years of age or older, the request is for the 30

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		mg/mL autoinjector, the member has a history of relapsing or refractory EGPA, and the member will be receiving standard of care while on therapy with glucocorticoid treatment (e.g., prednisone or prednisolone), with or without immunosuppressive therapy (e.g., cyclosporine, leflunomide, azathioprine, etc.). When a benefit, reauthorization of Fasenra may be approved when all of the following criteria are met: the request is for the 30 mg/mL autoinjector and the member meets one of the following: the prescriber attests that the member has experienced reduction in the frequency and/or severity of relapses, the prescriber attests that the member has experienced a reduction or discontinuation of doses of corticosteroids and/or immunosuppressant, the prescriber attests that the member has experienced disease remission, or the prescriber attests that the member has experienced a reduction in severity or frequency of EGPA-related symptoms. When a prior authorization is approved, Fasenra may be authorized for the following quantity: one 30 mg auto-injector every 4 weeks.
Isturisa (osilodrostat) – Commercial and Healthcare Reform	12/20/2024	Policy revised for Isturisa (osilodrostat) to remove criteria requiring endocrinologist prescribing.
JAK Inhibitors – Commercial and Healthcare Reform	12/20/2024	Policy revised for Jakafi (ruxolitinib) to require age based

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		on FDA-approved indication for polycythemia vera.
Korlym (mifepristone) – Commercial and Healthcare Reform	12/20/2024	Policy revised for Korlym (mifepristone) to remove criteria requiring endocrinologist prescribing.
Lumryz (sodium oxybate), Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates) – Commercial and Healthcare Reform	12/20/2024	Policy revised to change age requirement for Lumryz (sodium oxybate) from 18 to 7 years of age and older.
Niemann-Pick Disease Type C – Commercial and Healthcare Reform	12/20/2024	Policy created for Aqneursa (levacetylleucine) and Miplyffa (arimoclomol) requiring FDA-approved diagnosis (confirmed by genetic testing), neurological symptoms, and weight for initial authorization. For Miplyffa (arimoclomol), requirement of concurrent use with miglustat. Reauthorization requiring positive clinical response to therapy. Limitation of coverage that Aqneursa (levacetylleucine) and Miplyffa (arimoclomol) should not be used together.
Non-Preferred Riluzole Products – Commercial and Healthcare Reform	12/20/2024	Policy revised to add Teglutik (riluzole) to policy requiring diagnosis of amyotrophic lateral sclerosis and inability to swallow tablets.
Ophthalmic Cyclosporines for Dry Eye Disease – Commercial and Healthcare Reform	11/07/2024	Policy revised for brand Restasis (cyclosporine) to require documentation for generic cyclosporine step therapy with chart notes or pharmacy claims.
Parathyroid Hormone Analogs-Commercial and Healthcare Reform	12/20/2024	Updated additional restrictions to include NSF. Separate NSF policy terminated.
Parathyroid Hormone Analogs-Commercial National Select	TERMED 12/19/2024	Policy terminated.
PI3K Inhibitors – Commercial and Healthcare Reform	12/20/2024	Policy revised to add Itovebi (inavolisib) to require age and diagnosis based on FDA-approved indication.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Rivfloza (nedosiran) – Commercial and Healthcare Reform	12/20/2024	Policy revised to add the member's diagnosis of primary hyperoxaluria type 1 (PH1) to be confirmed by 1 of the following: Genetic testing demonstrating a mutation in the AGXT gene. OR liver biopsy demonstrating absence or significantly reduced AGT activity. Policy further revised to add that Rivfloza (nedosiran) is prescribed by or in consultation with a urologist or nephrologist and the member has not received a liver transplant. Policy revised to add that the member has not received a liver transplant in the reauthorization criteria. Policy revised to add that Rivfloza (nedosiran) is not to be used in combination with Oxlumo (lumasiran) for the treatment of PH1 in the limitations of coverage.
Talicia (omeprazole/amoxicillin/rifabutin) – Commercial and Healthcare Reform	12/20/2024	Policy revised to include updated first line recommendations of try/failure of bismuth quadruple therapy (proton pump inhibitor (PPI), bismuth subcitrate OR bismuth subsalicylate, tetracycline, and metronidazole). Removed criteria for try/failure of PPI-clarithromycin triple therapy. Removed criteria for try/failure or intolerance to Pylera (bismuth subcitrate potassium, metronidazole, and tetracycline).
Tarpeyo (budesonide) – Commercial and Healthcare Reform	12/20/2024	Policy revised to define risk of disease progression as proteinuria > 0.5 g/day and to remove requirement of risk of disease progression from reauthorization. For initial and reauthorization, options for concurrent use/trial/failure

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		expanded to include Filspari (sparsentan).
Tavneos (avacopan) – Commercial and Healthcare Reform	12/20/2024	Policy revised for Tavneos (avacopan) to remove requirement that member be on a systemic glucocorticoid as part of standard of care and removed reauthorization requirement that that member has a reduction in overall glucocorticoid dose from baseline.
Testosterone (Androgens) – Commercial and Healthcare Reform	12/20/2024	Policy revised to add Undecatrex (testosterone undecanoate) capsule as a target requiring FDA-approved diagnosis, laboratory tests supporting low testosterone, and trial/failure to 1 generic testosterone topical product.
Tezspire (tezepelumab-ekko) – Commercial and Healthcare Reform	12/20/2024	Policy revised to remove the prebronchodilator forced expiratory volume in 1 second (FEV1) below 80% in adults, prebronchodilator FEV1 below 90% in adolescents, and FEV1 reversibility of at least 12% and 200 milliliters after albuterol (salbutamol) administration.
Ustekinumab Biosimilars – Commercial and Healthcare Reform	TBD	Policy revised to add new products Imuldosa (ustekinumab-srlf) and Otulfi (ustekinumab-aauz) subcutaneous (SC) injection requiring age, FDA-approved diagnosis, specialist, dosing based on FDA-approved weight, and trial/failure to Stelara (ustekinumab). For psoriatic arthritis, trial/failure to one nonsteroidal anti-inflammatory drug (NSAID), non-biologic DMARD, or local glucocorticoid injection depending on disease classification. For plaque psoriasis, trial/failure to phototherapy or systemic

