Formulary Updates

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Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for December 2021. The formularies and pharmaceutical management procedures are updated on a bi-monthly basis, and the following changes reflect the decisions made in December 2021 by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Please reference the guide below to navigate this communication:

As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (accessible via NaviNet® or our website). Click the **Pharmacy Program/Formularies** link from the menu on the left.

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Important Drug Safety Updates

Enoxaparin Sodium Injection, USP 40mg/0.4 mL by Sandoz, Inc.: Recall – Temperature Excursion During Shipping

On December 2nd, 2021, Sandoz, Inc. recalled the above product due to temperature excursion during shipment.

The exposure to higher temperatures may have significantly impacted the recalled product's (lot SAB06761A) effectiveness and thus there may be reasonable probability of risk for patients with health conditions that the product is intended to treat. Such patients could be at risk for blood clots blocking blood vessels, an artery, or traveling to other tissues or organs causing pain, swelling, stroke, clots to the lung, or death as a result of the underlying condition. To date, Sandoz has not received any reports of adverse events or injuries related to this recall.

Lidocaine HCl Topical Solution USP 4%, 50ml by Teligent Pharma, Inc.: Recall – Super Potency

On December 7th, 2021, Teligent Pharma, Inc. recalled the above product due to super potency.

Use of the super potent product would result in a higher than intended lidocaine dose. An increased lidocaine dose could lead to the development of local anesthetic systemic toxicity depending on the duration of the treatment and the specific patient. Local anesthetic systemic toxicity can result in central nervous system reactions including excitation and/or depression and more serious signs of cardiovascular toxicity, such as bradycardia, hypotension, and even cardiovascular collapse can present very quickly. If local anesthetic systemic toxicity is not recognized and treated quickly, severe morbidity and even death can result. Adults and the elderly who are more likely to use this product as well as children of lower body weight are more likely to experience local anesthetic systemic toxicity if a higher than intended lidocaine concentration is administered. To date, Teligent Pharma, Inc. has not received any reports of adverse events related to this recall.

Nitroglycerin Lingual Spray by Padagis: Recall – Defective Delivery System

On December 27th, 2021, Padagis recalled the above product due to a complaint received that a unit may not dispense.

If the product does not deliver the appropriate amount of nitroglycerin, the patient will likely continue to experience chest pain. The label advises that if relief is not obtained after 3 doses over 15 minutes the patient should promptly seek medical attention. To date, Padagis has not received any reports of adverse events related to this recall.

Clobetasol Propionate Ointment USP, 0.05% by Taro Pharmaceuticals U.S.A.: Recall – Microbial Contamination

On December 30th, 2021, Taro recalled the above product due to the presence of Ralstonia pickettii bacteria.

R. pickettii is present in the natural environment (soil, water) and for healthy individuals with intact skin, is unlikely to cause any localized or systemic infections. However, for individuals who are immunocompromised, or whose skin is not intact (i.e. sunburn, psoriasis, abrasions), there is a reasonable possibility that systemic infections may occur if the product is contaminated with *R. pickettii* due to the presence of the corticosteroid component which enhances absorption of the ointment. If this bacterium is circulating in the human blood stream it can cause life-threatening, invasive infections such sepsis, pneumonia, meningitis, inflammation of the bone or bone marrow, and infection in the joint fluid and joint tissues. To date, Taro has not received any adverse event reports related to this lot.

Highmark Formulary Update – December 2021

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 January 2022, unless otherwise noted.

Brand Name	Generic Name	Comments
Zimhi*	naloxone	Opioid overdose

*Effective date to be determined.

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Exkivity	mobocertinib	Provider Discretion
Livmarli	marlixibat	Provider Discretion
Opzelura	ruxolitinib 1% topical cream	hydrocortisone 2.5% cream(gram), triamcinolone acetonide cream (gram)
Qulipta	atopgepant	topiramate tablet, propranolol hcl tablet, divalproex sodium tablet, enteric coated
Scemblix	asciminib	Iclusig
Seglentis*	celecoxib/tramadol	tramadol hcl 50 mg tablet, celecoxib capsule
Tavneos	avacopan	prednisone tablet; prednisolone solution, oral
Tyrvaya	varenicline	Restasis, Xiidra^
Vuity	pilocarpine 1.25% ophthalmic solution	Provider Discretion (eyeglasses, contact lenses)
Zercapli	sertraline oral capsules	sertraline hcl tablet

Coverage may be contingent upon plan benefits.

*Effective date to be determined.
^Commercial Comprehensive only
**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
Exkivity	mobocertinib
Livmarli	marlixibat
Opzelura	ruxolitinib 1% topical cream
Scemblix	asciminib
Tavneos	avacopan

Table 4. Products to Be Removed or Shifted to Higher Tier - Effective January 2022

Brand name	Generic Name	Preferred Alternatives
Healthcare Reform Comprehensive products		
Alomide 0.1% eye drops	lodoxamide tromethamine	olopatadine hcl, epinastine hcl
Apokyn 30 mg/3 ml cartridge	apomorphine hcl	Provider Discretion
Contrave er 8-90 mg tablet	naltrexone hcl/bupropion hcl	Provider Discretion
Crinone 4% gel	progesterone, micronized	Endometrin
Crinone 8% gel	progesterone, micronized	Endometrin
Dipentum 250 mg capsule	olsalazine sodium	mesalamine er
Fml forte 0.25% eye drops	fluorometholone	prednisolone acetate, fluorometholone
Fml s.o.p.0.1% ointment	fluorometholone	prednisolone acetate, fluorometholone
Genotropin 12 mg cartridge	somatropin	Norditropin Flexpro
Genotropin 5 mg cartridge	somatropin	Norditropin Flexpro
Genotropin Miniquick 0.2 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 0.4 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 0.6 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 0.8 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 1 mg	somatropin	Norditropin Flexpro

Brand name	Generic Name	Preferred Alternatives
Genotropin Miniquick 1.2 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 1.4 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 1.6 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 1.8 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 2 mg	somatropin	Norditropin Flexpro
Humatrope 12 mg cartridge	somatropin	Norditropin Flexpro
Humatrope 24 mg cartridge	somatropin	Norditropin Flexpro
Humatrope 5 mg vial	somatropin	Norditropin Flexpro
Humatrope 6 mg cartridge	somatropin	Norditropin Flexpro
Maxidex 0.1% eye drops	dexamethasone	prednisolone acetate, fluorometholone
Miacalcin 400 unit/2 ml vial	calcitonin,salmon,synthetic	calcitonin-salmon
Orfadin 4 mg/ml suspension	nitisinone	nitisinone, Nityr
Pred mild 0.12% eye drops	prednisolone acetate	prednisolone acetate, fluorometholone
Santyl ointment	collagenase clostridium hist.	silver sulfadiazine
Sutent 12.5 mg capsule	sunitinib malate	sunitinib malate
Sutent 25 mg capsule	sunitinib malate	sunitinib malate
Sutent 37.5 mg capsule	sunitinib malate	sunitinib malate
Sutent 50 mg capsule	sunitinib malate	sunitinib malate
Commercial Comprehensive products		
Alomide 0.1% eye drops	lodoxamide tromethamine	olopatadine hcl, epinastine hcl
Crinone 4% gel	progesterone, micronized	Endometrin
Crinone 8% gel	progesterone, micronized	Endometrin
Fml forte 0.25% eye drops	fluorometholone	prednisolone acetate, fluorometholone
Fml s.o.p.0.1% ointment	fluorometholone	prednisolone acetate, fluorometholone
Genotropin 12 mg cartridge	somatropin	Norditropin Flexpro
Genotropin 5 mg cartridge	somatropin	Norditropin Flexpro
Genotropin Miniquick 0.2 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 0.4 mg	somatropin	Norditropin Flexpro

Brand name	Generic Name	Preferred Alternatives
Genotropin Miniquick 0.6 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 0.8 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 1 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 1.2 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 1.4 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 1.6 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 1.8mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 2 mg	somatropin	Norditropin Flexpro
Humatrope 12mg cartridge	somatropin	Norditropin Flexpro
Humatrope 24mg cartridge	somatropin	Norditropin Flexpro
Humatrope 5mg vial	somatropin	Norditropin Flexpro
Humatrope 6mg cartridge	somatropin	Norditropin Flexpro
Maxidex 0.1% eye drops	dexamethasone	prednisolone acetate, fluorometholone
Miacalcin 400 unit /2 ml vial	calcitonin,salmon,synthetic	calcitonin-salmon
Orfadin 4 mg/ml suspension	nitisinone	nitisinone, Nityr
Pred mild 0.12% eye drops	prednisolone acetate	prednisolone acetate, fluorometholone
Santyl ointment	collagenase clostridium hist	silver sulfadiazine
Sutent 12.5 mg capsule	sunitinib malate	sunitinib malate
Sutent 25 mg capsule	sunitinib malate	sunitinib malate
Sutent 37.5 mg capsule	sunitinib malate	sunitinib malate
Sutent 50 mg capsule	sunitinib malate	sunitinib malate

B. Changes to the Highmark Healthcare Reform Essential Formulary

The Essential Formulary is a closed formulary for select Healthcare Reform (HCR) 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 January 2022 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Zimhi*	naloxone	2	Opioid overdose
Items listed below were not added to the formulary			
Exkivity	mobocertinib	NF	Provider Discretion
Livmarli	marlixibat	NF	Provider Discretion
Opzelura	ruxolitinib 1% topical cream	NF	hydrocortisone 2.5% cream(gram), tacrolimus ointment (gram), pimecrolimus cream (gram)
Qulipta	atopgepant	NF	topiramate tablet, propranolol hcl tablet, divalproex sodium TABLET, ENTERIC COATED
Scemblix	asciminib	NF	Iclusig
Seglentis*	celecoxib/tramadol	NF	tramadol hcl 50 mg tablet, celecoxib capsule
Tavneos	avacopan	NF	prednisone tablet; prednisolone solution, oral
Tyrvaya	varenicline	NF	Restasis
Vuity	pilocarpine 1.25% ophthalmic solution	NF	Provider Discretion (eyeglasses, contact lenses)
Zercapli	sertraline oral capsules	NF	sertraline hcl tablet

