Formulary Updates

December 2023

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for October 2023. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in October 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:

Section I. Highmark Commercial and Healthcare Reform Formularies

A. Changes to the Highmark Comprehensive Formulary and the Highmark Healthcare Reform Comprehensive Formulary
B. Changes to the Highmark Healthcare Reform Essential Formulary
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Section II. Highmark Medicare Part D Formularies

A. Changes to the Highmark Medicare Part D 5-Tier Open Formularies
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As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (accessible via NaviNet® or our website). Click the **Pharmacy Program/Formularies** link from the menu on the left.

HIGHMARK

Important Drug Safety Updates

Marlex Pharmaceuticals Inc, Digoxin 0.125mg and Digoxin 0.25mg

On August 30, 2023, Marlex Pharmaceuticals, Inc. started voluntarily recalling one lot of Digoxin Tablets USP, 0.125mg and one lot of Digoxin Tablets USP, 0.25mg to the consumer level due to Label Mix-Up.

The mix-up in labels can cause either overdosing or underdosing in patients who unknowingly take the wrong dose. Patients who intend to take Digoxin Tablets USP, 0.125mg, but unknowingly Digoxin 0.25mg would receive a super potent dose and can experience significant drug toxicity (mental disorientation, dizziness, blurred vision, memory loss and fainting) from the unintentional overdose. Patients who intend to take Digoxin Tablets USP, 0.25mg, but unknowingly take Digoxin 0.125mg would receive a sub potent dose which may lead to loss of control of heart rate and potential heart failure exacerbation. Marlex Pharmaceuticals, Inc has not received any reports of adverse events related to this recall.

VistaPharm LLC, Sucralfate Oral Suspension, 1g/10mL

On September 22, 2023, VistaPharm LLC started voluntarily recalling one lot of Sucralfate Oral Suspension, 1g/10mL, to the consumer level, due to Bacillus cereus contamination in the product.

In the population most at risk, the immunocompromised population, there is a reasonable probability that microbial contamination of the oral suspension can result in disseminated, life threatening infections such as endocarditis and necrotizing soft tissue infections. To date, VistaPharm LLC has not received any reports of adverse events related to this recall.

Scynexis, Brexafemme® (ibrexafungerp tablets)

On September 27, 2023, Scynexis, Inc**.** started conducting a voluntary nationwide recall of 2 lots of Brexafemme® (ibrexafungerp tablets) to the consumer level in the US market due to potential cross contamination with a non- antibacterial ß-lactam drug substance in the ibrexafungerp citrate used to manufacture the Brexafemme® tablets.

The potential cross contamination with a non-antibacterial beta-lactam drug substance could lead to hypersensitivity reactions such as swelling, rash, urticaria and anaphylaxis, a potentially life-threatening adverse reaction. To date, SCYNEXIS has not received any reports of adverse events established to be due to the possible beta-lactam cross contamination.

KVK-Tech Inc, Betaxolol Tablets, USP 10 mg

On September 29, 2023, KVK-Tech, Inc. started voluntarily recalling one lot (Batch Number: 17853A; “the batch”) of Betaxolol Tablets, USP 10 mg, White, Round, film coated biconvex tablets, debossed “K” above bisect “13” on one side and plain on the other side” to the consumer level. The batch was distributed nationwide to wholesalers and retailers. The batch is being recalled as a precautionary measure due to a single Oxycodone HCl tablet 5 mg foreign tablet found on the packaging line during the line clearance after the subject batch was packaged. KVK has not received any reports of foreign tablet in any bottle of Betaxolol Tablets, USP 10 mg (Batch Number 17853A) at this time.

The betaxolol package insert warns about slowing in the heart rate in elderly patients which is likely to be exacerbated by inadvertent opioid administration. Additionally, some patients prescribed low-dose betaxolol may have compromised heart and lung function that is also likely to be exacerbated by an opioid. Furthermore, there are minor differences in appearance between betaxolol 10 mg tablets and oxycodone 5 mg tablets, not likely to be noticed by a regular user of the 10 mg betaxolol tablet. Specific patient populations such as those with opioid use disorder (OUD) or at risk of OUD, infants, children, and the elderly are likely to be negatively affected by inadvertently receiving an opioid, especially if a substantial number of oxycodone tablets have been introduced into a bottle labeled as betaxolol. Therefore, inadvertent exposure to a controlled substance, such as oxycodone, in that patient population is likely to result in significant slowing in breathing, known as respiratory depression, which is a serious health risk.

Highmark Formulary Update – October 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 pleased 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 October 2023 unless otherwise noted.

Brand Name	Generic Name	Comments
Beyfortus	nirsevimab-alip	RSV Prevention
Cyfendus*	anthrax vaccine adsorbed, adjuvanted	Post-exposure anthrax prophylaxis
Xalkori oral pellets 20 mg, 50 mg*	crizotinib	ALK-positive NSCLC, ALCL, IMT
Xalkori oral pellets 150 mg*	crizotinib	ALK-positive NSCLC, ALCL, IMT

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

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Akeega	abiraterone acetate; niraparib	Prescriber discretion
lyuzeh	latanoprost	Latanoprost 0.005% Eye Drops, Bimatoprost 0.03% Eye Drops
Sohonos 1, 1.5, 2.5, 5 mg	palovarotene	prescriber discretion
Sohonos 10 mg	palovarotene	prescriber discretion
Vanflyta	quizartinib	prescriber discretion
Xdemvy	lotilaner	prescriber discretion

Brand Name	Generic Name	Preferred Alternatives
Zurzuvae 20 mg, 25 mg	zuranolone	sertraline tablet, citalopram tablet
Zurzuvae 30 mg	zuranolone	sertraline tablet, citalopram tablet

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
Akeega	abiraterone acetate; niraparib
Sohonos 1, 1.5, 2.5, 5 ,10 mg	palovarotene
Vanflyta	quizartinib
Xalkori oral pellets 20 mg, 50,150 mg (crizotinib)	crizotinib
Zurzuvae 20 mg, 25,30 mg	zuranolone

Table 4. Products to Be Removed or Shifted to Higher Tier – January 2024

Brand name	Generic Name	Preferred Alternatives
Alphagan P 0.1%	brimonidine tartrate	brimonidine 0.2% eye drop
Amjevita	adalimumab-atto	Cyltezo(CF), adalimumab-adaz(CF)
Brimonidine tartrate 0.1%	brimonidine tartrate	brimonidine 0.2% eye drop
Copaxone 20 mg/ml	glatiramer acetate	glatiramer acetate, glatopa
Cosentyx 150mg	secukinumab	Taltz autoinjector, enbrel
Cosentyx 300mg	secukinumab	Taltz autoinjector, enbrel
Cosentyx syringe	secukinumab	Taltz autoinjector, enbrel
Cosentyx unoready pen	secukinumab	Taltz autoinjector, enbrel
Firvanq	vancomycin hcl	vancomycin hcl
Flovent diskus	fluticasone propionate	fluticasone propionate hfa, arnuity ellipta
Flovent hfa	fluticasone propionate	fluticasone propionate hfa, arnutiy ellipta
Ibrance	palbociclib	Kisqali, Verzenio
Invokamet	canagliflozin/metformin hcl	Synjardy, Xigduo xr
Invokamet xr	canagliflozin/metformin hcl	Synjardy xr, Xigduo xr
Invokana	canagliflozin	jardiance, Farxiga
Millipred	prednisolone	prednisone
Mozobil	plerixafor	plerixafor
Penicillamine 250 mg tab	penicillamine	penicillamine 250 mg capsule

