Formulary Updates

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Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for December 2023. 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:

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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

FDA warns of rare but serious drug reaction to the antiseizure medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan)

On Nov. 28, 2023, the U.S Food and Drug Administration (FDA) released a drug safety communication warning that levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan) can cause reaction known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). The reaction can start as a rash but may progress to hospitalization or death. Patients should not stop taking their medications before talking to their health care providers first. Health care professionals should be aware that early recognition of DRESS (drug rash with eosinophilia and systemic symptoms) may improve outcomes.

Highmark Formulary Update – December 2023

SECTION I. Highmark Commercial and Healthcare Reform Formularies

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

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

- Highmark Comprehensive Formulary
- Highmark Healthcare Reform Comprehensive Formulary

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

Table 1. Products Added

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

Brand Name	Generic Name	Comments
Penbraya*	(meningococcal Groups A, B, C, W, and Y Vaccine)	Prevention of N. meningitidis

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

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Agamree*	vamorolone	prednisone tablet
Bimzelx	bimekizumab-bkzx	Taltz autoinjector, Adalimumab-adaz(cf), Skyrizi pen
Bosulif capsules*	bosutinib	Sprycel, Tasigna
Cabtreo	clindamycin phosphate, adapalene, benzoyl peroxide	adapalene 0.3% gel (gram), clindamycin phosphate 1% solution, non-oral
Coxanto	oxaprozin capsules	ibuprofen 400 mg tablet, meloxicam tablet, oxaprozin tablet
Entyvio subcutaneous	vedolizumab	Rinvoq, Xeljanz xr, Adalimumab-adaz(cf)
Exxua*	gepirone	bupropion sr, sertraline hcl tablet
Likmez	metronidazole	metronidazole tablets
Ojjaara	momelotinib	prescriber discretion

Brand Name	Generic Name	Preferred Alternatives
Omvoh pen	mirikizumab-mrkz	Rinvoq, Xeljanz xr, Adalimumab-adaz(cf)
Opfolda	miglustat	prescriber discretion
Pokonza	potassium	potassium chloride tablet, extended release, potassium chloride capsule, extended release
Qlosi*	pilocarpine HCl	prescriber discretion (eyeglasses, contact lenses)
Rivfloza 128 mg/0.8 mL, 160mg/mL pre-filled syringe*	nedosiran	prescriber discretion
Rivfloza vial*	nedosiran	prescriber discretion
Rozlytrek 50 mg oral pellets	entrectinib	prescriber discretion
Velsipity	etrasimod	Rinvoq, Xeljanz xr, Adalimumab-adaz(cf)
Voquezna	vonoprazan	omeprazole capsule, pantoprazole tablet
Wezlana 45 mg/0.5 mL prefilled syringe/vial*	ustekinumab-auub	Stelara syringe (ml) 45mg/0.5mL; Stelara vial (ml) 45mg/0.5mL
Wezlana 90mg/mL prefilled syringe*	ustekinumab-auub	Stelara syringe (ml) 90mg/mL
Xphozah	tenapanor	calcium acetate 667 mg capsule, calcium acetate 667 mg tablet , sevelamer carbonate tablet
Zepbound	tirzepatide	prescriber discretion
Zilbrysq*	zilucoplan	prescriber discretion
Zymfentra*	infliximab-dyyb	Rinvoq, Adalimumab-adaz(cf), Stelara syringe (ml) 90 mg/ml

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

Table 3. Additions to the Specialty Tier Copay Option

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

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

Brand Name	Generic Name
Agamree	vamorolone
Bimzelx	bimekizumab-bkzx
Bosulif capsules	bosutinib
Coxanto	oxaprozin capsules

Entyvio subcutaneous	vedolizumab
Ojjaara	momelotinib
Omvoh pen	mirikizumab-mrkz
Opfolda	miglustat
Pokonza	potassium
Rivfloza 128 mg/0.8 mL & 160 mg/mL pre-filled syringe	nedosiran
Rivfloza vial	nedosiran
Rozlytrek 50 mg oral pellets	entrectinib
Velsipity	etrasimod
Voquezna 10mg and 20 mg	vonoprazan
Wezlana (ustekinumab-auub) 45 mg/0.5 mL, 90 mg/mL prefilled syringe/vial	ustekinumab-auub
Xphozah	tenapanor
Zilbrysq	zilucoplan
Zymfentra	infliximab-dyyb

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 2023, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Penbraya*	meningococcal Groups A, B, C, W, and Y Vaccine	3	Prevention of N. meningitidis
Bosulif capsules*	bosutinib	4	Chronic phase Ph+ CML in 1+ YOA (previously only adults)
Items listed below were not added to the formulary			
Agamree*	vamorolone	NF	prednisone tablet
Bimzelx	bimekizumab-bkzx	NF	Taltz autoinjector, Adalimumab-fkjp(cf), Skyrizi pen
Cabtreo	clindamycin phosphate, adapalene, benzoyl peroxide	NF	adapalene 0.3% gel (gram), clindamycin phosphate 1% solution, non-oral
Coxanto capsules	oxaprozin	NF	ibuprofen 400 mg tablet, meloxicam tablet, oxaprozin tablet
Entyvio subcutaneous	vedolizumab	NF	Rinvoq, Xeljanz xr tablet, Adalimumab-fkjp(cf)
Exxua*	gepirone	NF	Bupropion Sr, Sertraline Hcl Tablet
Likmez	metronidazole	NF	metronidazole tablets
Ojjaara	momelotinib	NF	prescriber discretion

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Omvoh pen	mirikizumab-mrkz	NF	Rinvoq, Xeljanz xr tablet, Adalimumab-fkjp(cf)
Opfolda	miglustat	NF	prescriber discretion
Pokonza	potassium	NF	potassium chloride tablet, extended release, potassium chloride capsule, extended release
Qlosi*	pilocarpine HCl	NF	prescriber discretion (eyeglasses, contact lenses)
Rivfloza 128 mg/0.8 mL, 160 mg/mL pre-filled syringe*	nedosiran	NF	prescriber discretion
Rivfloza vial*	nedosiran	NF	prescriber discretion
Rozlytrek 50 mg oral pellets	entrectinib	NF	prescriber discretion
Velsipity	etrasimod	NF	Rinvoq, Xeljanz xr tablet, Adalimumab-fkjp(cf)
Voquezna	vonoprazan	NF	omeprazole capsule, pantoprazole tablet
Wezlana 45 mg/0.5 mL prefilled syringe/vial*	ustekinumab-auub	NF	Stelara syringe (ml) 45mg/0.5ml, Stelara vial (ml) 45mg/0/5ml
Wezlana 90mg/mL prefilled syringe*	ustekinumab-auub	NF	Stelara syringe (ml) 90mg/mL
Xphozah	tenapanor	NF	calcium acetate 667 mg capsule, calcium acetate 667 mg tablet , sevelamer carbonate tablet
Zepbound	tirzepatide	NF	prescriber discretion
Zilbrysq*	zilucoplan	NF	prescriber discretion
Zymfentra*	infliximab-dyyb	NF	Rinvoq, Adalimumab-fkjp(cf), Stelara syringe (ml) 90 mg/ml