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 – Effective January 2022

Brand Name	Generic Name	Preferred Alternatives
All Healthcare Reform Essential Products		
Acetamin-caf-dihydrocodein 325	acetaminophen/caff/dihydrocod	acetaminophen w/codeine
Apokyn 30 mg/3 ml cartridge	apomorphine hcl	Provider Discretion
Banzel 400 mg tablet	rufinamide	rufinamide
Bepreve 1.5% eye drops	bepotastine besilate	bepotastine besilate
Bystolic 10 mg tablet	nebivolol hcl	nebivolol hcl
Bystolic 2.5 mg tablet	nebivolol hcl	nebivolol hcl
Bystolic 20 mg	nebivolol hcl	nebivolol hcl
Bystolic 5 mg	nebivolol hcl	nebivolol hcl
Colchicine 0.6 mg capsule	colchicine	colchicine tablet
Doxycycline 50 mg tablet	doxycycline hyclate	doxycycline hyclate 50 mg cap
Durezol 0.05% eye drops	difluprednate	difluprednate
Dvorah 325-30-16 mg tablet	acetaminophen/caff/dihydrocod	acetaminophen w/codeine
Finacea 15% foam	azelaic acid	azelaic acid, metronidazole
Genotropin 12 mg/ml	somatropin	Norditropin Flexpro

Genotropin 5 mg/ml	somatropin	Norditropin Flexpro
Genotropin Miniquick 0.2 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 0.4 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 0.6 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 0.8 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 1 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 1.2 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 1.6 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 1.8 mg	somatropin	Norditropin Flexpro
Genotropin Miniquick 2 mg	somatropin	Norditropin Flexpro
Humatrope 12 mg cartridge	somatropin	Norditropin Flexpro
Humatrope 24 mg cartridge	somatropin	Norditropin Flexpro
Humatrope 5 mg vial	somatropin	Norditropin Flexpro
Humatrope 6 mg cartridge	somatropin	Norditropin Flexpro
Hysingla er 100 mg tablet	hydrocodone bitartrate	hydrocodone bitartrate
Hysingla er 120 mg tablet	hydrocodone bitartrate	hydrocodone bitartrate
Hysingla er 20 mg tablet	hydrocodone bitartrate	hydrocodone bitartrate
Hysingla er 30 mg tablet	hydrocodone bitartrate	hydrocodone bitartrate
Hysingla er 40 mg tablet	hydrocodone bitartrate	hydrocodone bitartrate
Hysingla er 60 mg tablet	hydrocodone bitartrate	hydrocodone bitartrate
Hysingla er 80 mg tablet	hydrocodone bitartrate	hydrocodone bitartrate
Imbruvica 140 mg tablet	ibrutinib	Imbruvica 140 mg capsule
Imbruvica 280 mg tablet	ibrutinib	Imbruvica 140 mg capsule
Orfadin 4 mg/ml suspension	nitisinone	nitisinone, Nityr
Perforomist 20 mcg/2 ml soln	formoterol fumarate	formoterol fumarate
Sutent 12.5 mg capsule	sunitinib malate	sunitinib malate
Sutent 25 mg capsule	sunitinib malate	sunitinib malate
Sutent 37.5 mg capsule	sunitinib malate	sunitinib malate
Sutent 50 mg capsule	sunitinib malate	sunitinib malate
Tyvaso 1.74 mg/2.9 ml solution	treprostinil	sildenafil citrate, ambrisentan
Tyvaso inhalation refill kit	treprostinil/neb accessories	sildenafil citrate, ambrisentan

Tyvaso inhalation starter kit	treprostinil/nebulizer/accesor	sildenafil citrate, ambrisentan
Tyvaso institutional start kit	treprostinil/nebulizer/accesor	sildenafil citrate, ambrisentan

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 January 2022 unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Zimhi*	naloxone	3	Opioid overdose
Items listed below were not added to the formulary			
Exkivity	mobocertinib	NF	Provider Discretion
Livmarli	marlixibat	NF	Provider Discretion
Opzelura	ruxolitinib 1% topical cream	NF	hydrocortisone 2.5% cream(gram), tacrolimus ointment (gram), pimecrolimus cream (gram)
Qulipta	atopgepant	NF	topiramate tablet, propranolol hcl tablet, divalproex sodium tablet, enteric coated
Scemblix	asciminib	NF	Iclusig
Seglentis*	celecoxib/tramadol	NF	tramadol hcl 50 mg tablet, celecoxib capsule
Tavneos	avacopan	NF	prednisone tablet; prednisolone solution, oral
Tyrvaya	varenicline	NF	Xiidra
Vuity	pilocarpine 1.25% ophthalmic solution	NF	Provider Discretion (eyeglasses, contact lenses)
Zercapli	sertraline oral capsules	NF	sertraline hcl tablet

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 – Effective January 2022

Brand Name	Generic Name	Preferred Alternatives
All Core Products		
Fenofibric acid 105 mg tablet	fenofibric acid	fenofibric acid 135 mg
Fenofibric acid 35 mg tablet	fenofibric acid	fenofibric acid 45 mg

Humatrope 12 mg cartridge	somatropin	Norditropin Flexpro
Humatrope 24 mg cartridge	somatropin	Norditropin Flexpro
Humatrope 6 mg cartridge	somatropin	Norditropin Flexpro
Humatrope 5 mg vial	somatropin	Norditropin Flexpro
Santyl ointment	collagenase clostridium hist.	silver sulfadiazine
Solu-medrol 500 mg vial	methylprednisolone sod succ	Provider Discretion
Sutent 12.5 mg capsule	sunitinib malate	sunitinib malate
Sutent 25 mg capsule	sunitinib malate	sunitinib malate
Sutent 37.5 mg capsule	sunitinib malate	sunitinib malate
Sutent 50 mg capsule	sunitinib malate	sunitinib malate

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)			
No changes at this time.			
Items listed below were added to the formulary (Non-Preferred)			
Exkivity	mobocertinib	3	Provider Discretion
Livmarli	marlixibat	3	Provider Discretion
Qulipta*	atopgepant	3	topiramate tablet, propranolol hcl tablet, divalproex sodium tablet, enteric coated
Tavneos*	avacopan	3	prednisone tablet; prednisolone solution, oral
Tyrvaya*	varenicline	3	Restasis, Xiidra
Vuity*	pilocarpine 1.25% ophthalmic solution	3	Provider Discretion (eyeglasses, contact lenses)
Seglentis*	celecoxib/tramadol	3	tramadol hcl 50 mg tablet, celecoxib capsule
Zimhi*	naloxone	3	Provider Discretion
Items listed below were not added to the formulary			
Zercapli oral capsules	sertraline oral capsules	NF	sertraline hcl tablet
Opzelura	ruxolitinib 1% topical cream	NF	hydrocortisone 2.5% cream(gram), triamcinolone acetonide cream (gram)
Scemblix	asciminib	NF	Iclusig

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
Exkivity	mobocertinib
Livmarli	marlixibat
Opzelura	ruxolitinib 1% topical cream
Scemblix	asciminib
Tavneos	avacopan

Table 3. Products to Be Removed or Shifted to Higher Tier – Effective January 2022

Brand Name	Generic Name	Preferred Alternatives
All National Select Products – Deletions		
Adderall xr 10 mg capsule	dextroamphetamine/amphetamine	dextroamphetamine-amphet er
Adderall xr 15 mg capsule	dextroamphetamine/amphetamine	dextroamphetamine-amphet er
Adderall xr 20 mg capsule	dextroamphetamine/amphetamine	dextroamphetamine-amphet er
Adderall xr 25 mg capsule	dextroamphetamine/amphetamine	dextroamphetamine-amphet er
Adderall xr 30 mg capsule	dextroamphetamine/amphetamine	dextroamphetamine-amphet er
Adderall xr 5 mg capsule	dextroamphetamine/amphetamine	dextroamphetamine-amphet er
Alinia 500 mg tablet	nitazoxanide	nitazoxanide
Alrex 2% eye drops	loteprednol etabonate	azelastine hcl, bepotastine besilate
Avsola 100 mg vial	infliximab-axxq	Inflectra
Azopt 1% eye drops	brinzolamide	brinzolamide
Bepreve 1.5% eye drops	bepotastine besilate	bepotastine besilate
Bynfezia 2,500 mcg/ml pen	octreotide acetate	octreotide acetate
Cipro hc otic suspension	ciprofloxacin/hydrocortisone	ciprofloxacin-dexamethasone
Dexilant dr 30 mg capsule	dexlansoprazole	omeprazole, pantoprazole sodium
Dexilant dr 60 mg capsule	dexlansoprazole	omeprazole, pantoprazole sodium
Doryx dr 200 mg tablet	doxycycline hyclate	doxycycline hyclate
Doryx mg 50 mg tablet	doxycycline hyclate	doxycycline hyclate
Doryx mpc dr 120 mg tablet	doxycycline hyclate	doxycycline hyclate
Invokamet 150-1,000 mg tablet	canagliflozin/metformin hcl	Synjardy, Xigduo xr