Brand name	Generic Name	Preferred Alternatives
Prednisolone 5 mg tablet	prednisolone	prednisone
Prezista 600 mg, 800 mg	darunavir ethanolate	darunavir
Symbicort	budesonide/formoterol fumarate	budesonide-formoterol fumarate, breyna
Xyrem	sodium oxybate	modafinil, sodium oxybate

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 October 2023, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Beyfortus	nirsevimab-alip	3	RSV Prevention
Cyfendus*	anthrax vaccine adsorbed, adjuvanted	3	Post-exposure anthrax prophylaxis
Xalkori oral pellets 20 mg, 50 mg*	crizotinib	4	ALK-positive NSCLC, ALCL, IMT
Xalkori oral pellets 150 mg*	crizotinib	4	ALK-positive NSCLC, ALCL, IMT
Zurzuvae 20 mg, 25 mg	zuranolone	4	postpartum depression
Zurzuvae 30 mg	zuranolone	4	postpartum depression
Items listed below were not added to the formulary			
Akeega	abiraterone acetate; niraparib	NF	Prescriber discretion
Iyuzeh	latanoprost	NF	Latanoprost 0.005% Eye Drops, Bimatoprost 0.03% Eye Drops
Sohonos 1, 1.5, 2.5, 5 mg	palovarotene	NF	prescriber discretion
Sohonos 10 mg	palovarotene	NF	prescriber discretion
Vanflyta	quizartinib	NF	prescriber discretion
Xdemvy	lotilaner	NF	prescriber discretion

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

Table 2. Products to Be Removed or Shifted to Higher Tier – January 2024

Brand Name	Generic Name	Preferred Alternatives
All Healthcare Reform Essential Products		
Aliskiren	aliskiren hemifumarate	losartan potassium, irbesartan
Amjevita	adalimumab-atto	Hadlima(CF),adalimumab-fkjp (CF)
Candesartan cilexetil	candesartan cilexetil	losartan potassium, irbesartan
Captopril	captopril	lisinopril, benazepril hcl
Celontin	methsuximide	methsuximide
Cholbam	cholic acid	provider discretion
Clindamycin phos-tretinoin	clindamycin/tretinoin	tretinoin, clindamycin-phosphate gel
Clovique	trientine hcl	provider discretion
Cosentyx 150mg	secukinumab	Taltz autoinjector, enbrel
Cosentyx 300mg	secukinumab	Taltz autoinjector, enbrel
Cosentyx syringe	secukinumab	Taltz autoinjector, enbrel
Cosentyx unoready pen	secukinumab	Taltz autoinjector, enbrel
Cycloserine	cycloserine	cycloserine 250 mg capsule (generic)
Edarbi	azilsartan medoxomil	losartan potassium, irbesartan
Eplerenone	eplerenone	spironolactone
Eprosartan mesylate	eprosartan mesylate	losartan potassium, irbesartan
Firmagon	degarelix acetate	provider discretion
Firvanq	vancomycin hcl	vancomycin hcl
Flovent diskus	fluticasone propionate	fluticasone propionate hfa, arnuity ellipta
Flovent hfa	fluticasone propionate	fluticasone propionate hfa, arnuity ellipta
Ibrance	palbociclib	kisqali, verzenio
Invokamet	canagliflozin/metformin hcl	Synjardy,xigduo xr
Invokamet xr	canagliflozin/metformin hcl	Synjardy xr, xigduo xr
Invokana	canagliflozin	Jardiance, Farxiga
Leukine	sargramostim	provider discretion
Moexipril hcl	moexipril hcl	lisinopril, benazepril hcl
Mozobil	plerixafor	plerixafor
Nadolol	nadolol	propranolol hcl, carvedilol
Panretin	alitretinoin	provider discretion
Paricalcitol	paricalcitol	provider discretion
Penicillamine 250 mg tab	penicillamine	penicillamine 250 mg capsule
Pindolol	pindolol	propranolol hcl, carvedilol
Prezista 600 mg, 800 mg	darunavir ethanolate	darunavir
Quillivant xr	methylphenidate hcl	methylphenidate hcl solution
Ravicti	glycerol phenylbutyrate	sodium phenylbutyrate
Sucraid	sacrosidase	provider discretion

Triamterene	triamterene	spironolactone, triamterene w/ hctz
Trientine hcl	trientine hcl	provider discretion
Viekira pak	ombita/paritap/riton/dasabuvir	provider discretion
Xuriden	uridine triacetate	provider discretion
Xyrem	sodium oxybate	modafinil, sodium oxybate

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 October2023 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Beyfortus	nirsevimab-alip	3	RSV Prevention
Cyfendus*	anthrax vaccine adsorbed, adjuvanted	3	Post-exposure anthrax prophylaxis
Xalkori oral pellets 20 mg, 50 mg*	crizotinib	4	ALK-positive NSCLC, ALCL, IMT
Xalkori oral pellets 150 mg*	crizotinib	4	ALK-positive NSCLC, ALCL, IMT
Zurzuvae 20 mg, 25 mg	zuranolone	4	postpartum depression
Zurzuvae 30 mg	zuranolone	4	postpartum depression
Items listed below were not added to the formulary			
Akeega	abiraterone acetate; niraparib	NF	Prescriber discretion
Iyuzeh	latanoprost	NF	Latanoprost 0.005% Eye Drops, Bimatoprost 0.03% Eye Drops
Sohonos 1, 1.5, 2.5, 5 mg	palovarotene	NF	Prescriber discretion
Sohonos 10 mg	palovarotene	NF	Prescriber discretion
Vanflyta	quizartinib	NF	Prescriber discretion
Xdemvy	lotilaner	NF	Prescriber discretion

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.