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		therapy, or contraindication to all. For Crohn's disease and ulcerative colitis, if the request is for SC, prescriber attestation of ustekinumab IV induction dose received within 2 months or currently undergoing induction. Reauthorization of positive clinical response to therapy. New indication for Selarsdi (ustekinumab-aekn) SC added for inflammatory bowel disease to align with other ustekinumab biosimilar criteria.
Vtama (tapinarof) and Zoryve (roflumilast) – Commercial and Healthcare Reform	10/22/2024	Policy revised for Zoryve (roflumilast) cream to remove requirement of therapeutic failure, contraindication or intolerance to topical corticosteroids for indications of atopic dermatitis and plaque psoriasis.
Vyleesi (bremelanotide injection) – Commercial and Healthcare Reform	12/20/2024	Policy revised for Vyleesi (bremelanotide injection) to require specific diagnosis of acquired and generalized hypoactive sexual desire disorder. For reauthorization, attestation that the female member is still premenopausal.
Xolair (omalizumab) Syringe – Commercial and Healthcare Reform	12/20/2024	Policy revised to remove the prebronchodilator forced expiratory volume in 1 second (FEV1) below 80% in adults, prebronchodilator FEV1 below 90% in adolescents, and FEV1 reversibility of at least 12% and 200 milliliters after albuterol (salbutamol) administration.
Alkindi Sprinkle (hydrocortisone) – Commercial and Healthcare Reform	12/20/2024	Policy revised to remove criteria of prescriber attestation of dose being titrated at least every 4 months for members ≤ 1 years old.

*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
Atypical Antipsychotics – Commercial	12/20/2024	Policy revised to include Cobenfy (xanomeline and trospium chloride) requiring age, diagnosis based on FDA-approved indication, and trial/failure/contraindication to one of the following: quetiapine product or aripiprazole tablets.
Atypical Antipsychotics – Healthcare Reform	12/20/2024	Policy revised to include Cobenfy (xanomeline and trospium chloride) requiring age, diagnosis based on FDA-approved indication, and trial/failure/contraindication to one of the following: quetiapine product or aripiprazole tablets.
Beta Blocker Management – Commercial and Healthcare Reform	12/20/2024	Updated additional restrictions to include NSF. Separate NSF policy terminated. Auto-auth criteria re-added.
Beta Blocker Management – Commercial National Select Formulary	TERMED 12/19/2024	Policy terminated.
Carbidopa/Levodopa – Commercial and Healthcare Reform	12/20/2024	Policy revised to add Vyalev (foscarbidopa/foslevodopa) requiring the member be 18 years of age or older, a diagnosis of advanced Parkinson's disease, using for the treatment of motor fluctuations, prescribed by or in consultation with a neurologist, therapeutic failure or intolerance to one of the following plan-preferred oral carbidopa/levodopa products: generic carbidopa-levodopa tablets or generic carbidopa-levodopa ER tablets, and therapeutic failure or intolerance to two of the following generic products: ropinirole, pramipexole, entacapone, selegiline, or rasagiline. Updated automatic approval criteria to none for Vyalev.
Colony-Stimulating Factors – Commercial and Healthcare Reform	12/20/2024	Policy revised for Neupogen (filgrastim) to require therapeutic failure or intolerance to Zarxio (filgrastim-sndz) for hematopoietic acute radiation syndrome.
Colony-Stimulating Factors – Commercial and Healthcare Reform	TBD	Policy revised for Nypozi (filgrastim-txid) to require therapeutic failure or intolerance to Zarxio (filgrastim-sndz) for hematopoietic syndrome of acute radiation syndrome.
Continuous Glucose Monitoring (CGM)	01/01/2025	Policy revised to add Eversense 365 products as targets.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Systems – Commercial and Healthcare Reform		
Continuous Glucose Monitoring (CGM) Systems – Commercial and Healthcare Reform	01/01/2025	Policy revised to add Guardian Sensor 3, Freestyle Libre 2 Plus Sensor, and Freestyle Libre 3 Plus Sensor as non-preferred targets. Auto-authorization criteria revised to apply to Dexcom only.
Dyanavel XR (amphetamine) – Commercial and Healthcare Reform	TERMED 12/31/2024	Termination of policy. Criteria moved to new policy J-XXXX Non-Preferred CNS Stimulant Products – Commercial and Healthcare Reform.
Evekeo (amphetamine sulfate) – Commercial and Healthcare Reform	TERMED 12/31/2024	Termination of policy. Criteria moved to new policy J-XXXX Non-Preferred CNS Stimulant Products – Commercial and Healthcare Reform.
HIV-1 Therapies – Commercial and Healthcare Reform	12/20/2024	Policy updated to remove New York as an applicable region.
HIV-1 Therapies – Commercial National Select Formulary	TERMED 12/19/2024	Policy terminated.
J-1098 Azstarys (serdexmethylphenidate/ dexmethylphenidate) – Commercial and Healthcare Reform	01/01/2025	Policy revised to remove requirement of trial/failure of one immediate release product.
J-1273 Non-Preferred Methylphenidate ER Products for ADHD – Commercial and Healthcare Reform	TERMED 12/31/2024	Termination of policy. Criteria moved to new policy J-XXXX Non-Preferred CNS Stimulant Products – Commercial and Healthcare Reform.
Lidocaine Patches and Topical System – Commercial and Healthcare Reform	12/20/2024	Policy revised to include Tridacaine XL (lidocaine 5%) as a target medication. No changes to existing criteria.
Nexiclon (clonidine) XR – Commercial and Healthcare Reform	12/20/2024	Policy revised for Nexiclon XR (clonidine) for reauthorization to required blood pressure reduction and trial/failure of plan-preferred generic clonidine HCL immediate-release tablet.
Non-Preferred CNS Stimulant Products – Commercial and Healthcare Reform	01/01/2025	New policy for brand Adderall XR (amphetamine mixed salts extended release (ER)), Adzenys XR-ODT (amphetamine ER), Cotempla XR-ODT (methylphenidate ER), Desoxyn (methamphetamine), brand Dexedrine Spansule (dextroamphetamine sulfate ER), Dyanavel XR (amphetamine ER) oral suspension, Jornay PM (methylphenidate ER), brand Mydayis

