SPECIAL eBULLETIN

OCTOBER 2019

FOURTH QUARTER 2019 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the Fourth Quarter 2019 update to the Highmark Drug Formularies and pharmaceutical management procedures. The formularies and pharmaceutical management procedures are updated on a quarterly basis, and the following changes reflect the decisions made in August 2019 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

Update: Health Professional and Consumer on Recent Recalled Products Due to Detection of Impurities and Potential Risk of Cancer

As part of an ongoing investigation into the voluntary recall of products due to the detection of probable human carcinogen impurities and increased risk of cancer, there were five additional voluntary recalls. Health care professionals should be aware that the recalled products pose an unnecessary risk to patients.

Pharmacists and physicians may direct patients to alternative treatment prior to returning to their medications. Physicians should evaluate the risk versus the benefit if treatment is stopped immediately, as stopping treatment immediately without alternative treatment may lead to a higher risk of harm to the patient's health.

The additional products that have been recalled due to the impurities are listed below. Not all products from all the manufacturers are recalled. Patients and physicians should check the FDA website to see if the lot number of their medication has been included in the recall.

Manufacturer	Recalled Drugs	Detected Impurity
Teva Pharmaceuticals USA, Inc.	Losartan potassium tablets	N-Nitroso N-Methyl 4-aminobutyric acid (NMBA)
Macleods Pharmaceuticals Limited	Losartan potassium tablets and Losartan potassium/ hydrochlorothiazide combination tablets	N-Nitroso N-Methyl 4-aminobutyric acid (NMBA)
Legacy Pharmaceutical Packaging, LLC	Losartan potassium tablets	N-Nitroso N-Methyl 4-aminobutyric acid (NMBA)
Torrent Pharmaceuticals Limited	Losartan potassium tablets USP and Losartan potassium/hydrochlorothiazide tablets USP	N-Methylnitrosobutyric acid (NMBA)
Sandoz Inc.	Ranitidine hydrochloride capsules	N-Nitrosodimethylamine (NDMA)
Apotex Corp.	Ranitidine tablets	N-Nitorosodimethylamine (NDMA)

Higher Dose of Tofacitinib (Xeljanz, Xeljanz XR) in Ulcerative Colitis Patients: Drug Safety Communication – Boxed Warning for Increased Risk of Blood Clots and Death

On July 26, 2019, the FDA announced it has approved new warnings, including a boxed warning, about an increased risk of blood clots and death with the 10 mg twice daily dose of tofacitinib (Xeljanz, Xeljanz XR), which is used in patients with ulcerative colitis. The approved use of tofacitinib for ulcerative colitis will be limited to certain patients who experience

therapeutic failure or intolerance to other treatments. Health care professionals should discontinue tofacitinib and promptly evaluate patients with symptoms of thrombosis. Health care professionals should counsel patients about the risks, avoid tofacitinib in patients who may have a higher risk of thrombosis, reserve tofacitinib to treat ulcerative colitis for patients who have failed or do not tolerate tumor necrosis factor (TNF) blockers, use tofacitinib at the lowest effective dose, and limit the use of the 10 mg twice daily dosage to the shortest duration needed.

Kogenate® FS Antihemophilic Factor (Recombinant) by Bayer: Recall – Product Mislabeling

On July 19, 2019, Bayer announced a voluntary recall of two lots of Kogenate FS antihemophilic factor (recombinant) 2000 IU vials to the patient level. Certain vials from the two lots that were labeled as Kogenate FS actually contain the FVIII hemophilia A treatment Jivi® antihemophilic factor (recombinant) PEGylated-aucl 3000 IU. The affected lots include Lot# 27118RK (expiration 06/12/21) and Lot# 27119CG (expiration 06/12/21).

Drospirenone and Ethinyl Estradiol Tablets, USP, by Jubilant Cadista Pharmaceuticals Inc.: Recall – Out-of-Specification (OOS) Dissolution Test Results

On July 23, 2019, Jubilant Cadista Pharmaceuticals Inc. announced a voluntary recall of one lot of Drospirenone and Ethinyl Estradiol Tablets, USP, 3mg/0.02mg, 28x3Blister Pack/Carton. The affected product was recalled due to out-of-specification (OOS) dissolution results at the 3-month stability time point which may decrease product efficacy due to incomplete absorption. The affected Drospirenone and Ethinyl Estradiol Tablets, USP, has been identified as Lot# 183222, with NDC# 59746-763-43 and expiration date of 11/2020.

Entacapone (Comtan and Stalevo) for Parkinson's Disease: Drug Safety Communication – No Increased Risk of Prostate Cancer

On August 13, 2019, the FDA announced that after reviewing additional data, no increased risk of prostate cancer was found with the use of entacapone to treat Parkinson's disease. As a result, the FDA's recommendations for using Comtan (entacapone) and Stalevo (entacapone, carbidopa, and levodopa) will remain the same in the prescribing information. Health care professionals should continue to follow standard prostate cancer screening recommendations, and patients should continue to take the medicine as prescribed.

Relpax (eletriptan hydrobromide) 40 mg tablets by Pfizer Inc.: Recall – Potential Microbiological Contamination

On August 14, 2019, Pfizer Inc. announced a voluntary recall of two lots of Relpax (eletriptan hydrobromide) 40 mg tablets to the patient level. The affected product lots were recalled because they may not meet Pfizer's in-house microbiological specification for the potential presence of Genus *Pseudomonas* and *Burkholderia*. Individuals who consume oral products contaminated with microorganisms are at risk of bacterial dissemination from the gut to the bloodstream potential resulting in serious, life-threatening infections. The affected Relpax lots include Lot# AR5407 and Lot# CD4565, with an expiration date of 02/2022.