Table 2. Products to Be Removed or Shifted to Higher Tier – January 2024

Brand Name	Generic Name	Preferred Alternatives
All Core Products		
Amjevita	adalimumab-atto	Hadlima(CF), adalimumab-fkjp(CF)
Basaglar kwikpen u-100	insulin glargine	rezvoglar kwikpen
Candesartan cilexetil	candesartan cilexetil	losartan potassium, irbesartan
Clovique	trientine hcl	penicillamine 250 mg capsule
Cosentyx 150mg	secukinumab	Taltz autoinjector, enbrel
Cosentyx 300mg	secukinumab	Taltz autoinjector, enbrel
Cosentyx syringe	secukinumab	Taltz autoinjector, enbrel
Cosentyx unoready pen	secukinumab	Taltz autoinjector, enbrel
Firvanq	vancomycin hcl	vancomycin hcl
Flovent diskus	fluticasone propionate	fluticasone propionate hfa, arnuity ellipta
Flovent hfa	fluticasone propionate	fluticasone propionate hfa, arnuity ellipta
Ibrance	palbociclib	Kisqali, Verzenzio
Insulin glargine-yfgn	insulin glargine-yfgn	rezvoglar kwikpen
Invokamet	canagliflozin/metformin hcl	Synjardy, Xigudo xr
Invokamet xr	canagliflozin/metformin hcl	Synjardy xr, Xigudo xr
Invokana	canagliflozin	jardiance, farxiga
Millipred	prednisolone	prednisone
Penicillamine 250 mg tab	penicillamine	penicillamine 250 mg capsule
Prednisolone 5 mg tab	prednisolone	prednisone
Prezista 600 mg, 800 mg	darunavir ethanolate	darunavir
Trientine hcl	trientine hcl	penicillamine 250 mg capsule

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)			
Beyfortus	nirsevimab-alip	2	RSV Prevention
Xdemvy	lotilaner	2	Demodex blepharitis
Items listed below were added to the formulary (Non-Preferred)			

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Cyfendus*	anthrax vaccine adsorbed, adjuvanted	3	Prescriber discretion
Sohonos 1, 1.5, 2.5, 5 mg	palovarotene	3	prescriber discretion
Sohonos 10 mg	palovarotene	3	prescriber discretion
Xalkori oral pellets 150 mg*	crizotinib	3	Prescriber discretion
Xalkori oral pellets 20 mg, 50 mg*	crizotinib	3	Prescriber discretion
Zurzuvae 20mg, 25 mg*	zuranolone	3	sertraline tablet, citalopram tablet
Zurzuvae 30 mg*	zuranolone	3	sertraline tablet, citalopram tablet
Items listed below were not added to the formulary			
Akeega	abiraterone acetate; niraparib	NF	abiraterone, Lynparza, Talzenna, Xtandi
Iyuzeh	latanoprost	NF	Latanoprost 0.005% Eye Drops, Bimatoprost 0.03% Eye Drops
Vanflyta	quizartinib	NF	Rydapt

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
Akeega	abiraterone acetate; niraparib
Sohonos 1, 1.5, 2.5, 5 mg	palovarotene
Sohonos 10 mg	palovarotene
Vanflyta	quizartinib)
Xalkori oral pellets 150 mg	crizotinib
Xalkori oral pellets 20 mg, 50 mg	crizotinib
Zurzuvae 20 mg, 25 mg	zuranolone
Zurzuvae 30 mg	zuranolone

Table 3. Products to Be Removed or Shifted to Higher Tier – January 2024

Brand Name	Generic Name	Preferred Alternatives
All National Select Products to be Removed		
Amjevita	adalimumab-atto	Cyltezo(CF), adalimumab-adaz
Aplenzin	bupropion hbr	Bupropion xl

Bevespi aerosphere	glycopyrrolate/formoterol fum	Anoro ellipta, stiolto respimat
Botox	onabotulinumtoxina	Dysport, myobloc
Braftovi	encorafenib	Tafinlar, zelboraf
Chorionic gonadotropin	chorionic gonadotropin, human	Novarel, ovidrel
Citranatal 90 dha	pnv72/iron,gluc/folic/dss/dha	Prenatal plus
Citranatal assure	pnv73/iron,gluc/folic/dss/dha	Prenatal plus
Citranatal b-calm	prenatal 48/iron/folic acid/b6	Prenatal plus
Citranatal bloom	iron carb,gl/fa/b12/c/docusate	Prenatal plus
Citranatal dha	pnv 76/iron,gluc/folic/dss/dha	Prenatal plus
Citranatal harmony	pnv59/iron,carb,fum/fa/dss/dha	Prenatal plus
Citranatal medley	mv-min102/iron carb,fum/fa/dha	Prenatal plus
Citranatal rx	prenatal81/iron/folic/docusate	Prenatal plus
Dyanavel xr	amphetamine	dextroamphetamine-amphet er, lisdexamfetamine dimesylate
Flovent diskus	fluticasone propionate	Arnuity ellipta, asmanex hfa
Flovent hfa	fluticasone propionate	Arnuity ellipta, asmanex hfa
Ibrance	palbociclib	Kisqali, verzenio
Ixinity	factor ix human recomb,thr 148	Benefix
Levemir	insulin detemir	Semglee (yfgn), Toujeo
Levemir flexpen	insulin detemir	Semglee (yfgn), Toujeo
Levemir flextouch	insulin detemir	Semglee (yfgn), Toujeo
Lupron depot-ped	leuprolide acetate	Provider discretion
Luzu	luliconazole	Ciclopirox, Ketoconazole
Mektovi	binimetinib	Mekinist,cotellic
Natesto	testosterone	Testosterone
Norditropin flexpro	somatropin	Genotropin, omnitrope
Osmolex er	amantadine hcl	Amantadine hcl
Oxaydo	oxycodone hcl	Oxycodone hcl
Quillichew er	methylphenidate hcl	Methylphenidate hcl, Methylphenidate er
Quillivant xr	methylphenidate hcl	Methylphenidate hcl, Methylphenidate er
Rebinyn	factor ix human rec,pegylated	Alprolix, Idelvion

Rixubis	factor ix human recombinant	Benefix
Serevent diskus	salmeterol xinafoate	Striverdi respimat
Sivextro	tedizolid phosphate	Linezolid
Steglujan	ertugliflozin/sitagliptin phos	Glyxambi
Supprelin la	histrelin acetate	Provider discretion
Voquezna dual pak	vonoprazan/amoxicillin	Bismuth-metronidazole-tetracyc,lansoprazole –amoxicil-clarithro
Voquezna triple pak	vonoprazan/amoxicillin/clarith	bismuth-metronidazole-tetracyc, lansoprazole-amoxicil-claritho
Xeomin	incobotulinumtoxina	Provider discretion
Xultophy 100-3.6	insulin degludec/liraglutide	Soliqua
Yonsa	abiraterone acet,submicronized	abiraterone acetate
Zarxio	filgrastim-sndz	Nivestym
Zolpimist	zolpidem tartrate	Zolpidem tartrate, ezopiclone
All National Select Products to be Shifted to a Higher Tier		
Endometrin	progesterone, micronized	Crinone 8% gel