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		(amphetamine mixed salts ER), Quillichew ER (methylphenidate ER), Quillivant XR (methylphenidate ER), brand Vyvanse (lisdexamfetamine dimesylate), and Zenzedi (dextroamphetamine sulfate). All products require FDA-approved indication and age. Adderall XR requires trial/failure of generic dextroamphetamine/amphetamine ER and one plan-preferred generic (dexmethylphenidate ER, dextroamphetamine ER, or methylphenidate ER). Adzenys XR-ODT, Cotempla XR-ODT, Dyanavel XR oral suspension, Jornay PM, Mydayis, Quillichew ER, and Quillivant require one plan-preferred generic (dextroamphetamine/amphetamine ER, dexmethylphenidate ER, dextroamphetamine ER, or methylphenidate ER). Desoxyn requires trial of two plan-preferred generic immediate release (IR) alternatives (amphetamine/dextroamphetamine, dextroamphetamine, methylphenidate, or dexmethylphenidate. Dexedrine Spansule requires trial/failure of two plan-preferred generic alternatives (dextroamphetamine/amphetamine ER, dexmethylphenidate ER, dextroamphetamine ER, or methylphenidate ER) when used for attention deficit hyperactivity disorder (ADHD). For narcolepsy, Dexedrine Spansule requires one of the following: multiple sleep latency test (MSLT) less than or equal to 8 minutes with at least 2 sleep onset rapid eye movement periods (SOREMPs), MSLT less than or equal to 8 minutes with at least 1 SOREMP on MSLT and polysomnography, or cerebrospinal fluid hypocretin less than 110 pg/mL or less than one-third the normal value based on reference range, baseline data via Epworth Sleepiness Scale (ESS) or Maintenance of Wakefulness Test (MWT), documentation of baseline cataplexy episodes, and trial/failure of generic dextroamphetamine ER. Brand Vyvanse requires trial/failure of 1 generic plan-preferred alternative (dextroamphetamine/amphetamine ER, dexmethylphenidate ER, dextroamphetamine ER, or methylphenidate ER) and generic lisdexamfetamine for ADHD. For binge eating disorder, trial/failure to generic lisdexamfetamine. For Zenzedi, trial/failure to 2 generic IR plan-

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
		preferred alternatives (dexmethylphenidate IR, dextroamphetamine/amphetamine IR, dextroamphetamine IR, or methylphenidate IR) for ADHD. For narcolepsy, Zenzedi requires one of the following: multiple sleep latency test (MSLT) less than or equal to 8 minutes with at least 2 sleep onset rapid eye movement periods (SOREMPs), MSLT less than or equal to 8 minutes with at least 1 SOREMP on MSLT and polysomnography, or cerebrospinal fluid hypocretin less than 110 pg/mL or less than one-third the normal value based on reference range, baseline data via Epworth Sleepiness Scale (ESS) or Maintenance of Wakefulness Test (MWT), documentation of baseline cataplexy episodes, and trial/failure to dextroamphetamine IR or methylphenidate IR and generic dextroamphetamine. Reauthorization for ADHD requires positive clinical response to therapy. Reauthorization for narcolepsy requires decrease in daytime sleepiness via ESS or MWT compared to baseline and decrease in cataplexy episodes from baseline if applicable. Evekeo, Dyanavel XR tablets, Metadate CD, Methylphenidate ER, Relexxii, and Xelstrym moved from their individual policies into this new policy.
Non-Preferred NSAIDs – Commercial and Healthcare Reform	12/20/2024	Policy revised to add Dolobid (diflunisal) (brand only); requires FDA-approved diagnosis and trial/failure to three (3) plan-preferred, generic products, or contraindication to all.
Tazarotene Products – Commercial and Healthcare Reform	12/20/2024	Policy revised to specify therapeutic failure or intolerance to generic tazarotene 0.1% cream.
Vimovo (naproxen and esomeprazole magnesium) – Commercial and Healthcare Reform	12/20/2024	Updated additional restrictions to include NSF. Separate NSF policy terminated.
Vimovo (naproxen and esomeprazole magnesium) – Commercial National Select	TERMED 12/19/2024	Policy terminated.
Xelstrym (dextroamphetamine) –	Termed 12/31/2026	Termination of policy. Criteria moved to new policy J-XXXX Non-Preferred CNS Stimulant Products – Commercial and Healthcare Reform.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Commercial and Healthcare Reform		

*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

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Zero-Dollar Cost Share: HIV PrEP Therapy – Commercial and Healthcare Reform plans Compliant with the Affordable Care Act Preventative Service Mandates	10/29/2024	Policy revised to remove the step requirement through generic Truvada from Descovy before $0 preventive coverage could be approved.