Natpara (parathyroid hormone) for Injection by Takeda Pharmaceutical Company Limited: Recall – Potential for Rubber Particulate

On September 5, 2019, Takeda Pharmaceutical Company Limited announced a recall of Natpara (parathyroid hormone) for injection (25 mcg, 50 mcg, 75 mcg, and 100 mcg). The affected product was recalled due to a potential issue related to rubber particulates originating from the rubber septum of the Natpara cartridge.

Adverse events or side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Highmark Formulary Update – October 2019

SECTION I. Highmark Commercial and Healthcare Reform Formularies

A. Changes to the Highmark Comprehensive Formulary and the Highmark Comprehensive Healthcare Reform 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:
(https://client.formularynavigator.com/Search.aspx?siteCode=8103967260)
Highmark Comprehensive Healthcare Reform Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=4906449921)

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 September 23, 2019, unless otherwise noted.)

Brand Name	Generic Name	Comments
Ruzurgi	amifampridine	Oral potassium channel blocker for Lambert-Eaton myasthenic syndrome (LEMS)
Dexcom*	blood-glucose meter; continuous	Blood glucose meter that offers continuous glucose monitoring
Freestyle*	blood-glucose meter; continuous	Blood glucose meter that offers continuous glucose monitoring
Ajovy ^	fremanezumab	Injectable calcitonin gene-related peptide (CGRP) receptor antagonist for migraine prophylaxis.

*Effective date January 1, 2020.
^Applies to Healthcare Reform formulary only.
Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Corlanor oral solution	ivabradine oral solution	metoprolol succinate, carvedilol
Eticovo*	etanercept-ykro	Enbrel
Duobrii	halobetasol propionate/tazarotene	betamethasone dipropionate lotion, triamcinolone acetonide lotion

Brand Name	Generic Name	Preferred Alternatives
Qternmet XR*	dapagliflozin/saxagliptin/metformin ER	metformin ER tablet extended release 24 HR, Januvia, Jardiance
Nayzilam nasal spray*	midazolam	diazepam kit
Slynd	drospirenone	Camila, Errin
Piqray	alpelisib	Ibrance, Verzenio
Thiola EC	tiopronin	potassium citrate ER 5 mEq & 10 mEq
Katerzia	amlodipine benzoate	amlodipine besylate tablets
AirDuo Digihaler*	fluticasone propionate/salmeterol	fluticasone/salmeterol, Breo Ellipta
Drizalma Sprinkle*	duloxetine	duloxetine 30 mg & 60 mg
Nubeqa	darolutamide	Erleada, Xtandi
Vyndaqel	tafamidis meglumine	Provider discretion
Vyndamax	tafamidis	Provider discretion
Nucala syringe & auto-injector	mepolizumab	Provider discretion
Vyleesi	bremelanotide	Provider discretion
Xpovio	selinexor	Provider discretion
Turalio	pexidartinib	Provider discretion

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, which can be accessed online in Highmark's Provider Resource Center. Under **Provider Forms, select **Miscellaneous Forms**, and select the form titled **Request for Non-Formulary Drug Coverage**.

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
Eticovo	etanercept-ykro
Duobrii	halobetasol propionate/tazarotene
Vyndaqel	tafamidis meglumine
Vyndamax	tafamidis
Ruzurgi	amifampridine
Piqray	alpelisib
Nucala	mepolizumab
Vyleesi	bremelanotide
Thiola EC	tiopronin
Xpovio	selinexor
Nubeqa	darolutamide
Turalio	pexidartinib

Table 4. Products to Be Removed or Shifted to Higher Tier – Effective January 1, 2020

Brand name	Generic Name	Preferred Alternatives
Only healthcare reform comprehensive products		
Norvir capsule	ritonavir	Provider discretion
Only commercial comprehensive products		
Pancreaze	lipase/protease/amylase	Creon, Zenpep
All commercial & healthcare reform comprehensive products		
Cuprimine	penicillamine	penicillamine, Depen
Delzicol	mesalamine	mesalamine DR
Eryped	erythromycin ethylsuccinate	erythromycin ethylsuccinate
Ery-Tab	erythromycin base	erythromycin
Exjade	deferasirox	deferasirox
Firazyr	icatibant acetate	icatibant acetate
Letairis	ambrisentan	ambrisentan
Mestinon syrup	pyridostigmine bromide	pyridostigmine bromide
Nexium Rx suspension packets	esomeprazole magnesium	omeprazole, pantoprazole
Novarel	chorionic gonadotropin; human	Pregnyl, Ovidrel
Picato	ingenol mebutate	fluorouracil, imiquimod
Tarceva	erlotinib HCL	erlotinib
Tracleer	bosentan	bosentan
Uloric	febuxostat	febuxostat
Vesicare	solifenacin succinate	solifenacin succinate
Viracept	nelfinavir mesylate	Provider discretion
Viread	tenofovir disoproxil fumarate	Provider discretion
Aptivus	tipranavir	Provider discretion
Crixivan	indinavir sulfate	Provider discretion
Edurant	rilpivirine HCL	Provider discretion
Emtriva	emtricitabine	Provider discretion
Intelence	etravirine	Provider discretion
nevirapine	nevirapine	Provider discretion
Rescriptor	delavirdine mesylate	Provider discretion
Ulesfia	benzyl alcohol	Provider discretion