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
ALK-Targeting Kinase Inhibitors – Commercial and Healthcare Reform	10/19/2023	Policy revised to add Xalkori (crizotinib) oral pellets to require age, diagnosis based on FDA-approved indication, and inability to swallow oral capsules or body surface area < 1.34 m2, based on indication.
Androgen Receptor Inhibitors – Commercial and Healthcare Reform	10/19/2023	Policy revised for Nubeqa (darolutamide) for hormone-sensitive prostate cancer indication to add a step requiring that the member is using Nubeqa (darolutamide) in combination with a GnRH analog, or the member has had a bilateral orchiectomy
Anti-Obesity – Commercial and Healthcare Reform	10/19/2023	Policy revised for Wegovy (semaglutide) to allow for titration to 1.7 mg once weekly for continuation in adults. For maintenance and continuation in adults, allowing for a requested dose of 1.7 mg once weekly.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Benlysta (belimumab) – Commercial and Healthcare Reform	10/19/2023	Policy revised for Benlysta (belimumab) subcutaneous to remove trial/failure to 2 standard of care drug classes (corticosteroid, antimalarial, or immunosuppressive). For lupus nephritis reauthorization, removed corticosteroids be used in maintenance.
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Commercial and Healthcare Reform	10/19/2023	Policy revised for Mekinist (trametinib) and Tafinlar (dabrafenib) for age based on FDA-approved expanded indication.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	10/19/2023	Policy revised for Commercial and Healthcare Reform Comprehensive formularies to add additional co-preferred adalimumab biosimilars: Cyltezo, Hyrimoz, adalimumab-adaz in addition to Humira and Amjevita standard list price.
Clotting Factor Products – Commercial and Healthcare Reform	10/19/2023	Policy revised to remove Xyntha (antihemophilic factor [recombinant]) as a target from the policy and to add Xyntha (antihemophilic factor [recombinant]) as an option for step therapy as one of the plan-preferred agents.
FGFR Kinase Inhibitors – Commercial and Healthcare Reform	10/19/2023	Policy revised for Truseltiq (infigratinib) to remove all criteria based on product market withdrawal.
FLT3 Kinase Inhibitors – Commercial and Healthcare Reform	10/19/2023	Policy revised for Vanflyta (quizartinib) to require age and diagnosis based on FDA-approved indication, as supported by FDA-approved companion diagnostic test.
Ingrezza (valbenazine) – Commercial and Healthcare Reform	10/19/2023	Policy revised for Ingrezza (valbenazine) to include authorization approval criteria for its new indication of chorea associated with Huntington's disease (HD) in adults. Must be 18 years of age or older and have a diagnosis of chorea associated with HD.
Interleukin-1b blockers – Commercial and Healthcare Reform	10/19/2023	Policy revised for Ilaris (canakinumab) to require age, diagnosis based on FDA-approved indication, and trial/failure/contraindication to oral nonsteroidal anti-inflammatory drugs, systemic corticosteroid, and colchicine.
Lonsurf (trifluridine-tipiracil) – Commercial and Healthcare Reform	10/19/2023	Policy revised for Lonsurf (trifluridine-tipiracil) to require concomitant therapy based on FDA-approved expanded indication.
Mozobil (plerixafor) – Commercial and Healthcare Reform	10/19/2023	Policy revised for Mozobil (plerixafor) to require trial and failure through generic plerixafor; and to clarify that Mozobil (plerixafor) is used in combination with G-CSF to mobilize

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation.
Opzelura (ruxolitinib) – Commercial and Healthcare Reform	10/19/2023	Policy revised for Opzelura (ruxolitinib) to allow body surface area of up to 20%.
PARP Inhibitors – Commercial and Healthcare Reform	10/19/2023	Policy revised to add Akeega (niraparib and abiraterone acetate) requiring age; diagnosis; use in combination with prednisone; and the member to be concurrently receiving a GnRH analog or the member to have a bilateral orchiectomy. Policy updated for Talzenna (talazoparib) and Lynparza (olaparib) to require the member to be concurrently receiving a GnRH analog or the member to have a bilateral orchiectomy for mCRPC. Policy revised for Lynparza (olaparib) to require applicable genetic mutation as detected by an FDA-approved test for members with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy .
Pennsylvania Step Therapy Exception - Commercial and Healthcare Reform	10/19/2023	Policy created to allow an exception to step-therapy criteria for medications which require such, based on exception criteria documented in PA Senate Bill 225; Act No. 146 of 2022.
RET Kinase Inhibitors - Commercial and Healthcare Reform	10/19/2023	Policy revised for Gavreto (pralsetinib) to remove criteria for medullary thyroid cancer following removal of the indication per FDA.
Sohonos (palovarotene) - Commercial and Healthcare Reform	10/19/2023	New policy for Sohonos (palovarotene) requiring age, prescription by or in consultation with an orthopedic or a provider that specializes in the treatment of fibrodysplasia ossificans progressiva (FOP), diagnosis of FOP with R206H mutation, and evidence of baseline heterotopic ossification (HO). Reauthorization to require attestation from prescriber that member has experienced a reduction in the volume of new HO from baseline.
Spinraza (nusinersen) – Commercial and Healthcare Reform	10/19/2023	Policy revised for Spinraza (nusinersen) to require the member be symptomatic and has 2, 3, or 4 copies of Survival Motor Neuron 2 (SMN2), not reliant on ventilator support or tracheostomy, and 15 years of age or younger at treatment initiation or if the member is asymptomatic, the member has 2 or 3 copies of SMN2 and is 1 year of age or younger at treatment initiation.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Ultomiris (ravulizumab-cwvz) Subcutaneous – Commercial and Healthcare Reform	10/19/2023	Criteria for approval of Ultomiris (ravulizumab-cwvz) for the treatment of paroxsmyal nocturnal hemoglobinuria (PNH) was revised to add a criterion to require that the member's baseline hemoglobin level is < 10.5 g/dL. The criterion under (3): anemia secondary to PNH (e.g., hemoglobin </= 9 g/dL with symptoms of anemia), is no longer an option. Reauthorization criteria revised to define positive clinical response.
Vtama (tapinarof) and Zoryve (roflumilast) – Commercial and Healthcare Reform	10/19/2023	Policy revised for Vtama (tapinarof) and Zoryve (roflumilast) to specify that facial psoriasis is a contraindication to vitamin D analog step.
Xdemvy (lotilaner) – Commercial and Healthcare Reform	10/19/2023	New policy for Xdemvy (lotilaner) requiring diagnosis based on age and FDA-approved indication supported by microscopic examination of pulled eyelashes or slit-lamp evaluation.
Zurzuvae (zuranolone) – Commerical and Healthcare Reform	10/19/2023	New policy created for Zurzuvae (zuranolone) to require that the member is 18 years of age or older, the member has a diagnosis of moderate to severe postpartum depression (F53.0), and the member is ≤ 12 months postpartum.