Invokamet 150-500 mg tablet	canagliflozin/metformin hcl	Synjardy, Xigduo xr
Invokamet 50-1,000 mg tablet	canagliflozin/metformin hcl	Synjardy, Xigduo xr
Invokamet 50-500 mg tablet	canagliflozin/metformin hcl	Synjardy, Xigduo xr
Invokamet xr 150-1,000 mg tab	canagliflozin/metformin hcl	Synjardy, Xigduo xr
Invokamet xr 50-1,000 mg tab	canagliflozin/metformin hcl	Synjardy, Xigduo xr
Invokamet xr 50-500 mg tablet	canagliflozin/metformin hcl	Synjardy, Xigduo xr
Invokana 100 mg tablet	canagliflozin	Jardiance, Farxiga
Invokana 300 mg tablet	canagliflozin	Jardiance, Farxiga
Kerydin 5% topical solution	tavaborole	tavaborole
Lantus 100 Unit/ML vial	insulin glargine	Semglee (YFGN)
Lantus Solostar 100 Unit/ML	insulin glargine	Semglee (YFGN) Pen
Nuvaring vaginal ring	etonogestrel/ethinyl estradiol	etonogestrel-ethinyl estradiol, eluryng
Nyvepria 6 mg/0.6 ml syringe	pegfilgrastim-apgf	Fulphila, Ziextenzo
Onzetra xsail 11 mg/nosepiece	sumatriptan succinate	sumatriptan, Zomig nasal
Otovel 0.3%-0.025% ear drops	ciprofloxacin hcl/fluocinolone	ciprofloxacin-dexamethasone
Relpax 20 mg tablet	eletriptan hydrobromide	eletriptan hydrobromide
Relpax 40 mg tablet	eletriptan hydrobromide	eletriptan hydrobromide
Remicade 100 mg vial	infliximab	Inflectra
Renflexis 100 mg vial	infliximab-abda	Inflectra
Sorilux 0.005% foam	calcipotriene	calcipotriene cream
Synthroid 300 mcg tablet	levothyroxine sodium	levothyroxine sodium, levoxyl
Synthroid 200 mcg tablet	levothyroxine sodium	levothyroxine sodium, levoxyl
Synthroid 175 mcg tablet	levothyroxine sodium	levothyroxine sodium, levoxyl
Synthroid 150 mcg tablet	levothyroxine sodium	levothyroxine sodium, levoxyl
Synthroid 137 mcg tablet	levothyroxine sodium	levothyroxine sodium, levoxyl
Synthroid 125 mcg tablet	levothyroxine sodium	levothyroxine sodium, levoxyl
Synthroid 112 mcgtablet	levothyroxine sodium	levothyroxine sodium, levoxyl
Synthroid 100 mcg tablet	levothyroxine sodium	levothyroxine sodium, levoxyl
Synthroid 88 mcg tablet	levothyroxine sodium	levothyroxine sodium, levoxyl
Synthroid 75 mg tablet	levothyroxine sodium	levothyroxine sodium, levoxyl
Synthroid 50 mg tablet	levothyroxine sodium	levothyroxine sodium, levoxyl
Synthroid 25 mg tablet	levothyroxine sodium	levothyroxine sodium, levoxyl
Tecfidera 120 mg capsule	dimethyl fumarate	dimethyl fumarate
Tecfidera 240 mg capsule	dimethyl fumarate	dimethyl fumarate

Tecfidera 120-240 mg starter pack	dimethyl fumarate	dimethyl fumarate
Tri-luma cream	fluocinolone/tretinoin/h-quin	fluocinolone acetonide, tretinoin
Vimovo 375 -20 mg tablet	naproxen/esomeprazole mag	naproxen-esomeprazole mag
Vimovo 500 -20 mg tablet	naproxen/esomeprazole mag	naproxen-esomeprazole mag
Vpriv 400 units vial	velaglucerase alfa	cerezyme
Zerviate 0.24% eye drops	cetirizine hcl	azelastine hcl, bepotastine besilate
Zilxi 1.5% cream	minocycline hcl	metronidazole, finacea foam
Zioptan 0.0015% eye drops	tafluprost/pf	latanoprost, bimatoprost
All national select products – tier changes		
Alphagan p 0.1% drops	BRIMONIDINE TARTRATE	brimonidine tartrate
Amzeeq 4% foam	minocycline hcl	clindamycin phosphate, erythromycin
Combigan 0.2%-0.5% eye drops	brimonidine tartrate/timolol	brimonidine tartrate, timolol maleate
Droxidopa 100 mg capsule	droxidopa	fludrocortisone acetate, midodrine hcl
Droxidopa 200 mg capsule	droxidopa	fludrocortisone acetate, midodrine hcl
Droxidopa 300 mg capsule	droxidopa	fludrocortisone acetate, midodrine hcl
Inveltys 1% eye drops	loteprednol etabonate	loteprednol etabonate, prednisolone acetate
Lotemax 0.5% eye ointment	loteprednol etabonate	loteprednol etabonate
Lotemax 0.5% ophthalmic gel	loteprednol etabonate	loteprednol etabonate
Lotemax sm 0.38% ophth gel	loteprednol etabonate	loteprednol etabonate
Lumigan 0.01% eye drops	bimatoprost	latanoprost, bimatoprost
Mvasi 100 mg/4 ml vial	bevacizumab-awwb	Zirabev
Mvasi 400 mg/16 ml vial	bevacizumab-awwb	Zirabev
Tobradex eye ointment	tobramycin/dexamethasone	tobramycin-dexamethasone

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Afinitor (everolimus) - Commercial and Healthcare Reform	12/16/2021	Policy revised for Afinitor (everolimus) 10 mg to require step through generic everolimus tablets; and for Afinitor Disperz

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		(everolimus tablets for suspension) to require step through generic everolimus tablets for suspension. Policy revised to require for reauthorization of brand Afinitor or brand Afinitor Disperz, documentation that the AB-rated generic is ineffective or not tolerated.
Anti-Angiogenesis and VEGF Kinase Inhibitors - Commercial and Healthcare Reform	12/17/2021	Policy revised for Cabometyx (cabozantinib) for use in members 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer that has progressed following prior VEGFR (vascular endothelial growth factor receptor) targeted therapy and who are radioactive iodine-refractory or ineligible; and for Lenvima (lenvatinib) to specify for the treatment of endometrial carcinoma use in combination with pembrolizumab.
Anti-Angiogenesis and VEGF Kinase Inhibitors - Commercial and Healthcare Reform	01/01/2022	Policy revised for Cabometyx (cabozantinib) for use in members 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer that has progressed following prior VEGFR (vascular endothelial growth factor receptor) targeted therapy and who are radioactive iodine-refractory or ineligible; and for Lenvima (lenvatinib) to specify for the treatment of endometrial carcinoma use in combination with pembrolizumab. Reauthorization criteria revised to include if the request is for brand Sutent, provision of documentation that the AB-rated generic is ineffective or not tolerated.
Arikayce (amikacin) - Commercial and Healthcare Reform	12/16/2021	Policy revised for Arikayce (amikacin) for initial authorization that the member did not achieve negative sputum cultures despite at least 6 months of treatment with a multidrug regimen utilizing at least two of the following: a macrolide (e.g., clarithromycin or azithromycin), a rifamycin, or ethambutol. Reauthorization criteria revised to require that Arikayce (amikacin) will continue to be used in conjunction with a background multidrug regimen. Authorization duration revised to 12 months.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
BCR-ABL Kinase Inhibitors - Commercial and Healthcare Reform	12/09/2021	Policy revised to add Scemblix (asciminib) for treatment of adults with chronic phase Philadelphia chromosome positive chronic myeloid leukemia treated with two or more tyrosine kinase inhibitors and for treatment of adults with chronic phase Philadelphia chromosome position chronic myeloid leukemia with the T315I mutation after failing Iclusig (ponatinib).
CDK Inhibitors - Commercial and Healthcare Reform	12/02/2021	Policy revised for Verzenio (abemaciclib) for use in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) as adjuvant treatment in members 18 years of age or older with HR-positive (hormone receptor), HER2-negative (human epidermal growth factor receptor 2), node-positive, early breast cancer at high risk of recurrence and a Ki-67 score of ≥ 20% per an FDA-approved test.
Cerdelga (eliglustat) - Commercial and Healthcare Reform	12/15/2021	Policy revised for Cerdelga (eliglustat) to require confirmation of type 1 Gaucher disease through either the member having a deficiency in glucocerebrosidase activity in peripheral leukocytes or genetic testing confirming mutant alleles.
CGRP Inhibitors - Commercial and Healthcare Reform	TBD	Policy revised to add criteria for Qulipta (atogepant) and revise criteria for Nurtec (rimegepant) for patients 18 years of age or older with a diagnosis of episodic migraine defined as 4 to 14 headache days per month, prescriber attestation of baseline monthly migraine days, attestation that headaches are not caused by medication rebound, overutilization, or lifestyle factors, therapeutic failure or intolerance to one agent from two different prophylactic migraine medication classes (alpha-agonists, angiotensin converting enzyme inhibitors or angiotensin II receptor blockers, antiepileptic drugs, beta-blockers, calcium channel blockers, serotonin-norepinephrine reuptake inhibitors, or tricyclic antidepressants), therapeutic failure or intolerance to a plan-preferred subcutaneous injectable calcitonin gene-related receptor (CGRP) inhibitor, and