B. Changes to the Highmark Progressive Formulary and the Highmark Healthcare Reform Progressive Formulary

Note: The Progressive Formulary does not apply to Highmark Delaware 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 members. For your convenience, you may search the following formularies online:

Highmark Progressive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=1176922773)
Highmark Healthcare Reform Progressive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=4909431197)

Table 1. Formulary Updates (All products added to the formulary effective September 23, 2019, unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below are preferred products			
Dexcom**	blood-glucose meter; continuous	2 - Preferred brand	Provider discretion
Freestyle**	blood-glucose meter; continuous	2 - Preferred brand	Provider discretion
Ajovy^	fremanezumab	2 - Preferred brand	Injectable calcitonin gene-related peptide (CGRP) receptor antagonist for migraine prophylaxis.
Ruzurgi	amifampridine	3 - Preferred specialty	Oral potassium channel blocker for Lambert-Eaton myasthenic syndrome (LEMS)
Items listed below are non-preferred products			
Corlanor oral solution	ivabradine oral solution	3 – Non-preferred brand	metoprolol succinate, carvedilol
Qternmet XR*	dapagliflozin/saxagliptin/metformin ER	3 – Non-preferred brand	metformin ER tablet extended release 24 HR, Januvia, Jardiance
Nayzilam nasal spray*	midazolam	3 – Non-preferred brand	diazepam kit
Slynd	drospirenone	3 – Non-preferred brand	Camila, Errin
Katerzia	amlodipine benzoate	3 – Non-preferred brand	amlodipine besylate tablet
AirDuo Digihaler*	fluticasone propionate/salmeterol	3 – Non-preferred brand	fluticasone/salmeterol, Breo Ellipta
Drizalma Sprinkle*	duloxetine	3 – Non-preferred brand	duloxetine 30 mg & 60 mg
Eticovo*	etanercept-ykro	4 – Non-preferred specialty	Enbrel
Duobrii	halobetasol propionate/tazarotene	4 – Non-preferred specialty	betamethasone dipropionate lotion, triamcinolone acetonide lotion

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Piqray	alpelisib	4 – Non-preferred specialty	Ibrance, Verzenio
Thiola EC	tiopronin	4 – Non-preferred specialty	potassium citrate ER 5 mEq & 10 mEq
Nubeqa	darolutamide	4 – Non-preferred specialty	Erleada, Xtandi
Vyndaqel	tafamidis meglumine	4 – Non-preferred specialty	Provider discretion
Nucala syringe & auto-injector	mepolizumab	4 – Non-preferred specialty	Provider discretion
Xpovio	selinexor	4 – Non-preferred Specialty	Provider discretion
Turalio	pexidartinib	4 – Non-preferred specialty	Provider discretion
Vyndamax	tafamidis	4 – Non-preferred specialty	Provider discretion
Vyleesi	bremelanotide	4 – Non-preferred specialty	Provider discretion

*Effective date to be determined.
**Effective date January 1, 2020.
^Applies to Healthcare Reform formulary only
Tier 1: Preferred generic drugs; **Tier 2:** Preferred brand drugs; **Tier 3:** Non-preferred generic drugs, non-preferred brand drugs, preferred specialty drugs; **Tier 4:** Non-preferred specialty drugs.

Table 2. Products to Be Removed or Shifted to Higher Tier – Effective **January 1, 2020**

Brand Name	Generic Name	Preferred Alternatives
Only healthcare reform progressive products		
Norvir capsules	ritonavir	Provider discretion
Viread	tenofovir disoproxil fumarate	Provider discretion
Only commercial progressive products		
Fuzeon	enfuvirtide	Provider discretion
All commercial & healthcare reform progressive products		
Cuprimine	penicillamine	penicillamine, Depen
Delzicol	mesalamine	mesalamine DR
Eryped	erythromycin ethylsuccinate	erythromycin ethylsuccinate
Ery-Tab	erythromycin base	erythromycin
Exjade	deferasirox	deferasirox
Firazyr	icatibant acetate	icatibant acetate
Letairis	ambrisentan	ambrisentan
Novarel	chorionic gonadotropin; human	Pregnyl, Ovidrel
Picato	ingenol mebutate	fluorouracil, imiquimod
Tarceva	erlotinib HCl	erlotinib

Brand Name	Generic Name	Preferred Alternatives
Ulesfia	benzyl alcohol	Provider discretion
Crixivan	indinavir sulfate	Provider discretion
Emtriva	emtricitabine	Provider discretion
nevirapine	nevirapine	Provider discretion
Rescriptor	delavirdine mesylate	Provider discretion

C. 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 at https://client.formularynavigator.com/Search.aspx?siteCode=6571849149.

Table 1. Formulary Updates
(All formulary changes effective September 23, 2019, unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Dexcom**	Blood-Glucose Meter; continuous	3	Provider discretion
Freestyle**	Blood-Glucose Meter; continuous	3	Provider discretion
Ruzurgi	amifampridine	4	Provider discretion
Aimovig	erenumab	4	Injectable calcitonin gene-related peptide (CGRP) receptor antagonist for migraine prophylaxis.
Ajovy	fremanezumab	4	Injectable calcitonin gene-related peptide (CGRP) receptor antagonist for migraine prophylaxis.
Items listed below were not added to the formulary			
Corlanor	(ivabradine) oral solution	NF	metoprolol succinate, carvedilol
Qternmet XR*	(dapagliflozin/saxagliptin/ metformin ER)	NF	metformin ER tablet extended release 24 HR, Januvia, Jardiance
Nayzilam nasal spray*	(midazolam)	NF	diazepam kit
Slynd	drospirenone	NF	Camila, Errin
Duobrii	halobetasol propionate/tazarotene	NF	betamethasone dipropionate lotion, triamcinolone acetonide lotion
Katerzia	amlodipine benzoate	NF	amlodipine besylate tablet
Drizalma Sprinkle*	duloxetine	NF	duloxetine 30 mg & 60 mg
Nubeqa	darolutamide	NF	Erleada, Xtandi
AirDuo Digihaler*	fluticasone propionate/salmeterol	NF	fluticasone/salmeterol, Breo Ellipta
Eticovo*	etanercept-ykro	NF	Enbrel