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 2023, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Penbraya*	meningococcal Groups A, B, C, W, and Y Vaccine	3	Prevention of N. meningitidis
Bosulif capsules*	Bosutinib	4	Chronic phase Ph+ CML in 1+ YOA (previously only adults)
Items listed below were not added to the formulary			
Agamree*	vamorolone	NF	prednisone tablet
Bimzelx	bimekizumab-bkzx	NF	Taltz autoinjector, Adalimumab-fkjp(cf), Skyrizi pen
Cabtreo	clindamycin phosphate, adapalene, benzoyl peroxide	NF	adapalene 0.3% gel (gram), clindamycin phosphate 1% solution, non-oral
Coxanto	oxaprozin capsules	NF	ibuprofen 400 mg tablet, meloxicam tablet, oxaprozin tablet
Entyvio subcutaneous	vedolizumab	NF	Rinvoq, Xeljanz xr tablet, Adalimumab-fkjp(cf)
Exxua*	gepirone	NF	bupropion sr, sertraline hcl tablet
Likmez	metronidazole	NF	metronidazole tablets
Ojjaara	momelotinib	NF	prescriber discretion
Omvoh pen	mirikizumab-mrkz	NF	Rinvoq, Xeljanz xr tablet, Adalimumab-fkjp(cf)
Opfolda	miglustat	NF	prescriber discretion
Pokonza	potassium	NF	potassium chloride tablet, extended release, potassium chloride capsule, extended release
Qlosi*	pilocarpine HCl	NF	prescriber discretion (eyeglasses, contact lenses)
Rivfloza 128 mg/0.8 mL, 160 mg/mL pre-filled syringe*	nedosiran	NF	prescriber discretion
Rivfloza vial*	nedosiran	NF	prescriber discretion
Rozlytrek 50 mg oral pellets	entrectinib	NF	prescriber discretion
Velsipity	etrasimod	NF	Rinvoq, Xeljanz xr tablet, Adalimumab-fkjp(cf)
Voquezna	vonoprazan	NF	omeprazole capsule, pantoprazole tablet
Wezlana 45 mg/0.5 mL prefilled syringe/vial*	ustekinumab-auub	NF	Stelara syringe (ml) 45mg/0.5ml; Stelara vial (ml) 45mg/0.5ml

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Wezlana 90mg/mL prefilled syringe*	ustekinumab-auub	NF	Stelara syringe (ml) 90mg/mL
Xphozah	tenapanor	NF	calcium acetate 667 mg capsule, calcium acetate 667 mg tablet , sevelamer carbonate tablet
Zepbound	tirzepatide	NF	prescriber discretion
Zilbrysq*	zilucoplan	NF	prescriber discretion
Zymfentra*	infliximab-dyyb	NF	Rinvoq, adalimumab-adaz(cf), Stelara syringe (ml) 90 mg/ml

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)			
Zepbound	tirzepatide	2	Weight loss
Rozlytrek 50 mg oral pellets	entrectinib	2	NSCLC and solid tumors
Items listed below were added to the formulary (Non-Preferred)			
Bosulif capsules*	bosutinib	3	Sprycel, Tasigna
Coxanto*	oxaprozin capsules	3	ibuprofen 400 mg tablet, meloxicam tablet, oxaprozin
Entyvio subcutaneous*	vedolizumab	3	Rinvoq, Xeljanz xr, Adalimumab-adaz(cf)
Likmez*	metronidazole	3	metronidazole tablets
Omvoh pen*	mirikizumab-mrkz	3	Rinvoq, Xeljanz xr, Adalimumab-adaz(cf)
Voquezna*	vonoprazan	3	omeprazole capsule, pantoprazole tablet
Agamree*	vamorolone	3	prednisone tablet
Exxua*	gepirone	3	bupropion sr, sertraline hcl tablet
Penbraya *	meningococcal Groups A, B, C, W, and Y Vaccine	3	prescriber discretion

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Qlosi *	pilocarpine HCl	3	provider discretion (eyeglasses, contact lenses)
Rivfloza pre-filled syringe*	nedosiran	3	prescriber discretion
Rivfloza vial*	nedosiran	3	prescriber discretion
Wezlana prefilled syringe/vial *	ustekinumab-auub	3	Stelara syringe (ml) 45mg/0.5ml; Stelara vial (ml) 45mg/0.5ml
Zilbrysq *	zilucoplan	3	prescriber discretion
Zymfentra*	infliximab-dyyb	3	Rinvoq, Adalimumab-adaz(cf), Stelara syringe (ml) 90 mg/ml
Opfolda	miglustat	3	prescriber discretion
Velsipity*	etrasimod	3	Rinvoq, Xeljanz xr, Adalimumab-adaz(cf)
Xphozah*	tenapanor	5	calcium acetate 667 mg capsule, calcium acetate 667 mg tablet (drug class = f), sevelamer carbonate tablet
Items listed below were not added to the formulary			
Pokonza	potassium	NF	potassium chloride tablet, extended release, potassium chloride capsule, extended release
Bimzelx	bimekizumab-bkzx	NF	Taltz autoinjector, Adalimumab-adaz(cf), skyrizi pen
Cabtreo	clindamycin phosphate, adapalene, benzoyl peroxide	NF	adapalene 0.3% gel (gram), clindamycin phosphate 1% solution, non-oral
Ojjaara	momelotinib	NF	Jakafi

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
Agamree	vamorolone
Bimzelx	bimekizumab-bkzx
Bosulif capsules	bosutinib
Coxanto	oxaprozin capsules
Entyvio subcutaneous	vedolizumab
Ojjaara	momelotinib
Omvoh pen	mirikizumab-mrkz
Opfolda	miglustat
Pokonza	potassium
Rivfloza 128 mg/0.8 mL, 160 mg/mL pre-filled syringe	nedosiran
Rivfloza vial	nedosiran

Rozlytrek 50 mg oral pellets	entrectinib
Velsipity	etrasimod
Voquezna	vonoprazan
Wezlana 45 mg/0.5 mL, 90 mg/mL prefilled syringe/vial	ustekinumab-auub
Xphozah	tenapanor
Zilbrysq	zilucoplan
Zymfentra	infliximab-dyyb