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		attestation of benefits outweighing risks if two chemically distinct CGRP inhibitors are used concomitantly with reauthorization requiring reduction in number of migraine days per month by 50% from baseline or at least 4 days from baseline. Criteria for Nurtec (rimegepant) for acute migraine updated to clarify diagnosis. Authorization duration for all CGRP inhibitors is 6 months initial authorization and 12 months for reauthorization.
Chenodal (chenodiol) - Commercial and Healthcare Reform	12/15/2021	Policy revised for Chenodal (chenodiol) to update reauthorization criteria to require at least partial dissolution of gallstones.
Cholbam (cholic acid) - Commercial and Healthcare Reform	12/15/2021	Policy revised for Cholbam (cholic acid) to require member to be 3 weeks of age or older and confirm member's diagnosis through either abnormal urinary bile acid detected by mass spectrometry (e.g., Fast Atom Bombardment ionization – Mass Spectrometry [FAB-MS]) or other biochemical or genetic testing. For Peroxisomal Disorders diagnosis only, member must be using Cholbam as adjunctive treatment. Initial authorization length is now 3 months, and reauthorization length is now 12 months.
Chronic Inflammatory Diseases - Commercial and Healthcare Reform	12/15/2021	Policy revised for Siliq (brodalumab) to remove maintenance requirement for documentation of improvement in the physician's global assessment score, psoriasis area severity index score, or a decrease in the affected body surface area of psoriatic plaque lesions. Initial authorization duration updated to 12 months.
Chronic Inflammatory Diseases - Commercial National Select Formulary	12/16/2021	Policy revised for Siliq (brodalumab) to remove maintenance requirement for documentation of improvement in the physician's global assessment score, psoriasis area severity index score, or a decrease in the affected body surface area of psoriatic plaque lesions. Initial authorization duration updated to 12 months.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Diclofenac Containing Products - Commercial and Healthcare Reform	01/25/2022	Policy updated to include a new single-source diclofenac potassium 25 mg tablet and Lofena (a generic diclofenac potassium 25 mg tablet). The following criteria must be met for the member to receive this medication: the member must be 18 years of age or older; the member must have a diagnosis of one of the following: primary dysmenorrhea, mild to moderate pain, osteoarthritis, or rheumatoid arthritis, and the member must have experienced therapeutic failure, contraindication, or intolerance to three (3) plan-preferred formulary, oral generic NSAIDs, one (1) of which must be oral diclofenac.
Dupixent (dupilumab) - Commercial and Healthcare Reform	TBD	Policy criteria revised for Dupixent (dupilumab) for atopic dermatitis to allow for the member to experience therapeutic failure or intolerance to one generic topical corticosteroid, or the member has atopic dermatitis with facial or anogenital involvement, or the prescriber submits documentation topical prescription therapies would not be advisable for severe atopic dermatitis maintenance therapy due to a large proportion of body surface area (BSA) affected making topical therapy impractical to apply, or severely damaged skin. Member must also experience therapeutic failure or intolerance to one generic topical calcineurin inhibitor or the prescriber submits documentation topical prescription therapies would not be advisable for severe atopic dermatitis maintenance therapy due to a large proportion of body surface area (BSA) affected making topical therapy impractical to apply, or severely damaged skin. Criteria revised for asthma to require the member is 6 years of age or older and if the member is 6 to 17 years of age, they have a pretreated forced expiratory volume in one second < 90% predicted. Asthma quantity limit table updated to allow two 100 mg syringes every four weeks for members with asthma 6-11 years of age and 15-<30 kg.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
EGFR-Targeting Kinase Inhibitors - Commercial and Healthcare Reform	12/27/2021	Policy revised to add criteria for Exkivity (mobocertinib) in members 18 years of age or older with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. Reauthorization criteria revised to add if the request is for brand Tarceva, documentation that the AB-rated generic is ineffective or not tolerated.
Horizant (gabapentin enacarbil) - Commercial and Healthcare Reform	12/16/2021	Policy revised for Horizant (gabapentin enacarbil) for restless leg syndrome to change antiepileptics to gabapentin.
Isturisa (osilodrostat) - Commercial and Healthcare Reform	12/14/2021	Policy revised for reauthorization for Isturisa (osilodrostat); requires attestation that urinary free cortisol (UFC) levels meet one of the following criteria (1. or 2.): 1. UFC levels meet one (1) of the following normal values (a., b., or c.): a. < 100 mcg/24 hours, b. <276 nmol/day, c. normal range per the laboratory reference range 2. UFC level that decreased by more than or equal to 50% from pre-treatment UFC level.
JAK Inhibitors – Commercial and Healthcare Reform	12/17/2021	Policy revised for Jakafi (ruxolitinib) to add criteria for members 12 years of age or older with chronic graft versus host disease after therapeutic failure or intolerance to at least one prior therapy; reauthorization criteria revised for Jakafi (ruxolitinib) to include prescriber attestation of disease improvement or delayed disease progression for either acute- or chronic graft versus host disease.
Korlym (mifepristone) - Commercial and Healthcare Reform	12/14/2021	Policy revised for Korlym (mifepristone) to remove lifestyle modifications for type 2 diabetes as an option and clarify that step therapy is pharmacologic for type 2 diabetes.
Livmarli (maralixibat) - Commercial and Healthcare Reform	12/15/2021	New policy for Livmarli (maralixibat) for patients 1 year of age and older with Alagille syndrome confirmed by genetic testing demonstrating a JAGGED 1 deletion or mutation, elevated serum bile acid levels above the laboratory reference range,

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		cholestatic pruritis explained only by liver disease, and the member does not have decompensated cirrhosis, portal hypertension, or history of a hepatic decompensation event. Reauthorization criteria of prescriber attestation of decrease in total serum bile acid levels from baseline and improvement in pruritis. Reauthorization requires prescriber attestation that patient has not progressed to cirrhosis, portal hypertension, or hepatic decompensation. Quantity limit approval criteria for quantities over 1 bottle per month based on FDA-approved weight based dosing.
Market Watch Programs - Delaware	01/25/2022	Policy revised to add Seglentis (celecoxib and tramadol hydrochloride) to the High Cost Low Value table asking for step through celecoxib and tramadol hydrochloride 50 mg, available separately. Also, revised to add diclofenac potassium 25 mg tablet and Lofena to require step through generic diclofenac, meloxicam, and ibuprofen. Sertraline 150 MG and 200 MG added to require a step through generic sertraline, fluoxetine, and citalopram. Additionally, rosuvastatin-ezetimibe added to require steps through single-entity rosuvastatin and ezetimibe and single entity atorvastatin and ezetimibe.
Market Watch Programs - New York, Pennsylvania, and West Virginia	01/25/2022	Policy revised to add Seglentis (celecoxib and tramadol hydrochloride) to the High Cost Low Value table asking for step through celecoxib and tramadol hydrochloride 50 mg, available separately. Also, revised to add diclofenac potassium 25 mg tablet and Lofena to require step through generic diclofenac, meloxicam, and ibuprofen. Sertraline 150 MG and 200 MG added to require a step through generic sertraline, fluoxetine, and citalopram. Additionally, rosuvastatin-ezetimibe added to require steps through single-entity rosuvastatin and ezetimibe and single entity atorvastatin and ezetimibe.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Miscellaneous Immunomodulators – Commercial and Healthcare Reform	TBD	Policy revised for Thalomid (thalidomide), Revlimid (lenalidomide), Pomalyst (pomalidomide) to add a step through the respective generic drug when available on the market. Reauthorization criteria revised to add if the request is for brand Thalomid, Revlimid, or Pomalyst, documentation that the AB-rated generic is ineffective or not tolerated.
Non-Preferred Basal Insulins - Commercial and Healthcare Reform	11/24/2021	Policy revised for Semglee (insulin glargine-yfgn) to add trial and failure through all the following: Basaglar, Lantus, Levemir, Toujeo, and Tresiba. Policy excludes members with the Commercial Core, Commercial NSF, and HCR Essential formularies.
Ofev (nintedanib) and Esbriet (pirfenidine) - Commercial and Healthcare Reform	12/19/2021	Policy revised for Ofev (nintedanib) and Esbriet (pirfenidine) for reauthorization to require prescriber attestation that the member has experienced a therapeutic response defined as one of the following: disease improvement or delayed disease progression and meets one of the following: is a non-smoker or has maintained smoking cessation.
Opzelura (ruxolitinib) - Commercial and Healthcare Reform	12/20/2021	Policy created for Opzelura (ruxolitinib) to require that the member is 12 years of age or older, prescriber attests that member has mild to moderate atopic dermatitis (AD), 3-20% of the body with AD involvement, and the member must have experienced therapeutic failure, contraindication, or intolerance to a topical prescription corticosteroid or have facial or anogenital involvement, and have experienced therapeutic failure, contraindication, or intolerance to generic topical tacrolimus (0.03% or 0.1%) or generic topical pimecrolimus 1%, and the member has experienced therapeutic failure, contraindication, or intolerance to plan-preferred Eucrisa (crisaborole). Reauthorization criteria requires documentation or attestation of improvement of response to therapy. Initial

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		authorization is for a period of 8 weeks; reauthorization period is one (1) year.
Parathyroid Hormone Analogs - Commercial and Healthcare Reform	12/14/2021	Policy revised to allow for Forteo (teriparatide) to allow therapy to exceed 24 months if the prescriber attests that the member remains at or has returned to having a high risk of fracture.
PCSK9 Inhibitors – Commercial and Healthcare Reform	12/14/2021	Policy revised for Repatha (evolocumab) to change age to 10 years of age or older for homozygous familial hypercholesterolemia (HoFH) and heterozygous familial hypercholesterolemia (HeFH). For HeFH, added familial hypercholesterolemia possibility of “definite” on the Make Early Diagnosis to Prevent Early Deaths (MEDPED) tool as one of three supporting diagnosis criteria, if the member is 17 years of age or younger, current LDL-C > 130 mg/dL, and if the member is 17 years of age or younger, the member will continue to receive concurrent lipid-lowering therapies for treatment of HeFH. For hypercholesterolemia with atherosclerotic cardiovascular disease (ASCVD), removed clinical documentation of ASCVD and replaced with diagnosis of ASCVD.
PCSK9 Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised for Repatha (evolocumab) and Praluent (alirocumab) for primary hyperlipidemia to remove coronary artery calcium or calcification score to replace with atherosclerotic cardiovascular disease (ASCVD) risk assessment classified as borderline, intermediate, or high. For Repatha (evolocumab) and Praluent (alirocumab) reauthorization criteria updated to ask that the member has experienced a reduction in LDL-C from baseline.
Somavert (pegvisomant) – Commercial and Healthcare Reform	04/01/2022	New policy created for Somavert (pegvisomant) requiring the member to be 18 years of age or older with diagnosis of acromegaly; high pretreatment insulin-like growth factor-1 (IGF-1) based on laboratory reference range; inadequate, partial response, or not a candidate for surgery or radiotherapy, and have experienced