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

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Additional Quantities of mRNA COVID-19 Vaccines – Commercial and Healthcare Reform	10/19/2023	New policy created for Comirnaty (COVID-19 Vaccine, mRNA), Moderna COVID-19 Vaccine, Pfizer COVID-19 Vaccine and Spikevax (COVID-19 Vaccine, mRNA) to receive additional COVID-19 vaccines. For Comirnaty (COVID-19 Vaccine, mRNA) and Spikevax (COVID-19 Vaccine, mRNA) a patient would be required to be 12 years or age or older and considered to be moderately or severely immunocompromised. For the Moderna COVID-19 Vaccine and Pfizer COVID-19 Vaccine a patient would be required to be between the ages of 6 months to 11 years of age and to be considered moderately or severely immunocompromised.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Bevespi (glycopyrrolate /formoterol) – Commercial	01/01/2024	Policy created for Bevespi (glycopyrrolate/formoterol) to require a diagnosis of chronic obstructive pulmonary disease and trial and failure of both Anoro Ellipta (umeclidinium bromide/vilanterol) and Stiolto (tiotropium bromide/olodaterol).
Combination Prescription Drug Safety – Commercial and Healthcare Reform	10/19/2023	Policy revised to remove Nayzilam (midazolam) from list of targeted products.
Evekeo (amphetamine sulfate) – Commercial and Healthcare Reform	10/19/2023	Policy revised for brand Evekeo (amphetamine sulfate) to require therapeutic failure or intolerance to generic amphetamine sulfate.
Intraocular Pressure Reducing Agents – Commercial and Healthcare Reform	10/20/2023	Policy revised to add Iyuzeh (latanoprost ophthalmic solution) requiring diagnosis based on FDA-approved indications and trial and failure to latanoprost and one other plan-preferred, generic, ophthalmic alternative.
Non-Preferred Combination GLP-1 RA and Basal Insulin Products – Commercial Core	1/1/2024	Policy to be terminated.
Non-preferred Inhaler Products – Commercial and Select Healthcare Reform	10/19/2023	Policy revised to remove budesonide/formoterol fumarate dihydrate - authorized generic from policy.
Non-preferred Inhaler Products – Commercial and Select Healthcare Reform	01/01/2024	Policy revised to remove fluticasone propionate HFA - authorized generic from the policy and add Flovent (fluticasone proprionate) - brand only and require a diagnosis of asthma and therapeutic failure or intolerance to generic fluticasone propionate and two of the following: Arnuity Ellipta (fluticasone furoate), Asmanex (momentasone furoate), Pulmicort (budesonide), and Qvar (beclomethasone dipropionate).
Non-Preferred NSAIDs – Commercial and Healthcare Reform	10/19/2023	Policy revised to remove off market products Fenortho (fenoprofen) and Profeno (fenoprofen).
Non-Preferred Selective Serotonin Reuptake Inhibitors (SSRIs) – Commercial and Healthcare Reform	10/19/2023	Policy revised to update initial authorization duration to 12 months.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Non-Preferred Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Commercial and Healthcare Reform	01/01/2024	Policy revised for canagliflozin (Invokana, Invokamet, Invokamet XR) to require diagnosis based on FDA-approved indication. For all indications, trial/failure/contraindication to a dapagliflozin- and empagliflozin-containing product; and a metformin-containing product for type 2 diabetes. Step through canagliflozin removed for all other non-preferred sodium-glucose co-transporter 2 inhibitors.
Non-Stimulant Treatment of ADHD – Commercial and Healthcare Reform	10/19/2023	Policy revised to require step through generic clonidine extended release 0.1 mg for requests for brand Kapvay and generic atomoxetine for requests for brand Strattera.
Pancreatic Enzymes – Commercial and Healthcare Reform	01/01/2024	Policy revised to add Healthcare Reform Comprehensive formulary targeting Pancreaze (pancrelipase) and Pertzye (pancrelipase) requiring FDA-approved diagnosis and trial/failure to plan-preferred Creon (pancrelipase) and Zenpep (pancrelipase).
Topical Acne Products – Commercial and Healthcare Reform	01/01/2024	Policy revised to target adapalene 0.1% swab to require FDA-approved diagnosis, and trial/failure to adapalene 0.1% gel and cream and adapalene-benzoyl peroxide 0.1%-2.5%. Reauthorization requiring clinical response and additional courses are needed.
Topical Antifungals – Commercial and Healthcare Reform	10/19/2023	Policy revised for Jublia (efinaconazole) and Kerydin (tavaborole) to require one: 1) 6-11 years of age, 2) if 12-17 years of age, trial/failure to ciclopirox 8% topical solution, or 3) if 18+, trial/failure to generic oral terbinafine and ciclopirox 8% topical solution.
Topical Antifungals – Commercial National Select	10/19/2023	Policy revised for Kerydin (tavaborole) to require one: 1) 6-11 years of age, 2) if 12-17 years of age, trial/failure to ciclopirox 8% topical solution, or 3) if 18+, trial/failure to generic oral terbinafine and ciclopirox 8% topical solution.
Topical Vitamin D Analogues – Commercial and Healthcare Reform	01/01/2024	Policy revised if the request is for brand Taclonex (calcipotriene/betamethasone dipropionate), the member has tried/failed an AB-rated generic equivalent.
Venlafaxine ER – Commercial and Healthcare Reform	10/19/2023	Policy revised for venlafaxine ER 150 mg to remove the criteria for additional quantities above 1 capsule/tablet per day.

Policy Name*	Policy Effective Date**	Updates and Automatic Approval Criteria
Zonisade (zonisamide) – Commercial and Healthcare Reform	10/19/2023	Policy revised for Zonisade (zonisamide) to include additional medications for therapeutic failure/intolerance or contraindication to 2 of: carbamazepine suspension, chewable tablet, extended-release capsule; gabapentin capsules, solution; lacosamide solution; levetiracetam solution; oxcarbazepine suspension; pregabalin tablets, capsules

*For Commercial and Healthcare Reform policies, an exception to some or all the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.
**All effective dates are tentative and subject to delay pending internal review or approval.
Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria.

3. Formulary Program

No changes at this time.

4. Quantity Level Limit (QLL) Programs*
Effective immediately upon completion of internal review and implementation, unless otherwise noted.