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Piqray	alpelisib	NF	Ibrance, Verzenio
Thiola EC	tiopronin	NF	potassium citrate ER 5 mEq & 10 mEq
Vyndaqel	tafamidis meglumine	NF	Provider discretion
Vyndamax	tafamidis	NF	Provider discretion
Nucala syringe & auto-injector	mepolizumab	NF	Provider discretion
Vyleesi	bremelanotide	NF	Provider discretion
Xpovio	selinexor	NF	Provider discretion
Turalio	pexidartinib	NF	Provider discretion

Formulary options: Tier 1, Tier 2, Tier 3, Tier 4, Non-formulary (NF).
*Effective date to be determined.
**Effective date January 1, 2020.

Table 2. Products to Be Removed or Shifted to Higher Tier – Effective January 1, 2020

Brand Name	Generic Name	Preferred Alternatives
Tier Changes		
desoximetasone 0.05% gel	desoximetasone	fluocinonide gel, betamethasone dipropionate gel
mirtazapine ODT	mirtazapine	mirtazapine tablets
ziprasidone HCl capsule	ziprasidone HCl	risperidone, quetiapine, olanzapine
desoximetasone 0.05% cream	desoximetasone	fluocinonide cream, betamethasone dipropionate cream
desoximetasone 0.05% ointment	desoximetasone	fluocinonide ointment, betamethasone dipropionate ointment
mirtazapine 7.5 mg tablet	mirtazapine	mirtazapine 15 mg tablet
nefazodone HCl tablet	nefazodone HCl	trazadone
venlafaxine HCl ER 150 mg capsules	venlafaxine HCl	venlafaxine HCI ER 75 mg capsules
diflorasone 0.05% cream	diflorasone diacetate	fluocinonide cream, betamethasone dipropionate cream, betamethasone valerate ointment
Halog 0.1% cream	halcinonide	fluocinonide cream, betamethasone dipropionate cream, betamethasone valerate ointment
Multaq	dronedarone HCl	amiodarone
zileuton ER	zileuton	montelukast, zafirlukast
Banzel	rufinamide	lamotrigine, topiramate
neomycin-polymyxin-HC ear solution	neomycin-polymyxin-HC	Provider discretion
neomycin-polymyxin-HC ear suspension	neomycin-polymyxin-HC	Provider discretion
ofloxacin 0.3% ear drops	ofloxacin	Provider discretion
progesterone capsule	progesterone	Provider discretion
fluphenazine tablet	fluphenazine	Provider discretion
Alinia	nitazoxanide	Provider discretion
Emverm	mebendazole	Provider discretion
Noxafil	posaconazole	Provider discretion

Brand Name	Generic Name	Preferred Alternatives
Products to be Removed		
brimonidine tartrate 0.15% drops	brimonidine tartrate	brimonidine tartrate 0.2%
Clobetasol emulsion foam	clobetasol propionate/emoll	clobetasol propionate solution
Clobetasol propionate foam	clobetasol propionate/emoll	clobetasol propionate solution
clocortolone pivalate	clocortolone pivalate	triamcinolone acetonide
diflorasone diacetate 0.05% ointment	diflorasone diacetate	betamethasone dipropionate, fluocinonide
flurandrenolide 0.05% cream	flurandrenolide	triamcinolone acetonide
metronidazole 0.75% lotion	metronidazole	metronidazole gel
risperidone ODT	risperidone	risperidone, olanzapine ODT
Trianex	triamcinolone acetonide	triamcinolone acetonide
Letairis	ambrisentan	ambrisentan
Exjade	deferasirox	deferasirox
Diclegis	doxylamine succinate/vitamin B6	doxylamine succinate-pyridoxine HCL
Tarceva	erlotinib HCL	erlotinib
Uloric	febuxostat	febuxostat
Firazyr	icatibant acetate	icatibant acetate
Cuprimine	penicillamine	penicillamine
Lyrica	pregabalin	pregabalin
Rozerem	ramelteon	ramelteon
Vesicare	solifenacin succinate	solifenacin succinate
adapalene 0.1% cream and gel	adapalene	tretinoin, Differin gel OTC*
ammonium lactate 12% cream and lotion	ammonium lactate	ammonium lactate OTC*
cimetidine	cimetidine	ranitidine HCL, cimetidine OTC*
levocetirizine dihydrochloride oral solution	levocetirizine dihydrochloride	Xyzal OTC*
lidocaine 5% adhesive patch	lidocaine	Lidocaine pain relief patch OTC*, Aspercreme patch OTC
lidocaine 5% ointment	lidocaine	Liocaine 5% cream OTC*, Topicaine 5% gel OTC*
Lido-K, Lidozion 3% lotion	lidocaine HCL	Liocaine 3% cream OTC*
Niacin ER tablet	niacin	Niacin ER OTC, Slo-Niacin OTC*
phenazopyridine HCL 100 mg and 200 mg tablet	phenazopyridine HCL	Azo urinary pain relief OTC*
cleansing wash 10%-4%-10% mL cleanser	sulfacetamide sodium/sulfur/urea	sodium sulfacetamide/sulfur 10%-5%
10-1 10%-1% cleanser	sulfacetamide sodium/sulfur	sodium sulfacetamide/sulfur 10%-5%
Gonal-F, Gonal-F RFF, Gonal-F RFF Redi-Ject	follitropin alfa; recombinant	Follistim AQ
Arcapta Neohaler	indacaterol maleate	Serevent diskus
Kisqali	ribociclib succinate	Ibrance, Verzenio