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		therapeutic failure, contraindication, or intolerance to generic octreotide acetate.
Targretin (bexarotene) - Commercial and Healthcare Reform	04/01/2022	Policy for Targretin (bexarotene) updated to separate the criteria for the capsule and gel formulations. Alternatives for the oral capsule have been updated to remove PUVA and add systemic retinoids and methotrexate. Criteria added for Targretin topical gel to require the member to be 18 years of age or older, be using Targretin gel for cutaneous lesions associated with Stage IA or IB cutaneous T-cell lymphoma, and have experienced therapeutic failure, contraindication, or intolerance to at least one (1) other guideline-directed therapy, including topical corticosteroids, topical chemotherapy, local radiation, topical retinoid, phototherapy, topical imiquimod, topical mechlorethamine, or total skin electron beam radiation. Reauthorization criteria updated to require prescriber documentation that the AB-rated generic is ineffective or not tolerated if the request is for brand Targretin capsules.
Tavneos (avacopan) - Commercial and Healthcare Reform	12/16/2021	Policy created for Tavneos (avacopan) to require that the member is 18 years of age or older, has a diagnosis of severe active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), has a positive test for anti-proteinase 3 (anti-PR3) or anti-myeloperoxidase (anti-MPO), and is receiving concomitant therapy with glucocorticoids and immunosuppressives. For reauthorization, the prescriber provides attestation that the member has had disease stability or disease improvement, will continue to receive concomitant therapy with glucocorticoids and immunosuppressives, and the prescriber provides attestation that the member has had a reduction in overall glucocorticoid dose. Initial authorization duration of 6 months and reauthorization duration of 12 months.
Testosterone (Androgens)	12/14/2021	Policy revised to add criterion for members 15 years of age and younger requiring that

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		the drug is prescribed by a clinician competent in the evaluation and induction of pubertal development. Criteria that the drug must be prescribed by an endocrinologist or provider that specializes in gender affirmation and that the goal of testosterone therapy is masculinization are removed.
Tyrvaya (varenicline solution) – Commercial and Healthcare Reform	01/25/2022	New policy created for Tyrvaya (varenicline solution) requiring members to be 18 years of age or older with a diagnosis of dry eye disease and have experienced therapeutic failure, contraindication, or intolerance to artificial tears and both Restasis (cyclosporine ophthalmic emulsion) and Xiidra (lifitegrast ophthalimc solution).
Vimpat (lacosamide) – Healthcare Reform	12/16/2021	Policy revised to update age requirement for partial-onset seizures to 1 month of age or older and reauthorization criteria added for diagnosis of primary generalized tonic-clonic seizures, to continue using as adjunctive therapy.
Vuity (pilocarpine hydrochloride) - Commercial and Healthcare Reform	01/25/2022	Policy created for Vuity (pilocarpine hydrochloride) to ask that member is 40 years of age or older, diagnosis of presbyopia, and has tried and failed eyeglasses or contact lenses. Reauthorization attesting positive clinical response.
Vyleesi (bremelanotide injection) - Commercial and Heathcare Reform	12/16/2021	Policy revised for Vyleesi (bremelanotide injection) to remove reauthorization criteria requiring prescriber to attest that the member is tolerating therapy.
Wakix (pitolisant) - Commercial and Healthcare Reform	12/16/2021	Policy revised to require therapeutic failure, contraindication, or intolerance to one generic CNS stimulant before use of Wakix (pitolisant) for patients with narcolepsy with cataplexy.
Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates) - Commercial and Healthcare Reform	12/16/2021	Policy revised for Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates). For Narcolepsy, added criteria regarding hypocretin-1 deficiency and now require members with cataplexy to experience therapeutic failure, contraindication, or

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		intolerance to a plan-preferred generic CNS stimulant (e.g., dextroamphetamine).

*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/or Approval Criteria
Albuterol Sulfate HFA – Commercial and Healthcare Reform	TBD	New policy created for Albuterol Sulfate HFA authorized generic requiring the member to be 4 years of age or older with diagnosis of bronchospasm (including exercise-induced bronchospasm) and therapeutic failure or intolerance to generic albuterol sulfate HFA for approval of the authorized generic.
Atypical Antipsychotics - Commercial	12/08/2021	Whenever an atypical antipsychotic is FDA-approved for a bipolar I condition, criteria was revised to allow coverage for a bipolar II condition as well. This change was made for Abilify, aripiprazole ODT (orally-dissolving tablet), Abilify Mycite, Seroquel XR, Symbyax, and Vraylar.
Atypical Antipsychotics - Healthcare Reform	12/08/2021	Whenever an atypical antipsychotic is FDA-approved for a bipolar I condition, criteria was revised to allow coverage for a bipolar II condition as well. This change was made for Abilify, aripiprazole ODT (orally-dissolving tablet), Abilify Mycite, Symbyax, and Vraylar.
Doxepin 5% Cream - Commercial and Healthcare Reform	12/09/2021	Policy revised for doxepin hydrochloride 5% creams to combine Commercial and Healthcare Reform criteria. Quantity limitation exception added for Commercial line of business that coverage of additional quantities of doxepin hydrochloride 5% creams when the member has received a prior authorization within the past 30 days, documentation submitted that an additional quantity is needed for the affected body surface area, and the total course of therapy will not exceed 8 days. Health care reform authorization duration updated to 1 month.
Doxepin 5% Cream - Healthcare Reform	12/01/2021	Policy terminated. Criteria combined into J-0757.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Eysuvis (loteprednol) - Commercial and Healthcare Reform	12/19/2021	Policy revised to remove step through generic loteprednol etabonate and added reauthorization criteria requiring the prescriber to attest that the member continues to have symptoms of dry eye syndrome.
Gout Therapy – Commercial and Healthcare Reform	12/16/2021	Policy revised to correct FDA approved indications for Colchicine capsules (authorized generic [AG]). The only FDA approved indication for this product is prophylaxis of gout attacks. Indications for prevention and treatment of gout flares (gouty arthritis) and treatment of familial Mediterranean fever (FMF) were removed. Criteria for Colchicine capsules (AG) was revised to require that the member is 18 years of age or older, using the medication for the prophylaxis of gout attacks, the member has experienced therapeutic failure or intolerance to allopurinol, and the member has experienced therapeutic failure or intolerance to generic colchicine tablets.
Gralise (gabapentin) - Commercial and Healthcare Reform	12/16/2021	Policy revised to add in reauthorization criteria of prescriber attestation that the member has experienced a positive clinical response to therapy.
Insomnia Medications - Commercial and Healthcare Reform	12/09/2021	Policy revised to require a step-through zolpidem tartrate for Ambien in addition to one other plan-preferred agent (zolpidem tartrate ER, eszopiclone, or zaleplon). Step-through zolpidem tartrate ER is required for Ambien ER, in addition to one other plan-preferred agent (zolpidem tartrate, eszopiclone, or zaleplon). Combined with policy J-0789 Insomnia Medications - Healthcare Reform.
Insomnia Medications - Healthcare Reform	12/01/2021	Terminated. Combined with J-0607 Insomnia Medications - Commercial to make single policy.
Latuda (lurasidone) - Commercial	12/08/2021	Whenever an atypical antipsychotic is FDA-approved for a bipolar I condition, criteria was revised to allow coverage for a bipolar II condition as well. Latuda criteria revised to include coverage for bipolar II.
Latuda (lurasidone) - Healthcare Reform	12/08/2021	Whenever an atypical antipsychotic is FDA-approved for a bipolar I condition, criteria was revised to allow coverage for a bipolar II condition as well. Latuda criteria revised to include coverage for bipolar II.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Non-Preferred Atypical Antipsychotic Medications - Healthcare Reform Essential Formulary	12/08/2021	Whenever an atypical antipsychotic is FDA-approved for a bipolar I condition, criteria was revised to allow coverage for a bipolar II condition as well. This change was made for Latuda and Saphris.
Non-Preferred Dipeptidyl Peptidase IV (DPP-IV) Inhibitors and Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Commercial and Healthcare Reform	01/01/2022	Policy revised for Qtern (dapagliflozin/saxagliptin) and Steglujan (ertugliflozin/sitagliptin) that member must try and fail either Glyxambi (empagliflozin/linagliptin) or Trijardy XR (empagliflozin/linagliptin/metformin) extended-release. Previous individual preferred dipeptidyl peptidase IV or sodium-glucose co-transporter 2 inhibitors removed.
Non-Preferred ICS & ICS-LABA Therapies - Commercial	TBD	Policy created for Advair Diskus (fluticasone-salmeterol), Alvesco (ciclesonide), and Airduo Respiclick (fluticasone-salmeterol). For Advair Diskus (fluticasone-salmterol), the member must be 4 years of age or older; have a diagnosis of asthma or chronic obstructive pulmonary disease (COPD); if the member is 11 years of age or younger, they have experienced therapeutic failure or intolerance to one of the following: Wixela Inhub (fluticasone-salmeterol) or generic fluticasone-salmeterol diskus; if the member is 12 years of age or older, they have experienced therapeutic failure or intolerance to one of the following: Wixela Inhub (fluticasone-salmeterol) or generic fluticasone-salmeterol diskus and they have experienced therapeutic failure, contraindication, or intolerance to two of the following: Advair HFA (fluticasone-salmeterol), Breo Ellipta (fluticasone-vilanterol), Dulera (mometasone-formoterol), or Symbicort (budesonide-formoterol). For Alvesco (ciclesonide), the member must be 12 years of age or older; have a diagnosis of asthma; and experienced therapeutic failure, contraindication, or intolerance to two of the following plan-preferred, drug-containing products: budesonide (Pulmicort Flexhaler or Brand Symbicort), fluticasone (Wixela Inhub, generic fluticasone-salmeterol diskus, Advair HFA, Breo Ellipta, Arnuity Ellipta, or Flovent), mometasone (Asmanex or Dulera), or