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Agamree (vamorolone) – Commercial and Healthcare Reform	TBD	New policy for Agamree (vamorolone) to require diagnosis of Duchenne muscular dystrophy (DMD) confirmed by a mutation in the dystrophin gene, the member is ambulatory, the medication is prescribed by a specialist, and the member has experienced a delay or decline in growth while on prednisone that is not expected to occur with Agamree. Reauthorization requiring positive clinical response to therapy.
BCR-ABL Kinase Inhibitors – Commercial and Healthcare Reform	12/22/2023	Policy revised for Bosulif (bosutinib) to require age and diagnosis based on expanded FDA-approved indication.
BCR-ABL Kinase Inhibitors – Commercial and Healthcare Reform	12/22/2023	Policy revised to add Bosulif (bosutinib) oral capsules to require diagnosis based on FDA-approved indication, inability to swallow oral tablets and the request is for the 100 mg capsules for adults, and inability to swallow oral tablets if the request is for the 100 mg oral capsules for pediatric patients.
CaroSpir (spironolactone) – Commercial and Healthcare Reform	12/22/2023	Policy revised to add generic spironolactone oral suspension requiring diagnosis, the member cannot swallow tablets, and failure/intolerance to spironolactone tablets. For brand CaroSpir, failure/intolerance to the generic susp was added for initial and reauthorization. For reauthorization, positive response to therapy required and documentation that member cannot swallow tablets.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Chenodal (chenodiol) – Commercial and Healthcare Reform	12/22/2023	Policy revised to require the member is 18 years of age or older.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	12/15/2023	Policy revised to add Bimzelx (bimekizumab-bkzx) requiring age, diagnosis, trial/failure/contraindication to systemic therapy or phototherapy, trial/failure to two step 1 or 2 preferred agents for plaque psoriasis, and documentation weight is consistent with FDA-approved dosing regimen. Entyvio (vedolizumab) subcutaneous (SC) added requiring age, diagnosis, trial/failure to at least 2 step 1 preferred agents for ulcerative colitis, and clinical response/remission achieved after at least 2 doses of Entyvio IV at least 6 weeks before initiating Entyvio SC. Omvoh (mirikizumab-mrkz) SC added requiring age, diagnosis, trial/failure to 2 step 1 agents for ulcerative colitis, and clinical response/remission achieved after 3 induction doses of Omvoh IV within 3 months before initiating Omvoh SC. Velsipity (etrasimod) added requiring age, diagnosis, trial/failure to 1 systemic therapy, trial/failure to 2 step 1 agents for ulcerative colitis. All new products added reauthorization requiring disease stability or beneficial response to therapy. New indication for Cosentyx (secukinumab) SC in hidradenitis suppurativa added requiring age, diagnosis, and quantity level limit exception. Enbrel (etanercept) and Orencia (abatacept) SC age updated from 18 months to 2 years for juvenile psoriatic arthritis.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	TBD	Policy revised to add Zymfentra (infliximab-dyyb) subcutaneous requiring age, diagnosis, trial/failure to 2 step 1 agents for ulcerative colitis or Crohn's disease, and clinical response/remission once the member has received at least 3 doses of infliximab IV at least 10 weeks before initiating therapy with Zymfentra. Reauthorization added requiring disease stability or beneficial response to therapy.
Chronic Inflammatory Diseases – Commercial National Select	12/15/2023	Policy revised to add Bimzelx (bimekizumab-bkzx) requiring age, diagnosis, trial/failure/contraindication to systemic therapy

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		or phototherapy, trial/failure to 2 step 1 or 2 preferred agents for plaque psoriasis, and documentation weight is consistent with FDA-approved dosing regimen. Entyvio (vedolizumab) subcutaneous (SC) added requiring age, diagnosis, trial/failure to at least 2 step 1 preferred agents for ulcerative colitis, and clinical response/remission achieved after at least 2 doses of Entyvio IV at least 6 weeks before initiating Entyvio SC. Omvoh (mirikizumab-mrkz) SC added requiring age, diagnosis, trial/failure to 2 step 1 agents for ulcerative colitis, and clinical response/remission achieved after 3 induction doses of Omvoh IV within 3 months before initiating Omvoh SC. Velsipity (etrasimod) added requiring age, diagnosis, trial/failure to 1 systemic therapy, trial/failure to 2 step 1 agents for ulcerative colitis. All new products added reauthorization requiring disease stability or beneficial response to therapy. New indication for Cosentyx (secukinumab) SC in hidradenitis suppurativa added requiring age, diagnosis, and quantity level limit exception. Enbrel (etanercept) and Orencia (abatacept) SC age updated from 18 months to 2 years for juvenile psoriatic arthritis.
Glucosylceramide Synthase Inhibitors for Gaucher Disease – Commercial and Healthcare Reform	12/22/2023	Policy revised to add Yargesa (miglustat) to require age, diagnosis based on FDA-approved indication supported by lab values or signs and symptoms, and trial/failure/contraindication to enzyme replacement therapy. Reauthorization requiring positive clinical response supported by signs/symptoms or lab values.
Human Growth Hormone – Commercial and Healthcare Reform	12/22/2023	Policy revised for growth hormone products to remove documentation of growth velocity < 2 cm/year and specification for clinical documentation of epiphyseal fusion in adults transitioning from pediatric care.
Human Growth Hormone – Delaware Commercial and Healthcare Reform	12/22/2023	Policy revised for growth hormone products to remove documentation of growth velocity < 2 cm/year and specification for clinical documentation of epiphyseal fusion in adults transitioning from pediatric care.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
IDH1 Inhibitors – Commercial and Healthcare Reform	12/22/2023	Policy revised for Tibsovo (ivosidenib) to require diagnosis based on expanded FDA-approved indication.
JAK inhibitors – Commercial and Healthcare Reform	12/22/2023	Policy revised to include Vonjo (pacritinib) and Ojjaara (momelolitinib) with criteria requiring age and FDA-approved indication. Criteria requiring primary or secondary designation of diagnosis removed for Jakafi (ruxolitinib) and Inrebic (fedratinib). Reauthorization criteria for Vonjo updated to remove platelet count.
Likmez (metronidazole) – Commercial and Healthcare Reform	TBD	New policy created for Likmez (metronidazole) requiring appropriate diagnosis and age based on FDA-approved indications, and that the member is either unable to swallow oral solid dosage forms or has experienced failure/intolerance to plan-preferred, generic metronidazole tablets. Reauthorization requiring documentation of repeat episode of infection, a minimum 4-week gap if repeat course is for trichomoniasis infection and either a continued inability to swallow solid dosage forms or failure/intolerance to plan-preferred, generic metronidazole tablets.
Lumryz (sodium oxybate), Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates) – Commercial and Healthcare Reform	01/01/2024	Policy revised to require a step through generic sodium oxybate for brand Xyrem (sodium oxybate) for initial and reauthorization.
Market Watch Programs – Delaware	TBD	Policy revised to add Pokonza (potassium chloride for oral solution) to high cost/low value medications to require trial/failure of potassium chloride oral capsules and tablets. Policy revised to add Coxanto (oxaprozin) to high cost/low value medications to require trial/failure of ibuprofen, meloxicam, and oxaprozin. Policy revised to update the methocarbamol 500 mg therapeutic alternative product to methocarbamol 500 mg or 750 mg.
Market Watch Programs – New York, Pennsylvania and West Virginia	TBD	Policy revised to add Pokonza (potassium chloride for oral solution) to high cost/low value medications to require trial/failure of potassium chloride oral capsules and tablets. Policy