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
Bimzelx (bimekizumab-bkzx) 160 mg/mL	3 syringes/autoinjectors (3 mL) per 56 days	3 syringes/autoinjectors (3 mL) per 56 days
Bimzelx (bimekizumab-bkzx) 160 mg/mL*	1 syringe/autoinjector (1mL) per 28 days	3 syringes/autoinjectors (3 mL) per 84 days
Bimzelx (bimekizumab-bkzx) 320 mg/2 mL	1 syringe/autoinjector (2 mL) per 56 days	1 syringe/autoinjector (2 mL) per 56 days
Cobenfy (xanomeline and trospium chloride) starter pack	1 pack (56 capsules) per 365 days	1 pack (56 capsules) per 365 days

Drug Name	Retail Edit Limit	Mail Edit Limit
Ebglyss (Lebrikizumab-Lbkz)	1 pen/syringe (2 mL) per 28 days	3 pens/syringes (6 mL) per 84 days
Hympavzi (marstacimab-hncq)	4 prefilled syringes/pens per 28 days	12 prefilled syringes/pens per 84 days
Imuldosa (ustekinumab-srlf) 45 mg/0.5 mL	1 syringe (0.5 mL) per 84 days	1 syringe (0.5 mL) per 84 days
Imuldosa (ustekinumab-srlf) 90 mg/mL	1 syringe (1 mL) per 84 days	1 syringe (1 mL) per 84 days
Lumryz (sodium oxybate) Starter Pack	28 packets per 274 days	28 packets per 274 days
Orlynvah (sulopenem etzadroxil and probenecid)	10 tablets per 5 days	10 tablets per 5 days
Otulfi (ustekinumab-aauz) 45 mg/0.5 mL	1 syringe (0.5 mL) per 84 days	1 syringe (0.5 mL) per 84 days
Otulfi (ustekinumab-aauz) 90mg/mL	1 syringe (1 mL) per 84 days	1 syringe (1 mL) per 84 days

*Effective date to be determined.

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

No Changes at this time

*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
Aqneursa (levacetylleucine)	4 granule packets per day
Cobenfy (xanomeline and trospium chloride)	2 capsules per day
Itovebi (inavolisib) 3 mg	2 tablets per day
Itovebi (inavolisib) 9 mg	1 tablet per day
Lumakras (sotorasib) 240 mg	4 tablets per day
Miplyffa (arimoclomol)	3 capsules per day
Undecatrex (testosterone undecanoate)	4 capsules per day
Vyalev (foscarbidopa and foslevodopa)	2 vials 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.

No changes at this time.

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

Brand Name	Generic Name	Preferred Alternatives
Orlynvah	sulopenem etzadroxil and probenecid	Prescriber Discretion
Undecatrex	testosterone undecanoate	testosterone cypionate; testosterone gel in metered-dose pump 20.25 mg/1.25 gram (1.62 %); testosterone gel in packet 1.62 % (40.5 mg/2.5 gram)

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.

No changes at this time.

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

Brand Name	Generic Name	Preferred Alternatives
Orlynvah	sulopenem etzadroxil and probenecid	Prescriber Discretion* Fosfomycin**

*This alternative only pertains to Venture Formulary
**This alternative pertains to Performance and Fundamental Formularies

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

Brand Name	Generic Name	Preferred Alternatives
Aqneursa	levacetylleucine	Prescriber Discretion
Ebglyss	lebrikizumab-lbkz	Dupixent
Imuldosa 130 mg/26 mL, 45 mg/0.5 mL, 90 mg/mL	ustekinumab-srlf	Stelara
Miplyffa	arimoclomol	Prescriber Discretion
Otulfi 130 mg/26 mL, 45 mg/0.5 mL, 90mg/mL	ustekinumab-aauz	Stelara
Selarsdi 130 mg/26 mL	ustekinumab-aekn	Stelara
Undecatrex	testosterone undecanoate	testosterone cypionate; testosterone gel in metered-dose pump 20.25 mg/1.25 gram (1.62 %); testosterone gel in packet
Vyalev	foscarbidopa and foslevodopa	carbidopa-levodopa, ropinirole, pramipexole

*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
Aqneursa*	levacetylleucine
Cobenfy	xanomeline and trospium chloride
Cobenfy starter pack	xanomeline and trospium chloride
Ebglyss*	Lebrikizumab-Lbkz
Imuldosa 130 mg/26 mL*	ustekinumab-srlf
Imuldosa 45 mg/0.5 mL*	ustekinumab-srlf