Table 1. Quantity Level Limits – Quantity per Duration for Commercial and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Austedo XR (deutetrabenazine) Titration Kit	1 pack per 365 days	1 pack per 365 days
Beyfortus (nirsevimab-alip)	2 doses per 720 days	2 doses per 720 days
Ingrezza (valbenazine) Huntington's chorea Titration Pack	1 pack per 365 days	1 pack per 365 days
Xdemvy (lotilaner)	1 bottle (10 mL) per 180 days	1 bottle (10 mL) per 180 days
Zurzuvae (zuranolone) 20 mg, 25 mg	28 capsules/180 days For DE carriers, 28 capsules/14 days	28 capsules/180 days For DE carriers, 28 capsules/14 days
Zurzuvae (zuranolone) 30 mg	14 capsules/180 days For DE carriers, 14 capsules/14 days	14 capsules/180 days For DE carriers, 14 capsules/14 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
Akeega (abiraterone acetate; niraparib)	2 tablets per day
Effexor XR (venlafaxine ER) 150 mg	2 capsules per day
Iyuzeh (latanoprost)	1 single-use droperette per day
Sohonos (palovarotene) 1, 1.5, 2.5, 5 mg	One (1) capsule per day
Sohonos (palovarotene) 10 mg	Two (2) capsules per day
Vanflyta (quizartinib)	2 tablets per day
Xalkori (crizotinib) oral capsules	4 capsules per day
Xalkori oral pellets 150 mg (crizotinib)	6 capsules of oral pellets per day
Xalkori oral pellets 20 mg, 50 mg (crizotinib)	4 capsules of oral pellets 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
Beyfortus	nirsevimab-alip	RSV Prevention

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

Brand Name	Generic Name	Preferred Alternatives
Daxxify	daxibotulinumtoxinA-lanm	prescriber discretion
Iyuzeh	latanoprost	Latanoprost 0.005% Eye Drops, Travoprost

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
Beyfortus	nirsevimab-alip	RSV Prevention

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

Brand Name	Generic Name	Preferred Alternatives
Daxxify	daxibotulinumtoxinA-lanm	prescriber discretion

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

Brand Name	Generic Name	Preferred Alternatives
Iyuzeh	latanoprost	Latanoprost 0.005% Eye Drops, Travoprost

*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
Akeega	abiraterone acetate; niraparib
Elrexfio	elranatamab-bcmm
Eylea HD	aflibercept
Izervay	avacincaptad pegol
Sohonos 1, 1.5, 2.5, 5 mg	palovarotene
Sohonos 10 mg	palovarotene
Talvey	talquetamab-tgvs
Tyruko	natalizumab-sztn
Vanflyta	quizartinib
Veopoz	pozelimab-bbfg
Xalkori oral pellets 150 mg	crizotinib
Xalkori oral pellets 20 mg, 50 mg	crizotinib
Xdemvy	lotilaner
Ycanth	cantharidin
Zurzuvae 20 mg, 25 mg	zuranolone
Zurzuvae 30 mg	zuranolone

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	10/19/2023	Policy revised to add Roctavian (valoctocegene roxaparvovec-rvox) as a target for BvD infusion pump review and removed Arzerra as a target for incident to provider service review.
Administrative Prior Authorizations for Medicare Part D Plans – Medicare	10/19/2023	Policy revised to add Daxxify (Daxibotulinumtoxin A) to Botulinum toxin review to require medically accepted indication and not being used for Medicare excluded cosmetic indication.
Adstiladrin (nadofaragene firadenovec-vncg) – Medicare	10/19/2023	New policy created for Adstiladrin (nadofaragene firadenovec-vncg) requiring diagnosis based on FDA-approved indication.
ALK-Targeting Kinase Inhibitors – Medicare	10/19/2023	Policy revised to add Xalkori (crizotinib) oral pellets to require age, diagnosis based on FDA-approved indication, and inability to swallow oral capsules or body surface area < 1.34 m2, based on indication.
Androgen Receptor Inhibitors – Medicare	10/19/2023	Policy revised for Nubeqa (darolutamide) for hormone-sensitive prostate cancer indication to add a step requiring that the member is using

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		Nubeqa (darolutamide) in combination with a GnRH analog, or the member has had a bilateral orchiectomy
Benlysta (belimumab) – Medicare	10/19/2023	Policy revised for Benlysta (belimumab) to remove step requirement of trial/failure to two standard of care drug classes (corticosteroid, antimalarial, or immunosuppressive).
Blood Glucose Testing Products – Medicare	10/19/2023	Policy revised to add Freestyle Libre 3 as preferred Abbott continuous glucose monitor.
Blood Glucose Testing Products - Medicare	10/19/2023	Dexcom products added as preferred Continuous Glucose Monitors (CGM). Nonpreferred CGM criteria revised to require failure on both a preferred Abbott and Dexcom product.
Chronic Inflammatory Diseases – Medicare	10/19/2023	Policy revised to add additional co-preferred adalimumab biosimilars: Cyltezo and Hyrimoz. Amjevita is directed to 1 preferred adalimumab product, all other non-preferred adalimumab biosimilars are directed to 2 preferred adalimumab products.
Chronic Inflammatory Diseases – Medicare	10/19/2023	Policy revised for Amjevita to require trial/failure to 2 preferred adalimumab products.
Complement Inhibitors for Geographic Atrophy – Medicare	10/19/2023	Policy revised to include Izervay (avacincaptad pegol) requiring diagnosis of geographic atrophy secondary to age-related macular degeneration based on FDA-approved indication.
Cystic Fibrosis Inhaled Medications – Medicare	10/19/2023	Policy revised to remove age criteria of 18 years of age and older for Bronchitol (mannitol inhalation powder).
Daytrana (methylphenidate patch) – Medicare	10/19/2023	Policy revised for Daytrana (methylphenidate patch) to require trial and failure to generic methylphenidate patch.
Drugs for Chagas Disease – Medicare	10/19/2023	Policy revised for benznidazole to remove age limitation of 2 years of age and older and to remove weight limitation of at least 2.5 kg for Lampit (nifurtimox).
Elagolix and Relugolix-Containing Products – Medicare	10/19/2023	Policy revised to combine Orilissa (elagolix) into this policy requiring members to experience trial/failure/contraindication to two (2) of the following: generic nonsteroidal anti-inflammatory drug (NSAID), combined hormonal contraceptive, progestin, or GnRH agonist. For all products in the policy, the member must be a premenopausal woman and the prescriber must attest that the member is not pregnant. The total combined treatment duration of Oriahnn (elagolix, estradiol,