Brand Name	Generic Name	Preferred Alternatives
Kisqali Femara co-pack	ribociclib succinate/letrozole	Ibrance, Verzenio
Jadenu	deferasirox	deferasirox
Jadenu Sprinkle	deferasirox	deferasirox
Lotemax	loteprednol etabonate	loteprednol etabonate
Ferriprox	deferiprone	deferasirox
octreotide acetate 500 mcg/mL syringe	octreotide acetate	Provider discretion
Rescriptor	delavirdine mesylate	Provider discretion
Emtriva	emtricitabine	Provider discretion
Intelence	etravirine	Provider discretion
Crixivan	indinavir sulfate	Provider discretion
Viracept	nelfinavir mesylate	Provider discretion
nevirapine 200 mg tablet	nevirapine	Provider discretion
nevirapine ER	nevirapine	Provider discretion
Edurant	rilpivirine HCL	Provider discretion
Norvir capsule	ritonavir	Provider discretion
Viread	tenofovir disoproxil fumarate	Provider discretion
Aptivus	tipranavir	Provider discretion
Carnitor SF	levocarnitine	Provider discretion
Ulesfia	benzyl alcohol	Provider discretion

*An alternative medication with the same active ingredient is available for members to purchase over the counter (OTC). Coverage of OTC products is contingent upon plan benefits.

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 at https://client.formularynavigator.com/Search.aspx?siteCode=3442182690.

Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (preferred)			
Vyndaqel	tafamidis meglumine	2	Treatment of wild type or hereditary transthyretin amyloid cardiomyopathy in adults to reduce cardiovascular (CV) mortality and CV-related hospitalizations.
Corlanor oral solution	ivabradine	2	New dosage form for the treatment symptomatic chronic heart failure in adults or symptomatic heart failure due to dilated cardiomyopathy in pediatric patients.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Nubeqa	darolutamide	2	New product indicated for the treatment of non-metastatic castration-resistant prostate cancer.
Nucala syringe and auto-injector	mepolizumab	2	New dosage forms for add-on maintenance treatment of patients with severe eosinophilic asthma or eosinophilic granulomatosis with polyangitis (EGPA).
Ruzurgi	amifampridine	2	New formulation for the treatment of Lambert-Eaton myasthenic syndrome (LEMS).
Items listed below were added to the formulary (non-preferred)			
Duobrii	halobetasol propionate/tazarotene	3	betamethasone dipropionate lotion, triamcinolone acetonide lotion
Slynd	drospireonone	3	Camila, Erinn
Thiola EC	tiopronin	3	potassium citrate ER
Eticovo*	etanercept-ykro	3	Enbrel
Qternmet XR*	dapagliflozin/saxagliptin/ metformin ER	3	Metformin ER tablet extended release 24 HR, Januvia, Jardiance
Vyndamax*	tafamidis	3	Provider discretion
Nayzilam nasal spray*	midazolam	3	diazepam kit
Vyleesi*	bremelanotide	3	Provider discretion
AirDuo Digihaler*	fluticasone propionate/ salmeterol	3	fluticasone/salmeterol, Breo Ellipta
Drizalma Sprinkle*	duloxetine 30 mg, 60 mg	3	duloxetine
Turalio*	pexidartinib	3	Provider discretion
Items listed below were not added to the formulary			
Xpovio	selinexor	NF	Darzalex, Kyprolis, Ninlaro, Pomalyst, Revlimid, Thalomid, Velcade
Piqray	alpelisib	NF	Ibrance, Verzenio
Katerzia	amlodipine benzoate	NF	amlodipine besylate tablets

Formulary options: Tier 1, Tier 2, Tier 3, Non-formulary (NF).
*Effective date and final formulary position to be determined.

Table 2. Products to Be Removed or Shifted to Higher Tier – Effective January 1, 2020