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		revised to add Coxanto (oxaprozin) to high cost/low value medications to require trial/failure of ibuprofen, meloxicam, and oxaprozin. Policy revised to update the methocarbamol 500 mg therapeutic alternative product to methocarbamol 500 mg or 750 mg.
NTRK Inhibitors – Commercial and Healthcare Reform	12/22/2023	Policy revised for Rozlytrek (entrectinib) approval criteria to include members older than one month of age for NTRK gene fusion cancers per the FDA-approved expanded indication
Pokonza (potassium chloride) – Commercial and Healthcare Reform	12/22/2023	New policy for Pokonza (potassium chloride for oral solution) requiring diagnosis based on FDA-approved indication, an inability to swallow solid oral dosage forms, and if the member is 18 years of age or older, trial/failure of potassium chloride oral capsules and tablets.
Rivfloza (nedosiran) – Commercial and Healthcare Reform	TBD	New policy for Rivfloza (nedosiran) requiring genetically confirmed FDA approved diagnosis, at least two elevated urinary oxalate levels more than 1.5 times the upper reference limit, and one of the following: biochemical unresponsive or partial responsiveness to pyridoxine or mutation consistent with pyridoxine unresponsiveness. Reauthorization requiring continued preserved kidney function and at least 30% decrease in reduction in urinary oxalate levels.
Tarpeyo (budesonide) – Commercial and Healthcare Reform	12/22/2023	Policy revised for Tarpeyo (budesonide) to require diagnosis confirmation via biopsy for initial authorization, and risk for rapid disease progression evidenced by urine protein-to-creatinine ratio ≥ 1.5 g/g or proteinuria ≥ 1 g/day for initial and reauthorization.
Trientine and Penicillamine Products - Commercial and Healthcare Reform	12/22/2023	Policy revised to add if the request is for trientine hydrochloride 500 mg capsules trial/failure of generic trientine hydrochloride 250 mg capsules in initial and reauthorization. Clarified that if the request is brand Syprine (trientine hydrochloride), the member has tried/failed its generic trientine hydrochloride 250 mg capsules.
Ustekinumab Biosimilars – Commercial and Healthcare Reform	TBD	New policy for Wezlana (ustekinumab-auub) requiring age and diagnosis based on FDA-approved indication; therapeutic failure/intolerance to Stelara (ustekinumab); the

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		member achieved clinical response or remission with intravenous induction dosing for Crohn's disease and ulcerative colitis; trial/failure of one non-steroidal anti-inflammatory drug, local glucocorticoid injection, and/or non-biologic disease-modifying antirheumatic drug for psoriatic arthritis (PsA), depending on type of PsA; or trial/failure/contraindication to phototherapy or systemic therapy for plaque psoriasis. Reauthorization to require attestation of disease stability or beneficial response to therapy. Quantity limitation criteria to allow for induction and maintenance dosing per FDA-label. For Crohn's disease, if the member is a non-responder or partial responder to one syringe every 8 weeks, one prefilled syringe every 4 weeks may be approved.
Veltassa (patiromer) and Lokelma (sodium zirconium cyclosilicate) – Commercial and Healthcare Reform	12/22/2023	Policy revised for Veltassa (patiromer) to lower age to 12 years and older.
Voquezna (vonoprazan) Products – Commercial and Healthcare Reform	12/22/2023	Policy revised for Voquezna (vonoprazan) to require age, FDA-approved indication, and trial and failure through omeprazole and pantoprazole if the request is for erosive esophagitis.
Vtama (tapinarof) and Zoryve (roflumilast) – Commercial and Healthcare Reform	12/22/2023	Policy revised for Zoryve (roflumilast) to update age to 6 years and older based on FDA-approved indication.
Xphozah (tenapanor) – Commercial and Healthcare Reform	12/22/2023	New policy created for Xphozah (tenapanor) to require a patient to be 18 years of age and older, the patient has a diagnosis of CKD and is on dialysis, and the member meets one of the following: the member is using Xphozah as add-on therapy for those who have an inadequate response to both calcium acetate and sevelamer carbonate tablet or the member has experienced intolerance or contraindication to both calcium acetate and sevelamer carbonate tablet.
Zilbrysq (zilucoplan) – Commercial and Healthcare Reform	TBD	Policy created for Zilbrysq (zilucoplan) to require diagnosis based on FDA-approved indication, positive serologic test for anti-acetylcholine receptor antibodies (AChR Ab+), member must

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		have Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of II to IV at start of therapy, member has had therapeutic failure, contraindication or intolerance pyridostigmine, the member has had a trial and inadequate response or intolerance to one or more immunosuppressive agents. Reauthorization requires an improvement in signs and symptoms of generalized myasthenia gravis (gMG) or a decrease in the number of exacerbations of gMG.