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		and norethindrone acetate capsules; elagolix capsules), Orilissa (elagolix), and Myfembree (relugolix, estradiol, norethindrone acetate) must not exceed 24 months. Reauthorization criteria ensures that the member has experienced a reduction in pain.
Elrexfio (elranatamab-bcmm) – Medicare	10/19/2023	New policy created for Elrexfio (elranatamab-bcmm) to require FDA-approved diagnosis, including prior lines of therapy.
Enzyme Replacement Therapy for Gaucher Disease – Medicare	10/19/2023	Policy revised for enzyme replacement therapy to clarify splenomegaly is larger than normal size which is 0.2% of total body weight and removed criteria for anemia that is less than or equal to 1 g/dL or more below the lower limit of normal for age and sex.
Epidiolex (cannabidiol oral solution) – Medicare	10/19/2023	Policy revised to remove reauthorization criteria.
FGFR Kinase Inhibitors – Medicare	10/19/2023	Policy revised for Truseltiq (infigratinib) to remove all criteria based on product market withdrawal.
FLT3 Kinase Inhibitors – Medicare	10/19/2023	Policy revised for Vanflyta (quizartinib) to require diagnosis based on FDA-approved indication, as supported by FDA-approved companion diagnostic test.
Gonadotropin-Releasing Hormone (GnRH) Antagonists – Medicare	10/19/2023	Policy revised to add Firmagon (degarelix) to require diagnosis based on FDA-approved indication.
Ingrezza (valbenazine) – Medicare	10/20/2023	Policy revised for Ingrezza (valbenazine) to include authorization approval criteria for its new indication of chorea associated with Huntington's disease (HD) in adults. Must have a diagnosis of chorea associated with HD.
Interleukin-1b blockers – Medicare	10/19/2023	Policy revised for Ilaris (canakinumab) to require diagnosis based on FDA-approved indication and trial/failure/contraindication to oral nonsteroidal anti-inflammatory drugs, systemic corticosteroid, and colchicine.
Leqembi (lecanemab-irmb) – Medicare	10/19/2023	New policy for Leqembi (lecanemab-irmb) requiring FDA labeled diagnosis of Alzheimer's disease (mild cognitive impairment (MCI) or mild dementia), the prescriber has ruled out all other possible causes of cognitive impairment or dementia, confirmed presence of amyloid beta pathology via positron emission tomography (PET) imaging, obtained a brain magnetic resonance imaging (MRI) prior to treatment, and

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		meets criteria in the National Coverage Determination (NCD) 200.3. For reauthorization, the member had MCI or mild dementia at treatment initiation, the member continues to meet the criteria in NCD 200.3, the member has obtained or will obtain a brain MRI prior to the 5th, 7th, and 14th infusion, has experienced a reduction from baseline in amyloid beta plaques via PET imaging, and has demonstrated positive clinical response as evidenced by slowed decline in cognition.
Lonsurf (trifluridine-tipiracil) – Medicare	10/19/2023	Policy revised for Lonsurf (trifluridine-tipiracil) to remove the requirement for age and to require concomitant therapy based on FDA-approved expanded indication.
Mozobil (plerixafor) – Medicare	10/19/2023	Policy revised for Mozobil (plerixafor) to require trial and failure through generic plerixafor.
Orgovyx (relugolix) – Medicare	10/19/2023	Policy revised for Orgovyx (relugolix) to remove age and androgen-deprivation therapy criteria.
Ozobax (baclofen) – Medicare	10/19/2023	Termination
PARP Inhibitors – Medicare	10/19/2023	Policy revised to add Akeega (niraparib and abiraterone acetate) requiring diagnosis; use in combination with prednisone; and the member to be concurrently receiving a GnRH analog or the member to have a bilateral orchiectomy. Policy revised for Lynparza (olaparib) to require applicable genetic mutation for members with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy.
PCSK9 Therapies – Medicare	10/19/2023	Policy revised for Leqvio (inclisiran) to require diagnosis based on expanded FDA-approved indication supported by lab values, trial/failure of a maximally tolerated statin or intolerance, trial/failure of Repatha (evolocumab), and adjunctive use with a statin (unless statin intolerant).
Programmed Death Receptor Therapies – Medicare	10/19/2023	Policy revised for Jemperli (dostarlimab-gxly) to add criteria for use in combination with carboplatin and paclitaxel, followed by Jemperli (dostarlimab-gxly) as a single agent, for primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR), as determined

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		by an FDA-approved test, or microsatellite instability-high (MSI-H).
RET Kinase Inhibitors – Medicare	10/19/2023	Policy revised for Gavreto (pralsetinib) to remove criteria for medullary thyroid cancer following removal of the indication per FDA; and for Gavreto (pralsetinib) and Retevmo (selpercatinib) to remove the requirement for age.
Rituximab Products – Medicare	10/19/2023	For shared indications, request for brand Rituxan (rituximab) or Riabni (rituximab-arrx) require trial/failure to either Truxima (rituximab-abbs) or Ruxience (rituximab-pvvr).
Saphnelo (anifrolumab-fnia) – Medicare	10/19/2023	Policy revised for Saphnelo (anifrolumab-fnia) to remove step requirement of trial/failure to two standard of care drug classes (corticosteroid, antimalarial, or immunosuppressive).
Sohonos (palovarotene) – Medicare	10/19/2023	New policy for Sohonos (palovarotene) requiring age, diagnosis of fibrodysplasia ossificans progressiva (FOP) with R206H mutation, and evidence of baseline heterotopic ossification (HO). Reauthorization to require attestation from prescriber that member has experienced a reduction in the volume of new HO from baseline.
Soliris (eculizumab) – Medicare	10/19/2023	Criteria for approval of Soliris (eculizumab) for paroxsymal nocturnal hemoglobinuria (PNH) diagnosis was revised to add a criterion to require the member's baseline hemoglobin level is < 10.5 g/dL. In addition, the criterion under (3): anemia secondary to PNH (e.g., hemoglobin </= 9 g/dL with symptoms of anemia is no longer an option.
Spravato (esketamine) – Medicare	10/19/2023	New policy created for Spravato (esketamine); for treatment-resistant depression (TRD), member must have diagnosis of major depressive disorder (MDD), as well as meet criteria for TRD and concomitantly be taking an oral antidepressant (one that was not previously failed). For depressive symptoms with MDD with acute suicidal ideation or behavior, the member must have a diagnosis of MDD, concomitantly be taking an oral antidepressant (one that was not previously failed) and must be experiencing an acute suicidal ideation with intent and may warrant hospitalization.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Talvey (talquetamab-tgvs) – Medicare	10/19/2023	New policy created for Talvey (talquetamab-tgvs) to require FDA-approved diagnosis, including prior lines of therapy.
Tysabri (natalizumab) and Tyruko (natalizumab-sztn) – Medicare	10/19/2023	Policy revised to add Tyruko (natalizumab-sztn) requiring FDA labeled diagnosis. For Crohn's disease reauthorization requires therapeutic benefit by 12 weeks after induction therapy. Policy revised to remove age requirement.
Ultomiris (ravulizumab-cwvz) – Medicare	10/19/2023	Policy revised for Ultomiris (ravulizumab-cwvz) to make the following criteria changes. Age criterion is removed from all three (3) diagnoses: paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), and generalized myasthenia gravis (gMG). Criteria for approval of Ultomiris (ravulizumab-cwvz) for the treatment of paroxsmyal nocturnal hemoglobinuria (PNH) was revised to add a criterion to require that the member's baseline hemoglobin level is < 10.5 g/dL.The criterion under (3): anemia secondary to PNH (e.g., hemoglobin </= 9 g/dL with symptoms of anemia is no longer an option.
Veopoz (pozelimab-bbfg) – Medicare	10/19/2023	New policy created for Veopoz (pozelimab-bbfg) requiring age and diagnosis based on FDA-approved indication.
Vtama (tapinarof) – Medicare	10/19/2023	Policy terminated. Criteria combined into J-1267.
Vtama (tapinarof) and Zoryve (roflumilast) – Medicare	10/19/2023	Policy revised for Vtama (tapinarof) and Zoryve (roflumilast) to specify that facial psoriasis is a contraindication to vitamin D analog step.
Vyondys 53 (golodirsen) and Viltepso (viltolarsen) – Medicare	10/19/2023	Policy revised for Viltepso (viltolarsen) and Vyondys 53 (golodirsen) to remove duration of steroid use and to remove the term stable dose of corticosteroid.
Xdemvy (lotilaner) – Medicare	10/19/2023	New policy for Xdemvy (lotilaner) requiring diagnosis based on FDA-approved indication supported by microscopic examination of pulled eyelashes or slit-lamp evaluation.
Yosprala (aspirin and omeprazole) – Medicare	10/19/2023	Policy has been terminated.
Zolinza (vorinostat) – Medicare	10/19/2023	Policy revised for Zolinza (vorinostat) to remove documentation and replace with attestation. Clarified that single agent or combination chemotherapies can be cyclophosphamide, vinblastine, or romidepsin per filing.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Zonisade (zonisamide) – Medicare	10/19/2023	Policy revised for Zonisade (zonisamide) to include additional medications for therapeutic failure/intolerance or contraindication to 2 of: carbamazepine suspension, chewable tablet, extended release capsule; gabapentin capsules, solution; lacosamide solution; levetiracetam solution; oxcarbazepine suspension; pregabalin tablets, capsules
Zurzuvae (zuranolone) – Medicare	10/19/2023	New policy created for Zurzuvae (zuranolone) to require that the member has a diagnosis of moderate to severe postpartum depression (F53.0), and the member is ≤ 12 months postpartum.