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		beclomethasone (QVAR Redihaler). For Airduo Respiclick (fluticasone-salmeterol), the member is 12 years of age or older; has a diagnosis of asthma; has experienced therapeutic failure or intolerance to one of the following: Wixela Inhub (fluticasone-salmeterol) or generic fluticasone-salmeterol diskus; and has experienced therapeutic failure, contraindication, or intolerance to two of the following: Advair HFA (fluticasone-salmeterol), Breo Ellipta (fluticasone-vilanterol), Dulera (mometasone-formoterol), or Symbicort (budesonide-formoterol). Reauthorization criteria to require prescriber attestation that the member has experienced positive clinical response to therapy. Authorization duration of 12 months.
Non-Preferred Tramadol Products - Commercial and Healthcare Reform	TBD	Policy revised to add Seglentis (celecoxib and tramadol hydrochloride) that member has a diagnosis of acute pain and tried and failed tramadol hydrochloride 50 mg and celecoxib available separately and taken together. For reauthorization added that the prescriber attests the member requires continued therapy for pain management.
Non-Preferred Tramadol Products - Commercial and Healthcare Reform	12/16/2021	Policy revised for non-preferred tramadol products to include "generic" in front of tramadol hydrochloride 50 mg step. For Qdolo (tramadol hydrochloride) oral solution, changed to attestation for inability to swallow. For reauthorization added that the prescriber attests the member requires continued therapy for pain management. Authorization duration changed to 6 months.
Oxycodone-Acetaminophen Products - Commercial and Healthcare Reform	TBD	Changed name of policy from Opioid-Acetaminophen Combination Products to Oxycodone-Acetaminophen Combination Products. Policy revised to remove Ultracet, Dvorah tablets, acetaminophen-caffeine-dihydrocodeine, Trezix, and Norco targets. Added oxycodone 5 mg-300 mg tablets and oxycodone 10 mg-300 mg tablets as targets. Added New York to regions.
Tazarotene Products - Healthcare Reform	12/01/2021	Terminated. Combined with J-0259 Tazarotene Products - Commercial to make single policy.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Topical Acne Products - Commercial and Healthcare Reform	TBD	Policy revised to add clindamycin phosphate gel once daily, requiring the member has a diagnosis of acne vulgaris and has tried and failed three generic topical agents: adapalene, clindamycin or clindamycin phosphate/benzoyl peroxide, erythromycin, sulfacetamide, or tretinoin. Reauthorization that the member has experienced positive clinical response to therapy and requires additional courses of treatment.
Topical Antifungals - Commercial National Select	12/14/2021	Policy revised for Kerydin (tavaborole) reauthorization criteria to add prescriber attestation that additional topical antifungal therapy is required.
Trazodone - Commercial and Healthcare Reform	TBD	Policy created for Trazodone 300 mg; the policy requires that the member has a diagnosis of major depressive disorder and the prescriber attests that the member has experienced therapeutic failure or intolerance to two (2) trazodone 150 mg tablets taken daily to achieve a daily dose of 300 mg.
Xifaxan 550 mg (rifaximin) – Commercial and Healthcare Reform	12/15/2021	Policy revised for Xifaxan (rifaximin) 550 mg to require therapeutic failure or intolerance to one (1) agent from two (2) different medication classes: anti-diarrheal, bile acid sequestrant, anti-spasmodic, tricyclic antidepressant, or selective serotonin reuptake inhibitor.
Zercapli (sertraline) – Commercial and Healthcare Reform	TBD	New policy created for Zercapli (sertraline) oral capsules for use in members with major depressive disorder and 18 years of age or older, or with obsessive compulsive disorder and 6 years of age or older. For either indication, the member has used a sertraline product other than Zercapli for initial dosage and titration; and has received sertraline 100 mg or sertraline 125 mg for ≥ 7 days; and has experienced therapeutic failure or intolerance to all of the following generic products: sertraline immediate release tablets; and has experienced therapeutic failure, contraindication, or intolerance to at least 2 other plan-preferred antidepressants (e.g., SSRI, TCA, MAOI). Initial authorization duration may be approved for up to 6 months with reauthorization duration of up to 12 months.

*For Commercial and Healthcare Reform policies, an exception to some or all the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.
**All effective dates are tentative and subject to delay pending internal review or approval.
*** 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
Self-Administered Injectables - Commercial and Healthcare Reform - New York	12/07/2021	Policy revised to include expanded indication for Cutaquig (immune globulin subcutaneous (human) – hipp) for treatment of primary humoral immunodeficiency in pediatrics two years of age and older.

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
Dupixent 100 mg/0.67 mL	2 syringes of 100 mg/0.67 mL (1.34 mL) per 28 days	6 syringes of 100 mg/0.67 mL (4.02 mL) per 84 days
Livmarli	30 mL per 25 days	90 mL per 75 days
Qulipta	30 tablets per 25 days	90 tablets per 75 days
Seglentis*	7 days' supply per fill or greater than 14 days' supply per 30 days for a member 18 years of age or older; 3 days' supply per fill or greater than 6 days' supply per 30 days for a pediatric member 17 years of age and younger; cumulative opioids not to exceed 90 MEqD	-
Tyrvaya	8.4 mL (2 bottles) per 30 days	25.2 mL (6 bottles) per 90 days
Vuity 1.25% ophthalmic solution	1 bottle (2.5 mL fill in 5 mL bottle) per 25 days	3 bottles (7.5 mL) per 75 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
Opzelura 1% topical cream	60 gm	180 gm

*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
Biktarvy 30 mg BIC, 120 mg FTC, 15 mg TAF	1 tablet per day
Exkivity	4 capsules per day
Scemblix	2 tablets per day
Tavneos	6 capsules per day
Zercapli oral capsules	1 capsule per day
Diclofenac potassium 25 mg tablet	3 tablets per day

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

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

SECTION II. Highmark Medicare Part D Formularies

A. Changes to the Highmark Medicare Part D 5-Tier Incentive Formulary

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

Table 1. Preferred Products

No changes at this time.

Table 2. Non-Preferred Products

Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Preferred Alternatives
Seglentis	celecoxib/tramadol	tramadol tablet, celecoxib capsule
Tyrvaya	varenicline	Restasis
Vuity 1.25% ophthalmic solution	pilocarpine 1.25% ophthalmic solution	Provider Discretion
Zercapli oral capsules	sertraline oral capsules	sertraline hcl tablet
Zimhi	naloxone	naloxone injection solution, Narcan nasal spray, Kloxxado nasal spray

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

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

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

Table 1. Preferred Products

No changes at this time.

Table 2. Non-Preferred Products

No changes at this time.

Table 3. Products Not Added*

Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Preferred Alternatives
Livmarli	marlixibat	Provider Discretion
Opzelura 1% topical cream	ruxolitinib 1% topical cream	Provider Discretion

Qulipta	atopgepant	topiramate tablet, propranolol tablet, divalproex
Seglentis	celecoxib/tramadol	tramadol tablet, celecoxib capsule
Tyrvaya	varenicline	Restasis
Vuity 1.25% ophthalmic solution	pilocarpine 1.25% ophthalmic solution	Provider Discretion
Zercapli oral capsules	sertraline oral capsules	sertraline hcl tablet
Zimhi	naloxone	naloxone injection solution, narcan nasal spray, kloxxado nasal spray

*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
Byooviz	ranibizumab-nuna
Exkivity	mobocertinib
Scemblix	asciminib
Susvimo ocular insert	ranibizumab ocular insert
Tavneos	avacopan
Tivdak	tisotumab vedotin-tftv
Xipere intraocular injection	triamcinolone acetonide intraocular injection
Livmarli*	marlixibat
Opzelura 1% topical cream*	ruxolitinib 1% topical cream
Qulipta*	atopgepant

*Product was added to Specialty Tier for Incentive Formulary but not added to Venture Formulary or Performance Formulary.

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Adalimumab BIOSIMILARS - Medicare	TBD	Policy revised for adalimumab biosimilars to add Hulio (adalimumab-fkjp) and Hadlima (adalimumab-bwwd) as target agents. Policy criteria revised for adalimumab biosimilars to specify a diagnosis of moderate to severe disease for all the following: rheumatoid arthritis, juvenile idiopathic arthritis, and Crohn's Disease. Criteria for psoriatic arthritis revised to remove step therapy through non-steroidal anti-inflammatory drugs, non-biologic disease modifying anti-rheumatic drugs, or local glucocorticoid injections. Plaque psoriasis criteria revised to require trial

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		and failure of phototherapy or systemic therapy, or contraindication to both phototherapy and systemic therapy. Reauthorization criteria removed.
Administrative Prior Authorizations for Medicare Part D Plans - Medicare	01/01/2022	Policy revised to add Prolia (denosumab) and Evenity (romosozumab-aqqg) to require criteria for incident to provider services and to remove Aduhelm due to Medicare D exclusion.
Afinitor (everolimus) - Medicare	01/01/2022	Policy revised for Afinitor (everolimus) 2.5 mg, 5 mg, and 7.5 mg to require for 2022 step through generic everolimus tablets 2.5 mg, 5 mg, and 7.5 mg.
Afinitor (everolimus) - Medicare	TBD	Policy revised for Afinitor (everolimus) 10 mg to require for 2023 step through generic everolimus 10 mg tablets; and for all strengths of Afinitor Disperz (everolimus tablets for solution) 2023 step through generic everolimus tablets for solution.
Anabolic Steroids - Medicare	12/14/2021	Policy revised for Anabolic Steroids to remove Anadrol-50 (oxymetholone) as both brand and generic are off market.
Anti-Angiogenesis and VEGF Kinase Inhibitors – Medicare	12/01/2021	Policy revised for Cabometyx (cabozantinib) for use in members with locally advanced or metastatic differentiated thyroid cancer after disease progression following prior VEGFR (vascular endothelial growth factor receptor) targeted therapy and who are radioactive iodine-refractory or ineligible.
Anti-EGFR and HER2 Kinase Inhibitors – Medicare	01/01/2022	Policy revised for Tykerb (lapatinib) to specify if the request is for brand Tykerb (lapatinib), the member has experienced therapeutic failure or intolerance to generic lapatinib.
Arikayce (amikacin) - Medicare	TBD	Policy revised for Arikayce (amikacin) to require that the prescriber attests that the member did not achieve negative sputum cultures despite at least 6 consecutive months of treatment with a multidrug background regimen that has utilized at least two (2) of the following agents: a macrolide (e.g., clarithromycin or azithromycin), a rifamycin, or ethambutol. Reauthorization criteria revised to require that Arikayce (amikacin) will continue to be used in conjunction with a background multidrug regimen. Authorization duration revised to 12 months.
BCR-ABL Kinase Inhibitors - Medicare	12/17/2021	Policy revised to add Scemblix (asciminib) for treatment of adults with chronic phase