Brand Name	Generic Name	Preferred Alternatives
Tier Changes		
Absorica	isotretinoin	Amnesteem, Claravis, isotretinoin, Myorisan, Zenatane
Amitiza	lubiprostone	Linzess, Trulance
Arcapta Neohaler	indacaterol maleate	Serevent diskus
Atrovent HFA	ipratropium bromide	Ventolin HFA, Proair HFA
Byvalson	nebivolol HCL/valsartan	metoprolol, valsartan, Bystolic
Firdapse	amifampridine phosphate	Ruzurgi
Fulphila	pegfilgrastim-jmdb	Neulasta, Udenyca
Gralise	gabapentin	gabapentin
Moxeza	moxifloxacin HCL	moxifloxacin HCL, ciprofloxacin HCL
Relenza	zanamivir	oseltamivir phosphate
Sancuso	granisetron	granisetron, ondansetron
Tabloid	thioguanine	mercaptopurine
Varubi	rolapitant HCL	aprepitant
Xofluza	baloxavir marboxil	oseltamivir phosphate
Zontivity	vorapaxar sulfate	Provider discretion
Adagen	pegademase bovine	Provider discretion
Arzerra	ofatumumab	Provider discretion
Hexalen	altretamine	Provider discretion
Lartruvo	olaratumab	Provider discretion
Products to be Removed		
Akynzeo	netupitant/palonosetron HCL	aprepitant, Varubi
Ambien	zolpidem tartrate	zolpidem tartrate
Ambien CR	zolpidem tartrate	zolpidem tartrate
Amrix	cyclobenzaprine HCL	cyclobenzaprine HCL
Aubagio	teriflunomide	Gilenya, Tecfidera, Mayzent
Cialis	tadalafil	tadalafil
Cuprimine	penicillamine	penicillamine
Elidel	pimecrolimus	pimecrolimus
Emend	aprepitant	aprepitant, Varubi
Epaned	enalapril maleate	enalapril maleate
Exjade	deferasirox	deferasirox
Focalin	dexmethylphenidate HCL	dexmethylphenidate HCL
Focalin XR	dexmethylphenidate HCL	dexmethylphenidate HCL
Granix	TBO-filgrastim	Nivestym, Zarxio
Jadenu	deferasirox	deferasirox
Jadenu Sprinkle	deferasirox	deferasirox
Lyrica	pregabalin	pregabalin
Mulpleta	lusutrombopag	Doptelet
Nuwiq	antihemophilia.FVIII; HEK B-delete	Advate, Adynovate, Afstyla, Eloctate, Jivi, Kogenate FS, Kovaltry, Novoeight
Onzetra Xsail	sumatriptan succinate	sumatriptan, Zomig

Orfadin	nitisinone	Nityr
Pennsaid	diclofenac sodium	diclofenac sodium, Flector
Qbrelis	lisinopril	lisinopril
Rapaflo	silodosin	silodosin
Rhofade	oxymetazoline HCL	Mirvaso
Sitavig	acyclovir	acyclovir, valacyclovir
Striverdi Respimat	olodaterol HCL	Serevent diskus
Subsys	fentanyl	fentanyl citrate
Tivorbex	indomethacin; submicronized	diclofenac sodium, meloxicam
Tudorza Pressair	aclidinium bromide	Incruse ellipta
Vivlodex	meloxicam; submicronized	diclofenac sodium, meloxicam
Xatmep	methotrexate	methotrexate
Zipsor	diclofenac potassium	diclofenac sodium, meloxicam

Table 3. Additions to the Specialty Tier Copay Option
(Effective upon completion of internal review and implementation unless otherwise noted.)

Brand Name	Generic Name
Eticovo	etanercept-ykro
Duobrii	halobetasol propionate/tazarotene
Vyndaqel	tafamidis meglumine
Vyndamax	tafamidis
Ruzurgi	amifampridine
Piqray	alpelisib
Nucala	mepolizumab
Vyleesi	bremelanotide
Thiola EC	tiopronin
Xpovio	selinexor
Nubeqa	darolutamide
Turalio	pexidartinib