*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
Cyclobenzaprine, Metaxalone, and Methocarbamol Products – Commercial and Healthcare Reform	12/22/2023	Policy revised to update the step therapy option from generic methocarbamol 500 mg tablets to generic methocarbamol tablets.
Exxua (gepirone) - Commercial and Healthcare Reform	TBD	New policy for Exxua (gepirone) to require age ≥ 18 years, diagnosis based on FDA-approved indication of MDD, and therapeutic failure, contraindication, or intolerance to two (2) other plan-preferred generic antidepressants (e.g., SSRI, SNRI, NDRI).
Furadantin (nitrofurantoin) Oral Suspension – Commercial and Healthcare Reform	12/22/2023	Policy updated to require both: therapeutic failure/intolerance to nitrofurantoin microcrystal capsules or nitrofurantoin monohydrate microcrystal capsules AND if the member has an inability to swallow capsules, therapeutic failure/intolerance to the nitrofurantoin microcrystal capsule opened and mixed with food or juice.
Gout Therapies – Commercial and Healthcare Reform	12/22/2023	Policy revised to require members ≥ 18 years of age if allopurinol 200 mg is being prescribed for primary or secondary gout, or recurrent calcium oxalate calculi per the FDA-approved indication. Policy revised to remove colchicine capsules — authorized generic and criteria was combined with existing Mitigare criteria.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Insomnia Medications – Commercial and Healthcare Reform	TBD	Policy revised to add flurazepam to targeted drug products. Member must have an FDA-approved diagnosis and therapeutic failure, contraindication, or intolerance to two of our plan-preferred agents.
Non-Preferred NSAIDs – Commercial and Healthcare Reform	TBD	Policy revised to add Coxanto (oxaprozin) to require trial of two generic alternatives (diclofenac, ibuprofen, indomethacin, meloxicam, nabumetone, (or naproxen), and generic oxaprozin.
Topical Acne Products – Commercial and Healthcare Reform	01/01/2024	Policy revised for all agents to update from triple step through individual agents to double step through plan-preferred agents: 1 topical retinoid and 1 topical antibiotic, and sulfasalazine removed as a qualifier. Avita (tretinoin) gel, generic Onexton (benzoyl peroxide/clindamycin) and generic Retin-A Micro Pump 0.08% (tretinoin microsphere) added to step therapy. Brand Retin-A (tretinoin) and Altreno (tretinoin) removed from step therapy.
Topical Acne Products – Commercial and Healthcare Reform	TBD	Policy revised to add generic tretinoin micronized products requiring step through one plan-preferred topical retinoid and one topical antibiotic
Topical Acne Products – Commercial and Healthcare Reform	TBD	Policy revised to add Cabtreo (clindamycin phosphate, adapalene, and benzoyl peroxide) as a target requiring the member is 12 years of age or older, the member has a diagnosis of acne vulgaris, and the member has experienced therapeutic failure or intolerance to one plan-preferred, generic topical acne product from two different therapeutic categories (topical retinoids and topical antibiotics), or all are contraindicated.
Topical Corticosteroids – Commercial and Healthcare Reform	12/22/2023	Policy revised to add amcinonide 0.1% ointment requiring therapeutic failure or intolerance to at least two plan preferred topical corticosteroids. Amcinonide 0.1% cream removed from policy due to being off market.

*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/or Approval Criteria
Zero-Dollar Cost Share Exception: Statins – Commercial and Healthcare Reform plans Compliant with the Affordable Care Act Preventative Service Mandates	12/22/2023	Policy revised to add generic pitavastatin to require a cost share exception review prior to coverage at $0, similar to other high-cost generics.

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)	2 pens/syringes (2 mL) per 56 days	2 pens/syringes (2 mL) per 56 days
Entyvio (vedolizumab) subcutaneous	2 syringes/pens (1.36 mL) per 28 days	6 syringes/pens (4.08 mL) per 84 days
Lupron Depot Ped 11.25 mg 1 month kit*	1 kit per 30 days	3 kits per 90 days
Lupron Depot Ped 11.25 mg 3 month kit*	1 kit per 90 days	1 kit per 90 days
Omvoh (mirikizumab-mrkz) pen	2 prefilled pens (2 mL) every 28 days	6 prefilled pens (6 mL) every 84 days
Opfolda (miglustat)	8 capsules per 28 days	24 capsules per 84 days
Qlosi (pilocarpine HCl)	24 mL (1 carton of 60 single-patient-use vials) per 30 days	72 mL (3 cartons of 180 single-patient-use vials) per 90 days
Rivfloza (nedosiran) pre-filled syringe	1 pre-filled syringe (per 28 days	3 pre-filled syringes per 84 days
Rivfloza (nedosiran) vial	2 vials (1 mL) per 28 days	6 vials (3 mL) per 84 days
Vuity (pilocarpine hydrochloride)	5 mL per 18 days	15 mL per 56 days
Wezlana (ustekinumab-auub) 45 mg/0.5 mL prefilled syringe/vial	1 syringe/vial (0.5 mL) per 84 days	1 syringe/vial (0.5 mL) per 84 days
Wezlana (ustekinumab-auub) 90 mg/mL prefilled syringe	1 syringe (1 mL) per 84 days	1 syringe (1 mL) per 84 days
Zepbound (tirzepatide)	4 pens per 21 days	12 pens per 63 days
Zymfentra (infliximab-dyyb)	2 syringes/pens (2 mL) per 28 days	6 syringes/pens (6 mL) per 84 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
Amcinonide 0.1% Ointment	60 grams per dispensing event	60 grams per dispensing event
Cabtreo (clindamycin phosphate, adapalene, benzoyl peroxide)	50 grams (1 tube/pump) per dispensing event	150 grams (3 tubes/pumps) 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
Agamree (vamorolone)	7.5 mL per day
Bosulif (bosutinib capsules) 100 mg	6 capsules per day
Bosulif (bosutinib capsules) 50 mg	1 capsule per day
Coxanto (oxaprozin capsules)	4 capsules per day
Exxua (gepirone)	1 tablet per day
Ojjaara (momelotinib)	1 tablet per day
Rozlytrek (entrectinib) 100 mg capsule	1 capsule per day
Rozlytrek (entrectinib) 50 mg oral pellets	1 packet (50 mg) per day
Trientine Hcl 500 Mg Capsule	4 capsules per day
Velsipity (etrasimod)	1 tablet per day
Voquezna (vonoprazan) 10 mg	1 tablet per day
Voquezna (vonoprazan) 20 mg	2 tablets per day
Xphozah (tenapanor)	2 tablets per day
Yargesa (miglustat)	3 capsules per day
Zilbrysq (zilucoplan)	1 single-dose prefilled syringe 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
Penbraya	(meningococcal Groups A, B, C, W, and Y Vaccine)	Prevention of N. meningitidis

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

Brand Name	Generic Name	Preferred Alternatives
Coxanto	oxaprozin capsules	ibuprofen, meloxicam, naproxen tablet
Exxua	gepirone	bupropion SR, sertraline HCL tablet
Likmez	metronidazole	metronidazole tablets
Opfolda	miglustat	prescriber discretion
Qlosi	pilocarpine HCl	prescriber discretion

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

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

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

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

Brand Name	Generic Name	Comments
Penbraya	meningococcal Groups A, B, C, W, and Y Vaccine	Prevention of N. meningitidis

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

Brand Name	Generic Name	Preferred Alternatives
Exxua	gepirone	bupropion SR, sertraline HCL Tablet