Imuldosa 90 mg/mL*	ustekinumab-srlf
Itovebi 3 mg	inavolisib
Itovebi 9 mg	inavolisib
Miplyffa*	arimoclomol
Ocrevus Zunovo	ocrelizumab and hyaluronidase-ocsq
Otulfi 130 mg/26 mL*	ustekinumab-aauz
Otulfi 45 mg/0.5 mL*	ustekinumab-aauz
Otulfi 90mg/mL*	ustekinumab-aauz
Selarsdi 130 mg/26 mL*	ustekinumab-aekn
Tecentriq Hybreza	atezolizumab and hyaluronidase-tqjs
Vyalev*	foscarbidopa and foslevodopa
Vyloy	zolbetuximab-clzb

*Pertains only to Incentive and Compass Formularies

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Anabolic Steroids – Medicare	12/20/2024	Policy revised to remove Oxandrin (oxandrolone) and Androxy (fluoxymesterone) as targets.
Anti-CD20 Multiple Sclerosis Agents – Medicare	12/20/2024	Policy revised to add Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) to require FDA-approved diagnosis and that the member will not be using in combination with another disease modifying therapy.
Atypical Antipsychotics – Medicare	01/01/2025	Policy revised to include Cobenfy (xanomeline and trospium chloride) requiring diagnosis based on FDA-approved indication and trial/failure/contraindication to one (1) other generic atypical antipsychotic (e.g., quetiapine).
BCR-ABL Kinase Inhibitors – Medicare	01/01/2025	Policy revised for Scemblix (asciminib) to require diagnosis based on expanded FDA-approved indication.
BCR-ABL Kinase Inhibitors – Medicare	TBD	Policy revised for brand Sprycel (dasatinib) to require therapeutic failure or intolerance to generic dasatinib.
CDK Inhibitors – Medicare	01/01/2025	Policy revised for Ibrance (palbociclib) to require a diagnosis of endocrine-resistant, hormone receptor-positive, human epidermal growth factor receptor-negative, locally advanced or

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		metastatic breast cancer; disease is PIK3CA-mutated as detected by an FDA-approved test; the member is using Ibrance (palbociclib) in combination with Itovebi (inavolisib) and fulvestrant; and the member has experienced recurrence on or after completing adjuvant endocrine therapy.
CDK Inhibitors – Medicare	12/20/2024	Policy revised for Kisqali (ribociclib) and Kisqali Femara Co-Pack (ribociclib; letrozole) to require diagnosis based on FDA-approved expanded indication for stage II and III early breast cancer.
Chronic Inflammatory Diseases – Medicare	01/01/2025	Policy revised for Cimzia (certolizumab) to add new indication for polyarticular juvenile idiopathic arthritis (pJIA) to require diagnosis and age based on FDA-approved indication, therapeutic failure or intolerance to at least one nonbiological DMARD, all are contraindicated or initial biologic therapy is needed due to involvement of high-risk joints, high disease activity, and/or member is judged by their physician to be at high risk of disabling joint damage and therapeutic failure or intolerance to 2 preferred biologic products for pJIA. Policy revised for Entyvio (vedolizumab) IV to require therapeutic failure or intolerance to two preferred biologics for the indication being request. Policy revised for Bimzelx (bimekizumab-bkzx) to add new indications of psoriatic arthritis (PsA), non-radiographic axial spondyloarthritis (nr-axSpA) and ankylosing spondylitis (AS) to require diagnosis and age based on FDA-approved indication, require therapeutic failure or intolerance to two preferred biologics for the indication being request, nr-axSpA requires therapeutic failure or intolerance to two

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		nonsteroidal anti-inflammatory drugs, or all are contraindicated and AS requires therapeutic failure or intolerance to one nonsteroidal anti-inflammatory drugs, or all are contraindicated.
Chronic Inflammatory Diseases – Medicare	01/01/2025	Policy revised for Entyvio (vedolizumab) subcutaneous (SC), Omvoh (mirikizumab-mrkz) SC, Skyrizi (risankizumab) SC, Stelara (ustekinumab) SC, Tremfya (guselkumab) SC and Zymfentra (infliximab-dyyb) to change the requirement of clinical response or remission to IV to received or currently undergoing IV induction.
Dupixent (dupilumab) – Medicare	01/01/2025	Policy revised to remove the prebronchodilator forced expiratory volume in 1 second (FEV1) below 80% in adults, prebronchodilator FEV1 below 90% in adolescents, and FEV1 reversibility of at least 12% and 200 milliliters after albuterol (salbutamol) administration for asthma.
Dupixent (dupilumab) – Medicare	10/31/2024	Policy revised to include chronic obstructive pulmonary disease (COPD) with an initial authorization requiring all of the following: a diagnosis of COPD, a blood eosinophil count of ≥ 300 cells/mcL and the member has inadequate symptom control despite regular treatment for at least 3 months with triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (LAMA/LABA/ICS), unless intolerant of, or has contraindications to these agents. Policy updated to include when a benefit, reauthorization of Dupixent (dupilumab) may be approved when one (1) of the following criteria is met: The prescriber attests that the member has experienced a reduction in