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Gattex (teduglutide) – Commercial and Healthcare Reform	8/27/2019	Policy revised to add criteria for the approval of Gattex (teduglutide) in pediatric patients with a diagnosis of Short Bowel Syndrome who are dependent on parenteral nutrition, weigh at least 10 kg, and have undergone fecal occult blood testing.
Testosterone (Androgens) – Commercial and Healthcare Reform	8/27/2019	Policy revised to include criteria that the documentation of testosterone levels is not necessary if the prescriber attests that the member is not producing any testosterone.
Hetlioz (tasimelteon) – Commercial and Healthcare Reform	8/27/2019	Policy revised to require daily sleep logs for at least 14 days rather than 1 month.
Tretinoin Therapy – Healthcare Reform	TBD	Policy revised to remove Commercial line of business.
PCSK9 Inhibitors – Commercial	8/27/2019	Policy revised for PCSK9 inhibitors that members with primary hyperlipidemia not associated with atherosclerotic cardiovascular disease, heterozygous familial hypercholesterolemia, or homozygous familial hypercholesterolemia step through Repatha (evolocumab) to obtain Praluent (alirocumab).
Rayaldee (calcifediol) – Commercial and Healthcare Reform	8/27/2019	Reauthorization criteria revised to require documentation of repeat vitamin D levels.
Etanercept Biosimilars – Commercial and Healthcare Reform	TBD	Policy revised to include newly-approved Eticovo (etanercept-ykro), which is the second biosimilar approved for Enbrel (entanercept).
Fosamax Plus D (alendronate sodium/cholecalciferol) – Healthcare Reform Essential Formulary	8/9/2019	Policy revised to include reauthorization criteria that the member requires additional therapy with Fosamax Plus D (alendronate sodium/cholecalciferol).
Emflaza (deflazacort) – Commercial and Healthcare Reform	8/27/2019	Policy revised to reflect newly approved expanded indications to include use in members 2 years of age and older. Also added prescribing information concerning immunizations and adverse effects with use of the suspension.
Hereditary Angioedema – Commercial and Healthcare Reform	1/1/2020	Policy revised to include step through generic icatibant for Berinert [C1 Esterase Inhibitor (Human)], brand Firazyr, and Ruconest [C1 Esterase Inhibitor (Recombinant)] for the treatment of acute attacks of hereditary angioedema (HAE) for members 18 years of age or older.
Addyi (filbanserin) – Commercial	8/9/2019	Policy revised to note availability only through a REMS (Risk Evaluation and Mitigation Strategy) program.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Endari (L-glutamine) – Commercial and Healthcare Reform	8/27/2019	Policy revised to include failure or intolerance to one over-the-counter L-glutamine product and reauthorization criteria added.
CGRP Inhibitors – Commercial and Healthcare Reform	8/27/2019	Policy revised to include coverage criteria for Emgality (galcanezumab) in adult members with cluster headache who are experiencing attack frequency at least once every other day during a cluster period.
Keveyis (dichlorphenamide) – Commercial and Healthcare Reform	8/27/2019	Policy revised for Keveyis (dichlorphenamide) to document the number of muscle weakness attacks per week. Reauthorization criteria added for documentation that the number of muscle weakness attacks per week has decreased from baseline. Initial authorization duration changed to 2 months. Reauthorization duration 12 months.
Ocaliva (obeticholic acid) – Commercial and Healthcare Reform	8/27/2019	Policy revised to include reauthorization criteria that the member requires additional therapy with Ocaliva (obeticholic acid) and that Ocaliva will be used with combination with ursodiol unless contraindicated.
Palynziq (pegvaliase-pqpz) – Commercial and Healthcare Reform	8/27/2019	Policy revised to require documentation that therapy has led to a 20% reduction in pretreatment blood phenylalanine levels or that the member has not had an adequate trial of Palynziq (pegvaliase-pqpz) at the maximum dose and requires additional therapy.
Venclexta (venetoclax) – Commercial and Healthcare Reform	8/27/2019	Policy revised to remove criteria for 17p deletion status and at least one prior therapy to reflect updated FDA-approved indication.
Epidiolex (cannabidiol) solution – Commercial and Healthcare Reform	8/27/2019	Policy revised to clarify that preferred generic alternatives for Dravet Syndrome include divalproex, topiramate, and clobazam.
Miscellaneous Immunomodulators – Commercial and Healthcare Reform	8/27/2019	Policy revised to include expanded FDA-approved indication for Revlimid (lenalidomide) in the treatment of previously treated follicular lymphoma (FL), in combination with a rituximab product; and previously treated marginal zone lymphoma (MZL), in combination with a rituximab product.
Tibsovo (ivosidenib) – Commercial and Healthcare Reform	8/27/2019	Policy revised to include expanded indication for newly-diagnosed acute myeloid leukemia (AML) with a susceptible IDH1 mutation, as detected by an FDA-approved test, in patients who are at least 75 years old or who have comorbidities that preclude the use of intensive induction chemotherapy.
Topical Non-Steroid Therapy for Atopic Dermatitis – Commercial and Commercial NSF	8/9/2019	Policy revised to update the strength of Elidel (pimecrolimus) to 1%.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Ingrezza (valbenazine) –- Commercial and Healthcare Reform	8/9/2019	Policy revised to include reauthorization criteria requiring provider attestation that the member has experienced positive clinical response to therapy.
Anti-Angiogenesis and VEGF Kinase Inhibitors – Commercial and Healthcare Reform	8/27/2019	Policy revised to remove for Inlyta (axitinib) the requirement of a diagnosis of stage IV predominantly clear cell renal cell carcinoma, and updated to include a diagnosis of advanced clear or non-clear cell histology with one prior systemic therapy.
Corlanor (ivabradine) – Commercial and Healthcare Reform	9/20/2019	Policy revised for Corlanor (ivabradine) to include treatment of symptomatic heart failure due to dilated cardiomyopathy in pediatrics with clinical documentation of normal sinus rhythm and resting heart rate greater than or equal to 70 bpm. For adults and pediatrics requesting Corlanor oral solution, member has an inability to swallow tablets. Removed adult age criteria.
Thiola and Thiola EC (tiopronin) – Commercial and Healthcare Reform	8/7/2019	Policy revised for Thiola (tiopronin) to add Thiola EC (tiopronin delayed-release). Policy revised to include approval for members that weigh 20 kg or greater and failure of urine alkalization to achieve a urinary pH of 6.5 to 7.0. Documentation required to support severe homozygous cystinuria diagnosis. Reauthorization criteria added for documentation of urine cysteine concentration < 250 mg/L or production of cysteine stones has decreased.
Provigil (modanfinil) and Nuvigil (armodafinil) – Commercial and Healthcare Reform	9/17/2019	Policy revised to eliminate ICD numbers and to remove Nuvigil (armodafinil) from reauthorization criteria for treatment of fatigue due to MS.
Hepatitis C Oral Agents – Commercial and Healthcare Reform, Commercial National Select Formulary, Commercial and Commercial Core	9/17/2019	Policy revised to include Mavyret's (glecaprevir and pibrentasvir) pediatric indication, background added to clarify the definition between acute and chronic hepatitis C (HCV), and administrative changes for ease of review.
Xerese Cream (acyclovir/hydrocortisone) – Commercial	8/9/2019	Added reauthorization criteria attesting clinical response.
Syndros (dronabinol oral solution) – Commercial and Healthcare Reform	9/17/2019	Policy revised to include reauthorization criteria of documentation of: for appetite stimulation therapy, weight increase from initial authorization; for anti-emetic therapy, positive clinical response.
Zytiga and Yonsa (abiraterone acetate) – Commercial and Healthcare Reform	8/9/2019	Policy revised to change duration of authorization to one year.
PCSK9 Inhibitors – Healthcare Reform	9/17/2019	Policy revised for PCSK9 inhibitors that members with heterozygous familial hypercholesterolemia or primary hyperlipidemia not associated with atherosclerotic cardiovascular disease,