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		Philadelphia chromosome positive chronic myeloid leukemia treated with two or more tyrosine kinase inhibitors and for treatment of adults with chronic phase Philadelphia chromosome position chronic myeloid leukemia with the T315I mutation.
Brand Albuterol and Levalbuterol Inhalers - Medicare	12/19/2021	Policy revised to require an FDA approved diagnosis for each of the inhalers. For albuterol, the diagnosis must be treatment or prevention of bronchospasm with reversible obstructive airway disease or prevention of exercise-induced bronchospasm. For levalbuterol, the diagnosis must be for treatment or prevention of bronchospasm with reversible airway disease.
Briviact (brivaracetam) – Medicare	11/01/2021	Policy termination due to PA removal effective 11/01/21.
CDK Inhibitors – Medicare	12/02/2021	Policy revised for Verzenio (abemaciclib) for use in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) as adjuvant treatment in members 18 years of age or older with HR-positive (hormone receptor), HER2-negative (human epidermal growth factor receptor 2), node-positive, early breast cancer at high risk of recurrence and a Ki-67 score of ≥ 20% per an FDA-approved test.
CGRP Inhibitors - Medicare	12/16/2021	Policy revised to add Nurtec (rimegepant) and Ubrelvy (ubrogepant). For Nurtec (rimegepant) for diagnosis of episodic migraine defined as 4 to 14 headache days per month, prescriber attestation of baseline average monthly migraine days, attestation that headaches are not caused by medication rebound, overutilization, or lifestyle factors, therapeutic failure or intolerance to one agent from two different prophylactic migraine medication classes (alpha-agonists, angiotensin converting enzyme inhibitors or angiotensin II receptor blockers, antiepileptic drugs, beta-blockers, calcium channel blockers, serotonin-norepinephrine reuptake inhibitors, or tricyclic antidepressants). Reauthorization criteria of prescriber attestation of a reduction in migraine frequency. For Nurtec (rimegepant) and Ubrelvy (ubrogepant) for a diagnosis of acute treatment of migraine, requirements of age 18 years or older, diagnosis of acute migraine headaches with or without aura, therapeutic failure, contraindication,

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		or intolerance to two generic triptans. Reauthorization requiring prescriber attestation of a reduction in migraine symptoms.
Chenodal (chenodiol) - Medicare	01/01/2022	01/01/2022 policy revised for Chenodal (chenodiol) to update "Member has experienced therapeutic failure on...ursodiol tablets" to "...ursodiol therapy." Reauthorization criteria updated to require "at least" partial dissolution of gallstones.
Chronic Inflammatory Diseases - Medicare 2022	01/01/2022	Policy revised to add Stelara (ustekinumab) intravenous induction dosing to quantity limitations table.
Combination Prescription Drug Safety - Medicare	01/01/2022	Policy revised to add Seglentis (celecoxib and tramadol hydrochloride) so it applies to combination prescription drug safety criteria.
Conjupri (levamlodipine) - Medicare	TBD	Policy revised for Conjupri (levamlodipine) to remove age.
Duexis (ibuprofen/famotidine) - Medicare	01/01/2022	Policy revised to match new CMS-submitted criteria. For both generic ibuprofen/famotidine tablet and Duexis brand name tablet, the member must be 18 years of age or older and have a diagnosis of osteoarthritis (OA) or Rheumatoid arthritis (RA). In addition, for ibuprofen-famotidine tablet the following criteria must be met: trial/failure of ibuprofen used in combination with famotidine AND trial/failure of one additional generic formulary NSAID (other than ibuprofen) used in combination with one additional generic formulary H2-receptor blocker (other than famotidine). For brand Duexis, in addition to the age and diagnosis criteria, the member must also have a trial/failure of ibuprofen/famotidine combination product AND trial/failure to naproxen/esomeprazole combination product.
Dupixent (dupilumab) - Medicare 2022	01/01/2022	Policy criteria revised for Dupixent (dupilumab) for atopic dermatitis to allow for the member to experience therapeutic failure or intolerance to one generic topical corticosteroid, or the member has atopic dermatitis with facial or anogenital involvement, or the prescriber submits documentation topical prescription therapies would not be advisable for severe atopic dermatitis maintenance therapy due to a large proportion of body surface area (BSA) affected making topical therapy impractical to apply, or

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		severely damaged skin. Member must also experience therapeutic failure or intolerance to one generic topical calcineurin inhibitor or the prescriber submits documentation topical prescription therapies would not be advisable for severe atopic dermatitis maintenance therapy due to a large proportion of body surface area (BSA) affected making topical therapy impractical to apply, or severely damaged skin.
Dymista (azelastine hydrochloride/fluticasone propionate) - Medicare	12/19/2021	Policy for Dymista (azelastine/fluticasone) updated to remove the requirement that the claim for the generic azelastine/fluticasone nasal spray must have been within the previous 90 days. Policy also updated to remove the automatic approval criteria.
EGFR-Targeting Kinase Inhibitors – Medicare	01/01/2022	Policy revised to add criteria for Exkivity (mobocertinib) in members 18 years of age or older with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. Policy revised to add for Tarceva (erlotinib) step through generic erlotinib.
Etanercept BIOSIMILARS - Medicare	TBD	Policy revised for etanercept biosimilars to specify a diagnosis of moderate to severe rheumatoid arthritis. Criteria for psoriatic arthritis revised to remove step therapy through non-steroidal anti-inflammatory drugs, non-biologic disease modifying anti-rheumatic drugs or local glucocorticoid injections. Plaque psoriasis criteria revised to require trial and failure of phototherapy or systemic therapy, or contraindication to both phototherapy and systemic therapy. Reauthorization criteria removed.
Gaucher Disease - Medicare	01/01/2022	Policy revised for Zavesca (miglustat) and Cerdelga (eliglustat) to require prescriber attestation that the member has a deficiency in glucocerebrosidase activity in peripheral leukocytes.
Intravitreal Injections - Medicare	01/01/2022	Policy updated to remove Macugen (pegaptanib) as it is no longer available on the market. Policy also updated to add Susvimo (ranibizumab injection) and require a diagnosis of neovascular (wet) age-related macular degeneration, patient to

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		have previously responded to at least two (2) intravitreal injections of a VEGF inhibitor (e.g., Eylea, Lucentis, Beovu, Avastin), and patient to experience therapeutic failure after an adequate trial, contraindication, or intolerance to Avastin (bevacizumab). Policy category changed from Prior Authorization to Step Therapy.
Intravitreal Injections - Medicare	TBD	Policy updated to add Byooviz (ranibizumab-nuna) and require a diagnosis of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, or myopic choroidal neovascularization and patient to experience therapeutic failure after an adequate trial, contraindication, or intolerance to Avastin (bevacizumab).
JAK Inhibitors – Medicare	12/01/2021	Policy revised for Jakafi (ruxolitinib) to add criteria for members with chronic graft versus host disease after therapeutic failure or intolerance to at least one prior therapy.
Jynarque (tolvaptan) – Medicare	01/01/2022	Policy revised for Jynarque (tolvaptan) that there is a 5% increase in total kidney volume and removed that measurements are taken at least 6 months apart.
Livmarli (maralixibat) - Medicare	12/15/2021	New policy for Livmarli (maralixibat) for patients with Alagille syndrome and cholestatic pruritis who do not have decompensated cirrhosis, portal hypertension, or history of a hepatic decompensation event. Reauthorization criteria of prescriber attestation of improvement in pruritis and attestation that patient has not progressed to portal hypertension, cirrhosis, or experienced a hepatic decompensation event.
Lubiprostone – Medicare	01/01/2022	Policy termination due to PA/ST removal effective 01/01/22.
Morphine Equivalent Daily Dose (M.E.D)- Medicare	TBD	Policy revised to add Seglentis (celecoxib and tramadol hydrochloride) so it applies to morphine equivalent daily dose requirements.
Non-Preferred Mupirocin Products - Medicare	01/01/2022	Policy revised to add brand Centany (mupirocin) 2% ointment and brand Bactroban (mupirocin) 2% cream to require diagnosis of impetigo or secondarily infected traumatic skin lesions and therapeutic failure or intolerance to generic mupirocin ointment.
Opzelura (ruxolitinib) - Medicare	12/20/2021	Policy created for Opzelura (ruxolitinib) to require that the member is 12 years of age or older,

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		prescriber attests that member has mild to moderate atopic dermatitis (AD), up to 20% of the body with AD involvement, and the member must have experienced therapeutic failure, contraindication or intolerance to a topical prescription corticosteroid or have facial or anogenital involvement, and have experienced therapeutic failure, contraindication, or intolerance to generic topical tacrolimus (0.03% or 0.1%) or generic topical pimecrolimus 1%. Reauthorization criteria requires documentation or attestation of improvement to response to therapy. Initial authorization is for a period of 8 weeks; reauthorization period is one (1) year.
Parathyroid Hormone Analogs - Medicare	01/01/2022	Policy revised to allow for Forteo (teriparatide) to allow therapy to exceed 24 months if the prescriber attests that the member remains at or has returned to having a high risk of fracture.
PCSK9 Inhibitors - Medicare	01/01/2022	Policy revised for Repatha (evolocumab) to change age to 10 years of age or older for homozygous familial hypercholesterolemia (HoFH) and heterozygous familial hypercholesterolemia (HeFH). For HeFH, added familial hypercholesterolemia possibility of “definite” on the Make Early Diagnosis to Prevent Early Deaths (MEDPED) tool as one of three supporting diagnosis criteria, if the member is 17 years of age or younger, current LDL-C > 130 mg/dL, and if the member is 17 years of age or younger, the member will continue to receive concurrent lipid-lowering therapies for treatment of HeFH.
Preventive CGRP Inhibitors - Medicare	12/16/2021	Policy revised to add criteria for Qulipta (atogepant) for patients 18 years of age or older with a diagnosis of episodic migraine defined as 4 to 14 headache days per month, prescriber attestation of baseline monthly migraine days, attestation that headaches are not caused by medication rebound, overutilization, or lifestyle factors, therapeutic failure or intolerance to one agent from two different prophylactic migraine medication classes (alpha-agonists, angiotensin converting enzyme inhibitors or angiotensin II receptor blockers, antiepileptic drugs, beta-blockers, calcium channel blockers, serotonin-norepinephrine reuptake inhibitors, or tricyclic