*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
Buprenorphine/Naloxone Step Therapy – Medicare	10/19/2023	Removed Bunavail (discontinued) from targeted drug products; administrative changes only
Intraocular Pressure Reduction Agents – Medicare	10/19/2023	Policy revised to add Iyuzeh (latanoprost ophthalmic solution) requiring diagnosis based on FDA-approved indications and trial and failure to latanoprost and one other generic, ophthalmic alternative.
Intravitreal Injections – Medicare	10/19/2023	Policy revised to add Eylea HD (aflibercept) requiring diagnosis based on FDA-approved indications; and the member to experience trial and failure to Avastin (bevacizumab) if the request is for Neovascular (Wet) Age-Related Macular Degeneration (nAMD).
Non-preferred Inhaler Products – Medicare	10/19/2023	Policy revised to add Flovent HFA (fluticasone propionate) to the policy and require a diagnosis of asthma and therapeutic failure or intolerance to two of the following: Asmanex (mometasone), fluticasone propionate HFA, or QVAR (beclomethasone). Symbicort (budesonide/formoterol fumarate) also added to the policy to require a diagnosis of either asthma or COPD and if the request is for brand Symbicort (budesonide/formoterol fumarate), the member has experienced therapeutic failure or intolerance to budesonide/formoterol fumarate or

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		Breyna. Criteria for fluticasone/salmeterol HFA removed.
Pennsaid (diclofenac) 2% topical solution – Medicare	01/01/2024	New policy created for Pennsaid (diclofenac sodium) topical solution 2% to require a diagnosis of osteoarthritis and failure, intolerance, or contraindication to diclofenac 1.5% topical drops.

3. Quantity Level Limit (QLL) Program
Effective date pending CMS approval, completion of internal review and implementation, unless otherwise noted.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Morphine Equivalent Daily Dose – Medicare	10/19/2023	Policy revised to follow the updated opioid conversion factor published in the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain. CMS is adopting the CDC list as the sole resource for opioid conversion factors. Conversion factors only apply to drugs taken orally or used transdermally and do not apply to opioids administered through other routes such as injection. Conversion factors removed from dihydrocodeine, pentazocine, propoxyphene, belladonna/opium, buprenorphine (single entity), butorphanol, fentanyl non-patch products, levorphanol and meperidine. Conversion factors updated for methadone, tramadol, oxycodone (Xtampza) and hydromorphone.
Quantity Level Limits – Medicare	10/19/2023	Quantity Level Limits - Medicare

Drug Name	Retail Quantity Limit (31 days)
Akeega (abiraterone acetate; niraparib)	2 tablets per day
Amjevita (adalimumab-atto) 20 mg/0.2 mL; adalimumab 20 mg/0.2 mL	2 syringes (0.4 mL) per 28 days
Amjevita (adalimumab-atto) 40 mg/0.4 mL; adalimumab 40 mg/0.4 mL	2 pens/syringes (0.8 mL) per 28 days

Drug Name	Retail Quantity Limit (31 days)
Amjevita (adalimumab-atto) 80 mg/0.8 mL; adalimumab 80 mg/0.8 mL	2 pens/syringes (1.6 mL) per 28 days
Arexvy (respiratory syncytial virus vaccine, adjuvanted)	2 doses per 365 days
Austedo XR (deutetrabenazine) Titration Kit	2 titration (84 tablets) packs per 365 days
Beyfortus (nirsevimab-alip)	3 doses per 999 days
Ingrezza (valbenazine) Huntington's chorea Titration Pack	2 titration (56 capsules) packs per 365 days
Iyuzeh (latanoprost)	1 single-use droperette per day
Izervay (avacincaptad pegol)	0.2 mL (2 single-dose vials) every 21 days
Sohonos (palovarotene) 1, 1.5, 2.5, 5 mg	1 capsule per day
Sohonos (palovarotene) 10 mg	2 capsules per day
Sublocade (buprenorphine ER) 100 mg/0.5 mL	1 injection per 30 days
Sublocade (buprenorphine ER) 300 mg/1.5 mL	1 injection per 30 days
Tyruko (natalizumab-sztn)	One vial (15 mL) per 28 days
Vanflyta (quizartinib)	2 tablets per day
Vanflyta (quizartinib) 17.7 mg tablet	2 tablets per day
Vanflyta (quizartinib) 26.5 mg tablet	2 tablets per day
Xalkori (crizotinib) oral capsules	4 capsules per day
Xalkori oral pellets 150 mg (crizotinib)	6 capsules of oral pellets per day

Drug Name	Retail Quantity Limit (31 days)
Xalkori oral pellets 20 mg, 50 mg (crizotinib)	4 capsules of oral pellets per day
Xdemvy (lotilaner)	1 bottle (10 mL) per 42 days
Ycanth (cantharidin)	2 applicators every 3 weeks
Zurzuvae (zuranolone) 20 mg, 25 mg	28 capsules per 180 days
Zurzuvae (zuranolone) 30 mg	14 capsules per 180 days

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