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		symptoms of chronic obstructive pulmonary disease (COPD), the prescriber attests that the member has experienced an improvement in exercise tolerance, the prescriber attests that the member has experienced delayed disease progression, or the prescriber attests that the member has experienced a reduction in the number of exacerbations.
Ebglyss (lebrikizumab-lbkz) – Medicare	12/20/2024	New policy for Ebglyss (lebrikizumab-lbkz) requiring diagnosis of moderate to severe atopic dermatitis (AD), therapeutic failure or intolerance to one generic topical corticosteroid, one generic calcineurin inhibitor or attestation that the member has severe AD where topical therapy is not advisable evidenced by large proportion body surface area or severely damaged skin, and therapeutic failure, contraindication or intolerance to Dupixent and Rinvoq. If the patient has already had a trial of at least one biologic agent the patient is not required to “step back” and try a non-biologic agent.
EGFR-Targeting Kinase Inhibitors – Medicare	01/01/2025	Policy revised for Tagrisso (osimertinib) to require diagnosis based on expanded FDA-approved indication for locally advanced, unresectable (stage III) non-small cell lung cancer.
EGFR-Targeting Kinase Inhibitors – Medicare	TBD	Policy revised for Gilotrif (afatinib), Iressa (gefitinib), Lazcluze (lazertinib), Tagrisso (osimertinib), Tarceva (erlotinib), and Vizimpro (dacomitinib) to require an FDA-approved test based on FDA-approved indication.
Filspari (sparsentan) – Medicare	12/20/2024	Policy revised to define risk of disease progression as proteinuria ≥ 0.5 g/day.
Filsuvez (birch triterpenes) – Medicare	12/20/2024	Policy revised for Filsuvez (birch triterpenes) to remove age restriction.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Givlaari (givosiran) – Medicare	01/01/2025	Policy revised for Givlaari (givosiran) to update supporting diagnostic criteria requiring elevated urine porphobilinogen (PBG), increased aminolevulinic acid (ALA), or genetic testing confirming a mutation. Added the member has a history of symptoms of acute hepatic porphyria (AHP) chronically or during previous acute attack(s).
Glucosylceramide Synthase Inhibitors for Gaucher Disease and Niemann-Pick Disease – Medicare	12/20/2024	Policy revised to add a diagnosis of Niemann-Pick Disease, type C (NPC) to Yargesa and Zavesca (miglustat). For coverage, members must have a molecularly confirmed diagnosis of NPC, the prescriber must attest that the member is experiencing neurological symptoms from NPC, and miglustat will be given in combination with Miplyffa (arimoclomol). If the request is for brand Zavesca, the member has experienced therapeutic failure or intolerance to generic miglustat.
Human Growth Hormone – Medicare	01/01/2025	Policy revised to replace ask for bone age and/or chronological age with the member has open epiphyses.
Increlex (mecasermin) – Medicare	01/01/2025	Policy revised to replace ask for bone age and/or chronological age with the member has open epiphyses.
Interleukin (IL)-5 Antagonists – Medicare	01/01/2025	Policy revised to remove the prebronchodilator forced expiratory volume in 1 second (FEV1) below 80% in adults, prebronchodilator FEV1 below 90% in adolescents, and FEV1 reversibility of at least 12% and 200 milliliters after albuterol (salbutamol) administration for the diagnosis of severe asthma for Cinqair (reslizumab), Nucala (mepolizumab), and Fasenra (benralizumab). Policy updated for Fasenra to include an initial authorization may be approved when all of the following criteria are met: the member has a diagnosis of

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		eosinophilic granulomatosis with polyangiitis (EGPA), the member has a history of relapsing or refractory disease. and the member will be receiving standard of care while on Fasenra therapy with glucocorticoid treatment (e.g., prednisone or prednisolone), with or without immunosuppressive therapy (e.g., cyclosporine, leflunomide, azathioprine). When a benefit, reauthorization of Fasenra may be approved when one (1) of the following criteria are met: the prescriber attests that the member has experienced reduction in the frequency and/or severity of relapses, the prescriber attests that the member has experienced a reduction or discontinuation of doses of corticosteroids and/or immunosuppressant, the prescriber attests that the member has experienced disease remission, or the prescriber attests that the member has experienced a reduction in severity or frequency of EGPA-related symptoms.
JAK Inhibitors – Medicare	12/20/2024	Policy revised for Inrebic (fedratinib) to remove age limitation.
Lidocaine Patches – Medicare	01/01/2025	Policy revised to require that member experience a therapeutic failure or intolerance to generic lidocaine patch 5% if the request is for brand Lidoderm.
Lidocaine Patches – Medicare	01/01/2025	Policy revised to add Tridacaine XL (lidocaine) patch as a target medication. No changes to existing criteria.
Mechanistic Target of Rapamycin Kinase (mTOR) Inhibitors – Medicare	TBD	Policy revised for Afinitor (everolimus) to require that the disease be unresectable, locally advanced, or metastatic for a diagnosis of neuroendocrine tumors of pancreatic origin.

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Niemann-Pick Disease Type C – Medicare	12/20/2024	Policy revised to add Miplyffa (arimoclomol) requiring FDA-approved age and diagnosis, neurologic symptoms, and concurrent use with miglustat.
Niemann-Pick Disease Type C – Medicare	TBD	Policy revised to add Aqneursa (levacetylleucine) requiring FDA-approved age and diagnosis, and neurologic symptoms. For reauthorization, requiring positive clinical response to therapy. Limitation of coverage added that Miplyffa (arimoclomol) and Aqneursa (levacetylleucine) should not be used in combination.
Non-Preferred Riluzole Products – Medicare	12/20/2024	Policy revised to add Teglutik (riluzole) to policy requiring diagnosis of amyotrophic lateral sclerosis and inability to swallow tablets.
Onfi (clobazam) and Sympazan (clobazam oral films) – Medicare	TBD	Policy revised to require therapeutic failure or intolerance to generic clobazam for requests for brand Onfi (clobazam).
Oxlumo (lumasiran) – Medicare	TBD	Policy revised to add the member's diagnosis of primary hyperoxaluria type 1 (PH1) to be confirmed by 1 of the following: Genetic testing demonstrating a mutation in the AGXT gene. OR liver biopsy demonstrating absence or significantly reduced AGT activity. Policy revised to add that the member has not received a liver transplant in initial authorization criteria and the reauthorization criteria. Policy revised to add that Oxlumo (lumasiran) is not to be used in combination with Rivfloza (nedosiran) for the treatment of PH1 in the limitations of coverage.
PI3K Inhibitors – Medicare	01/01/2025	Policy revised to add Itovebi (inavolisib) to require diagnosis based on FDA-approved indication.
Programmed Death Receptor Therapies – Medicare	10/28/2024	Policy revised to add Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs) to require diagnosis based on FDA-approved