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

Brand Name	Generic Name	Preferred Alternatives
Agamree	vamorolone	prednisone
Bimzelx	bimekizumab-bkzx	Taltz Autoinjector, Humira (CF) Pen, Skyrizi pen injector
Cabtreo	clindamycin phosphate, adapalene, benzoyl peroxide	Adapalene, Benzoyl Peroxide, Clindamycin Phosphate
Cosentyx Intravenous	secukinumab	Taltz Autoinjector, Rinvoq tablet extended release 24 hr 15 mg, Simponi Aria
Coxanto	oxaprozin capsules	ibuprofen, meloxicam, naproxen tablet
Entyvio subcutaneous	vedolizumab	Rinvoq, Xeljanz XR, Humira (CF) Pen
Likmez	metronidazole	Metronidazole tablets
Omvoh pen	mirikizumab-mrkz	Rinvoq, Xeljanz XR, Humira (CF) Pen
Omvoh vial	mirikizumab-mrkz	Rinvoq, Xeljanz XR, Humira (CF) Pen
Opfolda	miglustat	prescriber discretion
Pokonza	potassium	potassium chloride tablet extended release, potassium chloride capsule extended release, potassium chloride liquid
Pombiliti	cipaglucosidase alfa-atga	prescriber discretion
Qlosi	pilocarpine HCl	prescriber discretion
Tofidence	tocilizumab-bavi	methotrexate Sodium, leflunomide
Velsipity	etrasimod	Rinvoq, Xeljanz XR, Humira (CF) Pen
Voquezna 10 mg	vonoprazan	omeprazole capsule, pantoprazole tablet
Voquezna 20 mg	vonoprazan	lansoprazole-amoxicillin-clarithromycin, omeprazole capsule
Wezlana 130 mg/26 mL, 45 mg/0.5 mL, 90 mg/mLvial	ustekinumab-auub	Stelara
Zymfentra	infliximab-dyyb	Rinvoq, Humira (CF) Pen, Stelara syringe 90 mg/mL

*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
Aphexda	motixafortide
Bosulif 50mg and 100 mg	bosutinib capsules
Loqtorzi	toripalimab-tpzi
Ojjaara	momelotinib
Rivfloza 128 mg/0.8 mL, 160 mg/mL pre-filled syringe	nedosiran
Rivfloza vial	nedosiran
Rozlytrek 50 mg oral pellets	entrectinib
Zilbrysq	zilucoplan

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Administrative Prior Authorizations for Medicare Part D Plans – Medicare	12/22/2023	Policy revised to remove Photofrin (porfimer) as a target for BvD infusion pump review. Policy revised to reference National Coverage Determination: Infusion Pumps (280.14) as the source for infusion pump coverage criteria.
Agamree (vamorolone) – Medicare	TBD	New policy for Agamree (vamorolone) to require diagnosis of Duchenne muscular dystrophy (DMD) confirmed by a mutation in the dystrophin gene, therapeutic failure, intolerance, or contraindication to prednisone or decline/delay in growth while on prednisone.
Auvelity (dextromethorphan hydrobromide and bupropion hydrochloride) and Exxua (gepirone) – Medicare	TBD	Policy updated to add Exxua (gepirone) to require diagnosis based on FDA-approved indication of MDD, therapeutic failure, contraindication, or intolerance to one (1) other generic antidepressant (e.g., SSRI, SNRI), and therapeutic failure or intolerance to generic bupropion hydrochloride tablets.
BCR-ABL Kinase Inhibitors – Medicare	01/01/2024	Policy revised for Bosulif (bosutinib) to require age and diagnosis based on expanded FDA-approved indication.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
BCR-ABL Kinase Inhibitors – Medicare	01/01/2024	Policy revised to add Bosulif (bosutinib) oral capsules to require diagnosis based on FDA-approved indication, inability to swallow oral tablets for adults, and inability to swallow oral tablets if the request is for the 100 mg oral capsules for pediatric patients.
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Medicare	12/22/2023	Policy revised for Braftovi (encorafenib) and Mektovi (binimetinib), used in combination, to require diagnosis based on expanded FDA-approved indication for non-small cell lung cancer with a BRAF V600E mutation.
Chronic Inflammatory Diseases – Medicare	01/01/2024	Policy revised for Kevzara (sarilumab) to remove step through one non-biologic disease modifying anti-rheumatic drug (DMARD).
Chronic Inflammatory Diseases – Medicare	12/15/2023	Policy revised to add Bimzelx (bimekizumab-bkzx) requiring age, diagnosis, trial/failure/contraindication to systemic therapy or phototherapy, trial/failure to at least 2 preferred biologics for plaque psoriasis, and documentation weight is consistent with FDA-approved dosing regimen. Cosentyx (secukinumab) intravenous (IV) added to require age, diagnosis, trial/failure to 1 NSAID for ankylosing spondylitis and 2 NSAIDs for non-radiographic axial spondyloarthritis, and trial/failure to at least 2 preferred biologics for respective indication. Entyvio (vedolizumab) subcutaneous (SC) added requiring age, diagnosis, trial/failure to at least 2 preferred biologics for ulcerative colitis, and clinical response/remission achieved after at least 2 doses of Entyvio IV at least 6 weeks before initiating Entyvio SC. Criteria combined with J-0934 for Entyvio IV. Omvoh (mirikizumab-mrkz) IV/SC added requiring age, diagnosis, trial/failure to at least 2 preferred biologics for ulcerative colitis, and if requesting Omvoh SC – clinical response/remission achieved after 3 induction doses of Omvoh IV within 3 months before initiating Omvoh SC. Velsipity (etrasimod) added requiring diagnosis, trial/failure to 1 systemic therapy, trial/failure to at least 2 preferred biologics for ulcerative colitis. New indication for Cosentyx (secukinumab) SC in hidradenitis suppurativa