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		antidepressants). Reauthorization criteria of prescriber attestation of a reduction in migraine frequency. Initial approval for 6 months and reauthorization for 12 months.
Programmed Death Receptor Therapies – Medicare	12/19/2021	Policy revised for Keytruda (pembrolizumab) for use in combination with chemotherapy, with or without bevacizumab, for members with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (Programmed Death Ligand-1, CPS [Combined Positive Score] ≥1), as determined by an FDA-approved test.
Quantity Level Limits - Medicare	01/01/2022	Addition of blood glucose testing and DME supply quantity limits to align with CMS limits.
Tavneos (avacopan) - Medicare	12/16/2021	Policy created for Tavneos (avacopan) to require that the member is 18 years of age or older, has a diagnosis of severe active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), has a positive test for anti-proteinase 3 (anti-PR3) or anti-myeloperoxidase (anti-MPO), and is receiving concomitant therapy with glucocorticoids and immunosuppressives. For reauthorization, the prescriber provides attestation that the member has had disease stability or disease improvement and will continue to receive concomitant therapy with glucocorticoids and immunosuppressives. Initial authorization duration of 6 months and reauthorization duration of 12 months.
Tecentriq (atezolizumab) – Medicare	12/17/2021	Policy revised for Tecentriq (atezolizumab) to add criteria for use in Stage II to IIIA NSCLC as adjuvant treatment following resection and platinum-based chemotherapy when tumors have PD-L1 expression on ≥ 1% of tumor cells, as determined by an FDA-approved test. Policy revised for Tecentriq (atezolizumab) to remove criteria for patients with unresectable locally advanced or metastatic triple negative breast cancer with PD-L1 tumor expression, as determined by an FDA-approved test, in combination with protein-bound paclitaxel, following removal of the indication per FDA.
Tegsedi (inotersen) – Medicare	01/01/2022	Policy revised for Tegsedi (inotersen) to remove the requirement for polyneuropathy disability (PND) score of IIIb or lower and peripheral

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		neuropathy impairment score (NIS) of 10 or greater.
Tegsedi (inotersen) – Medicare	TBD	Policy revised for Tegsedi (inotersen) for reauthorization, the member has experienced an improvement in polyneuropathy from baseline.
Tivdak (tisotumab vedotin-tftv) - Medicare	12/17/2021	Policy created for Tivdak (tisotumab vedotin-tftv) to require that the member is 18 years of age or older, has a diagnosis of recurrent or metastatic cervical cancer, and has experienced disease progression on or after chemotherapy.
Tyrvaya (varenicline solution) – Medicare	12/20/2021	New policy created for Tyrvaya (varenicline) requiring diagnosis of dry eye disease and have experienced therapeutic failure, contraindication, or intolerance to Restasis (cyclosporine ophthalmic emulsion).
"Viberzi (eluxadoline) - Medicare	01/01/2022	Policy revised for Viberzi (eluxadoline) for irritable bowel syndrome with diarrhea (IBS-D) to require therapeutic failure or intolerance to one (1) of the following: anti-diarrheal, anti-spasmodic, tricyclic antidepressant, or contraindication to all.
Vimovo (naproxen/esomeprazole) - Medicare	01/01/2022	Policy revised to match new CMS-submitted criteria. For both naproxen-esomeprazole tablet and Vimovo (brand name), member must be 12 years of age or older, and the members must have a diagnosis of one of the following: osteoarthritis (OA), Rheumatoid arthritis (RA), Ankylosing Spondylitis (AS) or Juvenile Idiopathic Arthritis (JIA). In addition, for naproxen/esomeprazole (generic), member must meet all the following criteria: trial/failure of naproxen used in combination with omeprazole AND trial and failure of one additional generic formulary NSAID (other than naproxen) used in combination with another generic formulary PPI (other than omeprazole). For brand Vimovo, in addition to the age and diagnosis restrictions, the member must have a trial/failure of ibuprofen/famotidine combination product AND trial/failure to naproxen/esomeprazole combination product.
Vimpat (lacosamide) – Medicare	11/01/2021	Policy termination due to PA removal effective 11/01/2021.
Vuity (pilocarpine hydrochloride) - Medicare	TBD	Policy created for Vuity (pilocarpine hydrochloride) to ask that member is 40 years of age or older and diagnosis of presbyopia.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Wakix (pitolisant) - Medicare	TBD	Policy revised to require therapeutic failure, contraindication, or intolerance to one generic CNS stimulant before use of Wakix (pitolisant) for patients with narcolepsy with cataplexy.
Xifaxan 550 mg (rifaximin) – Medicare	01/01/2022	Policy revised for Xifaxan (rifaximin) 550 mg for irritable bowel syndrome with diarrhea (IBS-D) to require therapeutic failure or intolerance to one (1) of the following: anti-diarrheal, anti-spasmodic, tricyclic antidepressant, or contraindication to all.
Zaltrap (ziv-aflibercept) - Medicare	01/01/2022	New policy created for Zaltrap (ziv-aflibercept) for use in members with a diagnosis of metastatic colorectal cancer, in combination with fluorouracil, leucovorin, irinotecan (FOLFIRI); with disease resistant to or has progressed following a regimen containing oxaliplatin.
Zercapli (sertraline) – Medicare	TBD	New policy created for Zercapli (sertraline) oral capsules for use in members with major depressive disorder or with obsessive compulsive disorder. For either indication, the member has used a sertraline product other than Zercapli for initial dosage and titration; and has received sertraline 100 mg or sertraline 125 mg for ≥ 7 days; and has experienced therapeutic failure or intolerance to sertraline immediate release tablets; and has experienced therapeutic failure, contraindication, or intolerance to at least one (1) other antidepressant (e.g., SNRI, SSRI, TCA, MAOI).
Zytiga and Yonsa (abiraterone acetate)- Medicare	01/01/2022	Policy revised for Zytiga (abiraterone) to require that if the request is for brand Zytiga (abiraterone), the member has experienced therapeutic failure or intolerance to generic abiraterone.

*All effective dates are tentative and subject to delay pending internal review or approval.

2. Step Therapy

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Brand Albuterol and Levalbuterol Inhalers - Medicare	12/19/2021	Policy revised to require an FDA approved diagnosis for each of the inhalers. For albuterol, the diagnosis must be treatment or prevention of bronchospasm with reversible obstructive airway disease or prevention of exercise-induced bronchospasm. For levalbuterol, the diagnosis

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		must be for treatment or prevention of bronchospasm with reversible airway disease.
Dymista (azelastine hydrochloride/fluticasone propionate) - Medicare	12/19/2021	Policy for Dymista (azelastine/fluticasone) updated to remove the requirement that the claim for the generic azelastine/fluticasone nasal spray must have been within the previous 90 days. Policy also updated to remove the automatic approval criteria.
Intravitreal Injections - Medicare	01/01/2022	Policy updated to remove Macugen (pegaptanib) as it is no longer available on the market. Policy also updated to add Susvimo (ranibizumab injection) and require a diagnosis of neovascular (wet) age-related macular degeneration, patient to have previously responded to at least two (2) intravitreal injections of a VEGF inhibitor (e.g., Eylea, Lucentis, Beovu, Avastin), and patient to experience therapeutic failure after an adequate trial, contraindication, or intolerance to Avastin (bevacizumab). Policy category changed from Prior Authorization to Step Therapy.
Non-Preferred Mupirocin Products - Medicare	01/01/2022	Policy revised to add brand Centany (mupirocin) 2% ointment and brand Bactroban (mupirocin) 2% cream to require diagnosis of impetigo or secondarily infected traumatic skin lesions and therapeutic failure or intolerance to generic mupirocin ointment.

*All effective dates are tentative and subject to delay pending internal review or approval.

3. Quantity Level Limit (QLL) Program

Effective date pending CMS approval, completion of internal review, and implementation unless otherwise noted.

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Biktarvy 30 mg BIC, 120 mg FTC, 15 mg TAF	1 tablet per day	1 tablet per day
Dupixent 100 mg/0.67 mL	2 syringes of 100 mg/0.67 mL (1.34 mL) per 28 days	6 syringes of 100 mg/0.67 mL (4.02 mL) per 84 days
Exkivity	4 capsules per day	4 capsules per day
Livmarli	3 mL per day	3 mL per day
Opzelura 1% topical cream	60 gm/7 days (8.57 gm/day)	60 gm/7 days (8.57 gm/day)
Qulipta	1 tablet per day	1 tablet per day
Scemblix	10 tablets per day	10 tablets per day

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Seglentis	124 tablets per 31 days (4 tablets per day)	360 tablets per 90 days (4 tablets per day)
Susvimo ocular insert	0.2 mL (2 vials) per 24 weeks	0.2 mL (2 vials) per 24 weeks
Tavneos	6 capsules per day	6 capsules per day
Tivdak	200 mg (5 vials) per 21 days	200 mg (5 vials) per 21 days
Tyrvaya	8.4 mL (2 bottles) per 30 days	25.2 mL (6 bottles) per 90 days
Vuity 1.25% ophthalmic solution	1 bottle (2.5 mL fill in 5 mL bottle) per 25 days	3 bottles (7.5 mL) per 75 days
Xipere intraocular injection	8 mg (0.2 mL) per 12 weeks	8 mg (0.2 mL) per 12 weeks
Zercapli oral capsules	1 capsule per day	1 capsule per day

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