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		indication. Tecentriq (atezolizumab) criteria from policy J-0633 carried over to this policy. Policy revised for Keytruda (pembrolizumab) to require diagnosis based on expanded FDA-approved indication for malignant pleural mesothelioma. Policy revised for Opdivo (nivolumab) to require diagnosis based on expanded FDA-approved indication for neoadjuvant and adjuvant treatment of non-small cell lung cancer. Policy revised for Opdivo (nivolumab) to remove age limitations.
Repository Corticotropin Injections – Medicare	01/01/2025	Policy revised to remove criteria that member is unable to take first-line therapies from gout. Approval duration changed to 1 month initial and 6 months reauthorization for diagnoses of rheumatoid arthritis, juvenile rheumatoid arthritis, and collagen diseases.
Rivfloza (nedosiran) – Medicare	TBD	Policy revised to add the member's diagnosis of primary hyperoxaluria type 1 (PH1) to be confirmed by 1 of the following: Genetic testing demonstrating a mutation in the AGXT gene. OR liver biopsy demonstrating absence or significantly reduced AGT activity. Policy revised to add that the member has not received a liver transplant in the reauthorization criteria. Policy further revised to add that Rivfloza (nedosiran) is not used in combination with Oxlumo (lumasiran) for the treatment of PH1 in the limitations of coverage.
Rybrevant (amivantamab-vmjw) – Medicare	12/20/2024	Policy revised for Rybrevant (amivantamab-vmjw) to require diagnosis based on FDA-approved expanded indication for use in non-small cell lung cancer with disease progression on or after an epidermal growth factor receptor tyrosine kinase inhibitor.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Sarclisa (isatuximab-irfc) – Medicare	01/01/2025	Policy revised for Sarclisa (isatuximab-irfc) to require diagnosis based on expanded FDA-approved indication for newly diagnosed multiple myeloma.
Somatuline (lanreotide) Depot – Medicare	12/20/2024	Policy revised for Somatuline (lanreotide) Depot to require step through generic lanreotide when used for carcinoid syndrome.
Talicia (omeprazole/amoxicillin/rifabutin) – Medicare	01/01/2025	Policy revised to include updated first line recommendations of try/failure of Pylera (bismuth subcitrate potassium, tetracycline, and metronidazole) plus proton pump inhibitor (PPI). Removed criteria for try/failure of PPI-clarithromycin triple therapy.
Tarpeyo (budesonide) – Medicare	01/01/2025	Policy revised to remove requirement of risk of disease progression from reauthorization. For initial and reauthorization, options for concurrent use expanded to include Filspari (sparsentan).
Tarpeyo (budesonide) – Medicare	01/01/2025	Policy revised to define risk of disease progression as proteinuria ≥ 0.5 g/day.
Tavneos (avacopan) – Medicare	12/20/2024	Policy revised for Tavneos (avacopan) to remove age restriction and requirement that member be on a systemic glucocorticoid as part of standard of care.
Tecentriq (atezolizumab) – Medicare	termed 12/19/2024	Policy to be terminated. Criteria for Tecentriq (atezolizumab) carried over to policy J-0411.
Testosterone (Androgens) – Medicare	12/20/2024	Policy revised to add Undecatrex (testosterone undecanoate) capsule as a target requiring FDA-approved diagnosis and laboratory tests supporting low testosterone.
Tezspire (tezepelumab-ekko) – Medicare	12/20/2024	Policy revised to remove the prebronchodilator forced expiratory volume in 1 second (FEV1) below 80% in adults, prebronchodilator FEV1 below 90% in adolescents, and FEV1 reversibility of at least 12% and 200 milliliters after albuterol (salbutamol) administration.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Tiering Exception – Medicare	01/01/2025	Policy revised to include Medicare Part D coverage requirements, add biological products, and align criteria with new cost-share designs. Background updated to better articulate CMS guidelines and applicable drug products.
Tivdak (tisotumab vedotin-tftv) – Medicare	12/20/2024	Policy revised for Tivdak (tisotumab vedotin-tftv) to remove age limitation.
Ustekinumab Biosimilars – Medicare	TBD	Policy revised to add new products Imuldosa (ustekinumab-srlf) and Otulfi (ustekinumab-aauz) subcutaneous (SC) injection and intravenous (IV) infusion requiring age, FDA-approved diagnosis, dosing based on FDA-approved weight, and trial/failure to Stelara (ustekinumab). For plaque psoriasis, trial/failure to phototherapy or systemic therapy, or contraindication to all. For Crohn's disease and ulcerative colitis, if the request is for an ustekinumab SC biosimilar, prescriber attestation of ustekinumab IV induction dose received within 2 months or currently undergoing induction. Selarsdi (ustekinumab-aekn) SC and intravenous (IV) new indication for inflammatory bowel disease added to align with other ustekinumab biosimilar criteria.
Vyalev (foscarbidopa/foslevodopa) – Medicare	12/20/2024	Policy created for Vyalev (foscarbidopa/foslevodopa) requiring the product to be eligible for coverage under Part D per policy J-0030, a diagnosis of advanced Parkinson’s disease, using for the treatment of motor fluctuations, therapeutic failure or intolerance to one of the following oral carbidopa/levodopa products: generic carbidopa-levodopa tablets or orally disintegrating tablets (ODT), generic carbidopa-levodopa ER tablets, or carbidopa/levodopa/entacapone tablets, and therapeutic failure or