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		added requiring age, diagnosis, and quantity level limit exception. Enbrel (etanercept) and Orencia (abatacept) SC age updated from 18 to 2 years for juvenile psoriatic arthritis.
Chronic Inflammatory Diseases – Medicare	TBD	Policy revised to add Zymfentra (infliximab-dyyb) subcutaneous requiring age, diagnosis, trial/failure to at least 2 preferred biologics for ulcerative colitis or Crohn's disease, and clinical response/remission once the member has received at least 3 doses of infliximab IV at least 10 weeks before initiating therapy with Zymfentra.
Disease-Modifying Medications for Generalized Myasthenia Gravis – Medicare	01/01/2024	Policy revised to add Zilbrysq (zilucoplan) to require diagnosis based on FDA-approved indication, the member must be anti-acetylcholine receptor (AChR) antibody positive (Ab+) and the member has experienced therapeutic failure, contraindication, or intolerance to generic pyridostigmine.
Elevidys (delandistrogene moxeparvovec-rokl) – Medicare	01/01/2024	New policy for Elevidys (delandistrogene moxeparvovec-rokl) requiring FDA approved diagnosis, the member does not have a deletion in exon 8 and/or 9 of the Duchenne Muscular Dystrophy (DMD) gene, anti-AAVrh74 total binding tiers <1:400., and that a corticosteroid regimen will be initiated for a minimum of 60 days unless earlier tapering is clinically indicated. A limitation of coverage that additional approvals should not be granted.
Entyvio (vedolizumab) – Medicare	12/20/2023	Policy terminated. Criteria combined with J-0561.
Enzyme Replacement Therapy (ERT) for Pompe Disease – Medicare	01/01/2024	Policy revised for Enzyme Replacement Therapy for Lumizyme (alglucosidase alfa) and Nexviazyme (avalglucosidase alfa-ngpt) to apply reauthorization requiring improvement in signs or symptoms or reduction in glycogen accumulation.
Enzyme Replacement Therapy (ERT) for Pompe Disease – Medicare	01/01/2024	Policy revised for Enzyme Replacement Therapy to add Lumizyme (alglucosidase alfa), Nexviazyme (avalglucosidase alfa-ngpt), Opfolda (miglustat), and Pombiliti (cipaglucosidase alfa-atga) into one policy. For Opfolda (miglustat) and Pombiliti (cipaglucosidase alfa-atga) requiring age, weight >= 40 kg, diagnosis based on FDA-approved

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		indication, member is not improving on current enzyme replacement therapy, and member is using both drugs together. Reauthorization to require improvement in signs or symptoms or reduction in glycogen accumulation and both drugs continue to be used together.
Glucosylceramide Synthase Inhibitors for Gaucher Disease – Medicare	12/22/2023	Policy revised to add Yargesa (miglustat) to require diagnosis based on FDA-approved indication supported by lab values or signs and symptoms, and enzyme replacement therapy is not a therapeutic option.
Hematopoietic Stem Cell Mobilizers – Medicare	TBD	Policy revised to add Aphexda (motixafortide) to require a diagnosis of multiple myeloma and concomitant use with filgrastim.
High Risk Medications in the Elderly – Medicare	01/01/2024	Policy revised to remove ergotamine tartrate sublingual tablet and ergotamine tartrate/caffiene tablets from criteria.
Human Growth Hormone – Medicare	12/22/2023	Policy revised for growth hormone products to remove documentation of growth velocity < 2 cm/year in adults transitioning from pediatric care.
IDH1 Inhibitors – Medicare	01/01/2024	Policy revised for Tibsovo (ivosidenib) to require diagnosis based on expanded FDA-approved indication.
Interleukin (IL)-5 Antagonists – Medicare	01/01/2024	Policy revised to add Cinqair (reslizumab) requiring diagnosis of severe asthma confirmed by forced expiratory volume in 1 second (FEV1) testing; either ≥ 2 exacerbations in last 12 months or inadequate symptom control with an inhaled corticosteroid plus ≥ 3 months of a controller medication, unless intolerance/ contraindications to all these agents; and blood eosinophil count at baseline ≥ 150 cells/mCL within past 6 weeks or ≥ 300 cells/mcL within past 12 months. Reauthorization requires decreased rescue medication or oral corticosteroid use, decreased frequency of severe exacerbations, increase in pulmonary function, or reduced asthma-related symptoms.
JAK inhibitors – Medicare	12/22/2023	Policy revised to include Ojjaara (momelolitinib) and Vonjo (pacritinib) with criteria requiring FDA-approved indication. Criteria requiring primary or secondary designation of diagnosis

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		removed for Jakafi (ruxolitinib) and Inrebic (fedratinib).
Lidoderm (lidocaine patch) – Medicare	12/22/2023	Policy updated to add a step for the member to experience a therapeutic failure or intolerance to generic lidocaine patch 5% if the request is for brand Lidoderm (lidocaine patch).
Likmez (metronidazole) – Medicare	TBD	New policy created for Likmez (metronidazole) requiring appropriate diagnosis based on FDA-approved indications, and that the member is either unable to swallow oral solid dosage forms or has experienced failure/intolerance to plan-preferred, generic metronidazole tablets. Reauthorization requiring documentation of repeat episode of infection and a minimum 4-week gap if repeat course is for trichomoniasis infection.
Lodoco (colchicine) – Medicare	11/20/2023	Policy revised for Lodoco (colchicine) to remove step through Repatha (evolocumab).
Lumizyme (alglucosidase alfa) – Medicare	12/20/2023	Terminating as drug is combined into J-1113 Enzyme Replacement Therapy (ERT) for Pompe Disease – Medicare
Mechanistic Target of Rapamycin Kinase (mTOR) Inhibitors – Medicare	01/01/2024	Policy updated for Afinitor (everolimus) to align indications with package insert.
Mechanistic Target of Rapamycin Kinase (mTOR) Inhibitors – Medicare	01/01/2024	Policy updated for Afinitor Disperz (everolimus tablets for oral suspension) for the treatment of tuberous sclerosis complex with subependymal giant cell astrocytoma to require the member experience therapeutic failure or intolerance to generic everolimus tablets or that the member is unable to swallow generic everolimus tablets, and that the member experience therapeutic failure or intolerance to generic everolimus tablets for suspension.
Oxlumo (lumasiran) – Medicare	01/01/2024	Policy revised to require genetically confirmed diagnosis and 1 of the following: ≥ 2 elevated urinary oxalate (OXU) > 1.5x the upper reference limit or plasma oxalate > reference limit. Reauthorization requiring 1 of the following: a 30% reduction in OXU from baseline or 20% reduction in plasma oxalate levels from baseline.
Pokonza (potassium chloride) – Medicare	TBD	New policy for Pokonza (potassium chloride for oral solution) requiring diagnosis based on FDA-approved indication, an inability to swallow solid