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		intolerance to one of the following generic products: ropinirole, pramipexole, entacapone, selegiline, or rasagiline.
Vyloy (zolbetuximab-clzb) – Medicare	12/20/2024	New policy for Vyloy (zolbetuximab-clzb) requiring a diagnosis based on FDA-approved indication supported by immunohistochemistry and FDA-approved diagnostic tests, along with being used in combination with fluoropyrimidine- and platinum-containing chemotherapy.
Wegovy (semaglutide) – Medicare Incentive and Compass	01/01/2025	Policy revised for Wegovy (semaglutide) to require step through statin only if diagnosis of atherosclerotic cardiovascular disease is present.
Xolair (omalizumab) – Medicare	01/01/2025	Policy revised to remove the prebronchodilator forced expiratory volume in 1 second (FEV1) below 80% in adults, prebronchodilator FEV1 below 90% in adolescents, and FEV1 reversibility of at least 12% and 200 milliliters after albuterol (salbutamol) administration.
Xpovio (selinexor) – Medicare	12/20/2024	Policy revised for Xpovio (selinexor) to remove age limitations.
Zytiga and Yonsa (abiraterone acetate) – Medicare	12/20/2024	Policy updated to remove age criteria of 18 years for both Zytiga (abiraterone acetate) and Yonsa (abiraterone acetate).

*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	01/01/2025	Policy revised for Neupogen (filgrastim) to require therapeutic failure or intolerance to Zarxio. (filgrastim-sndz) for hematopoietic syndrome of acute radiation syndrome.
Colony-Stimulating Factors – Medicare	TBD	Policy revised for Nypozi (filgrastim-txid) to require therapeutic failure or intolerance to Zarxio

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		(filgrastim-sndz) for hematopoietic syndrome of acute radiation syndrome.
Non-preferred Inhaler Products – Medicare	01/01/2025	Policy revised to add the member has experience therapeutic failure or intolerance to products when utilized for the same age group for the indication of asthma for Advair Diskus (fluticasone propionate/salmeterol), Flovent HFA/Diskus (fluticasone propionate HFA/Diskus), fluticasone furoate/vilanterol, fluticasone propionate/salmeterol (AirDuo RespiClick), and Symbicort (budesonide/formoterol fumarate).

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)
Aqneursa (levacetylleucine)	4 granule packets per day
Aurlumyn (iloprost)	8 single-dose, 1 mL vials per year
Bimzelx (bimekizumab-bkzx) 160 mg/mL	1 injection (1 mL) per 28 days
Bimzelx (bimekizumab-bkzx) 320 mg/2 mL	1 injection (2 mL) per 28 days
Cobenfy (xanomeline and trospium chloride)	2 capsules per day or 62 capsules per 31 days
Cobenfy (xanomeline and trospium chloride) starter pack	2 packets (112 capsules) per 365 days
Ebglyss (Lebrikizumab-Lbkz)	1 pen/syringe (2 mL) per 28 days
Entyvio (vedolizumab) 300 mg vial	1 vial (300 mg) per 8 weeks
Imuldosa (ustekinumab-srlf) 130 mg/26 mL	8 vials (208 mL) per 365 days
Imuldosa (ustekinumab-srlf) 45 mg/0.5 mL	1 syringe (0.5 mL) per 84 days
Imuldosa (ustekinumab-srlf) 90 mg/mL	1 syringe (1 mL) per 56 days
Itovebi (inavolisib) 3 mg	2 tablets per day
Itovebi (inavolisib) 9 mg	1 tablet per day
Lumakras (sotorasib) 240 mg	2 tablets per day
Lumryz (sodium oxybate) Starter Pack	2 starter packs (56 packets) per year
Miplyffa (arimoclomol)	3 capsules per day
Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq)	1 vial (23 mL) per 180 days
Orlynvah (sulopenem etzadroxil and probenecid)	10 tablets per 5 days

Drug Name	Retail Quantity Limit (31 days)
Otulfi (ustekinumab-aauz) 130 mg/26 mL	8 vials (208 mL) per 365 days
Otulfi (ustekinumab-aauz) 45 mg/0.5 mL	1 syringe (0.5 mL) per 84 days
Otulfi (ustekinumab-aauz) 90mg/mL	1 syringe (1 mL) per 56 days
Selarsdi (ustekinumab-aekn) 130 mg/26 mL	8 vials (208 mL) per 365 days
Selarsdi (ustekinumab-aekn) 90 mg/mL	1 syringe (1 mL) per 56 days
Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs)	1 vial (15 mL) per 21 days
Undecatrex (testosterone undecanoate)	4 capsules per day
Vyalev (foscarbidopa and foslevodopa)	2 vials (20 mL) per day
Zavesca (miglustat) and Yargesa (miglustat)	6 capsules per day