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		oral dosage forms, and if the member is 18 years of age or older, trial/failure of potassium chloride oral capsules and tablets.
Programmed Death Receptor Therapies – Medicare	12/22/2023	Policy revised to add Loqtorzi (toripalimab-tpzi) to policy. Member must have an FDA-approved diagnosis.
Programmed Death Receptor Therapies – Medicare	12/22/2023	Policy revised for Keytruda (pembrolizumab) and Opdivo (nivolumab) to require diagnosis based on expanded FDA-approved indications.
Qlosi and Vuity (pilocarpine hydrochloride) – Medicare	TBD	Policy revised to add Qlosi (pilocarpine hydrochloride) to require age and diagnosis based on FDA-approved indication.
Rivfloza (nedosiran) – Medicare	TBD	New policy for Rivfloza (nedosiran) requiring genetically confirmed FDA approved diagnosis and at least two elevated urinary oxalate levels more than 1.5 times the upper reference limit. Reauthorization requiring continued preserved kidney function and at least 30% decrease in reduction in urinary oxalate levels.
Sucraid (sacrosidase) – Medicare	01/01/2024	Policy revised for Sucraid (sacrosidase) to remove requirement for sucrase deficiency.
Symproic (naldemedine) and Relistor (methylnaltrexone bromide) – Medicare	01/01/2024	Policy revised to remove the one month requirement of patients taking opioids.
Tarpeyo (budesonide) – Medicare	01/01/2024	Policy revised for Tarpeyo (budesonide) to require diagnosis confirmation with biopsy, and the member is at risk of rapid disease progression, evidenced by urine protein-to-creatinine ratio ≥ 1.5 g/g or proteinuria ≥ 1 g/day for initial and reauthorization.
Tezspire (tezepelumab-ekko) – Medicare	01/01/2024	Policy updated to add a step for the member to experience therapeutic failure, intolerance or contraindication to one (1) of the following products: Cinqair, Dupixent, Fasenra, Nucala, or Xolair.
Trientine Products – Medicare	12/22/2023	Policy revised to add trientine hydrochloride 500 mg capsule to require diagnosis based on FDA-approved indication, intolerant of penicillamine, and trial/failure of generic trientine hydrochloride 250 mg capsules.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Veltassa (patiromer) and Lokelma (sodium zirconium cyclosilicate) – Medicare	12/22/2023	Policy revised for Veltassa (patiromer) to lower age to 12 years and older.
Vonjo (pacritinib) – Medicare	12/22/2023	Policy terminated (combined with J-0904).
Voquezna (vonoprazan) Products – Medicare	01/01/2024	New policy for Voquezna (vonoprazan), Voquezna Triple Pak (vonoprazan/amoxicillin/clarithromycin), and Voquezna Dual Pak (vonoprazan/amoxicillin) to require FDA-approved indication, and trial and failure through omeprazole and pantoprazole if the request is for erosive esophagitis for Voquezna (vonoprazan).
Voxzogo (vosoritide) – Medicare	12/22/2023	Policy revised for Voxzogo (vosoritide) to allow use in pediatrics 17 years of age and younger.
ZTLido (lidocaine 1.8% topical system) – Medicare	12/22/2023	Policy updated to change third criteria to require the member has experienced therapeutic failure, contraindication, or intolerance to generic lidocaine patch 5%.

*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	01/01/2024	Policy revised to add Stimufend (pegfilgrastim-fpgk) requiring FDA-approved indication and a step through two of the following: Neulasta (filgrastim), Fulphila (pegfilgrastim-jmdb), or Ziextenzo (pegfilgrastim-bmez) if the request is for the reduction in the duration of severe neutropenia. If the request is for Hematopoietic Subsyndrome of Acute Radiation Syndrome, the member must try and fail Neulasta (filgrastim).
Intravitreal Injections – Medicare	12/22/2023	Policy revised for Vabysmo (faricimab-svoa) to allow approval for expanded indication of macular edema following retinal vein occlusion.
Mupirocin Cream – Medicare	12/22/2023	Policy revised to remove brand Centany (mupirocin) ointment since it is not covered by Medicare Part D and remove brand Bactroban (mupirocin) cream since it is no longer available on the market. The diagnosis of impetigo was removed for generic mupirocin cream.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Non-Preferred Rapid-Acting Insulins – Medicare Compass	01/01/2024	Policy revised to clarify that step therapy applies when utilized for the same age and indication.
Non-Preferred Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Medicare	01/01/2024	Policy revised for Farxiga (dapagliflozin) to require trial/failure/contraindication to Jardiance (empagliflozin) for a diagnosis of chronic kidney disease.
Topical Vitamin D Analogues – Medicare	01/01/2024	Qualifier medications calcipotriene cream, ointment, or solution are not FDA approved for use in members less than 18 years of age. Policy was revised; members can bypass step criteria when the member has a diagnosis of plaque psoriasis and is 17 years of age or younger.

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)
Agamree (vamorolone)	300 ml per 40 days
Bimzelx (bimekizumab-bkzx)	2 pens/syringes (2 mL) per 28 days
Bosulif (bosutinib capsules) 100 mg	186 capsules per 31 days
Bosulif (bosutinib capsules) 50 mg	341 capsules per 31 days
Cabtreo (clindamycin phosphate, adapalene, benzoyl peroxide)	50 g per 28 days
Cosentyx (secukinumab) Intravenous	3 vials (15 mL) every 28 days
Coxanto (oxaprozin capsules)	4 capsules per day
Entyvio (vedolizumab) subcutaneous	2 syringes/pens (1.36 mL) per 28 days
Exxua (gepirone)	31 tablets per 31 days
Lupron Depot Ped 11.25 mg 1 month kit	1 kit per 30 days
Lupron Depot Ped 11.25 mg 3 month kit	1 kit per 90 days
Ojjaara (momelotinib)	31 tablets per 31 days
Omvoh (mirikizumab-mrkz) pen	2 pens (2 mL) per 28 days
Omvoh (mirikizumab-mrkz) vial	6 vials (90 mL) per 365 days
Opfolda (miglustat)	8 capsules per 28 days

Drug Name	Retail Quantity Limit (31 days)
Qlosi (pilocarpine HCl)	24 mL (1 carton of 60 single-patient-use vials) per 30 days
Rivfloza (nedosiran) 128 mg/0.8 mL pre-filled syringe	1 pre-filled syringe (0.8 mL) per 28 days
Rivfloza (nedosiran) 160 mg/mL pre-filled syringe	1 pre-filled syringe (1 mL) per 28 days
Rivfloza (nedosiran) vial	2 vials (1 mL) per 28 days
Rozlytrek (entrectinib) 50 mg oral pellets	12 packets (600 mg) per day
TRIENTINE HCL 500 mg Capsule	4 capsules per day
Velsipity (etrasimod)	1 tablet per day
Voquezna (vonoprazan) 10 mg	31 tablets per 31 days
Voquezna (vonoprazan) 20 mg	2 tablets per day
Vuity (pilocarpine hydrochloride)	5 mL per 25 days
Wezlana (ustekinumab-auub) 130 mg/26 mL vial	8 vials (208 mL) per 365 days
Wezlana (ustekinumab-auub) 45 mg/0.5 mL prefilled syringe/vial	1 syringe/vial (0.5 mL) per 84 days
Wezlana (ustekinumab-auub) 90 mg/mL prefilled syringe	1 syringe (1 mL) per 56 days
Yargesa (miglustat)	3 capsules per day
Zilbrysq (zilucoplan)	1 single-dose prefilled syringe per day
Zymfentra (infliximab-dyyb)	2 syringes/pens (2 mL) per 28 days
Agamree (vamorolone)	300 ml per 40 days

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