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		heterozygous familial hypercholesterolemia, or homozygous familial hypercholesterolemia step through Repatha (evolocumab) to obtain Praluent (alirocumab).
Market Watch Programs – PA, WV, and DE	8/9/2019	Policy revised to include generic product, Orphengesic Forte (same ingredients as Norgesic Forte).
Dupixent (dupilumab) – Commercial and Healthcare Reform	9/17/2019	Policy revised to include expanded indication for chronic rhinosinusitis with nasal polyposis. Policy revised to move the Investigator's Static Global Assessment (ISGA) therapeutic failure and response definitions for atopic dermatitis from the criteria to the Background section.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	9/17/2019	Policy revised to include expanded indication of Behçet's Disease for Otezla (apremilast) that requires members to step through a triamcinolone topical product and colchicine. Policy revised to include exception criteria for members that may require initial biologic therapy for juvenile idiopathic arthritis and revise step through two immunosuppressants to one corticosteroid for severe ulcerative colitis. Cimzia (certolizumab) will require a trial of Humira (adalimumab) specifically for Crohn's disease indication only. The maintenance therapy quantity limit was updated for Humira to allow use of four prefilled syringes every four weeks when there is clinical documentation that treatment with two prefilled syringes every four weeks was ineffective for plaque psoriasis and ulcerative colitis indications. The induction therapy quantity limit was updated for Humira to allow for six prefilled syringes within the first four weeks of therapy to mirror the quantity limit in place for Crohn's disease.
Prolia (denosumab) and Evenity (romosozumab-aqqg) – Commercial and Healthcare Reform	9/17/2019	Policy revised to include criteria limiting members to a maximum of 12 monthly doses.
CFTR Modulators – Commercial and Healthcare Reform	9/17/2019	Policy revised to include expanded indications for Symdeko (tezacaftor and ivacaftor) and Kalydeco (ivacaftor). Removed 'inability to swallow' as a criteria for Orkambi (lumacaftor and ivacaftor) granules.
Jynarque (tolvaptan) – Commercial and Healthcare Reform	9/17/2019	Policy revised for Jynarque (tolvaptan) to include reauthorization criteria that the member's kidney function (e.g. total kidney volume, estimated glomerular filtration rate) decline has slowed. In limitations of coverage added that Jynarque should

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		not be used in patients with stage 5 chronic kidney disease or dialysis.
Doptelet (avatrombopag) and Mulpleta (lusutrombopag) – Commercial and Healthcare Reform	9/17/2019	Policy revised for Doptelet (avatrombopag) to add chronic immune thrombocytopenia (ITP) in members 18 years of age or older who have tried and failed corticosteroid therapy, immunoglobulin therapy, or splenectomy and documented platelet count of < 50 x 10^9/L with risk factor or platelet count ≤ 30 x 10^9/L. Policy revised thrombocytopenia with chronic liver disease to provide platelet count < 50 x 10^9/L. Reauthorization criteria attesting clinical response for ITP and documentation of procedure and platelet count for thrombocytopenia with CLD. Reauthorization duration changed to 1 month for thrombocytopenia with CLD and 12 months for ITP.
PI3K Inhibitors – Commercial and Healthcare Reform	9/17/2019	Policy revised to include FDA-approved Piqray (alpelisib) in combination with fulvestrant for males or postmenopausal women with advanced or metastatic breast cancer that is HR-positive, HER2-negative, PI3K-mutation positive, after disease progression with an endocrine-based regimen.
Ruzurgi (amifampridine) and Firdapse (amifampridine) – Commercial and Healthcare Reform	8/9/2019	Policy revised to include new agent Ruzurgi (amifampridine). Members requesting Firdapse (amifampridine) must step through Ruzurgi.
Cequa (cyclosporine) – Commercial and Healthcare Reform	9/17/2019	Policy revised to include an additional step through Xiidra (lifitegrast) prior to receiving Cequa (cyclosporine) for dry eye disease.
EGFR Kinase Inhibitors – Commercial and HCR	9/17/2019	Policy revised to add a step through generic erlotinib for Tarceva (erlotinib) coverage approval.
JAK Inhibitors – Commercial and Healthcare Reform	9/17/2019	Policy revised to include expanded FDA-approved indication for Jakafi (ruxolitinib) in the treatment of steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older.
PARP Kinase Inhibitors – Commercial and Healthcare Reform	9/17/2019	Policy revised to reflect FDA-approved indication of deleterious or suspected deleterious gBRCAm, HER2-negative locally advanced or metastatic breast cancer. Policy updated to include documentation of FDA-approved companion test for Talzenna (talazoparib). Policy updated to remove criteria for previous treatment with chemotherapy in the neoadjuvant, adjuvant and/or metastatic setting for Talzenna (talazoparib).
AirDuo Digihaler (fluticasone propionate and salmeterol) – Commercial and Healthcare Reform	Best Date	New policy created to reserve use of AirDuo Digihaler (fluticasone propionate and salmeterol) for members who have experienced an inadequate response to a non-digitized asthma combination

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		inhaler containing an inhaled corticosteroid and a long-acting beta2-adrengergic agonist.
Drizalma Sprinkle (duloxetine) – Commercial and Healthcare Reform	Best Date	New policy created to ensure use of Drizalma Sprinkle (duloxetine) for FDA-approved indications in members who have the inability to swallow capsules.
Interleukin (IL)-5 Antagonists – Commercial and Healthcare Reform	8/9/2019	New policy created to ensure appropriate use of Nucala (mepolizumab) for eosinophilic asthma and Eosinophilic Granulomatosis with Polyangiitis (EGPA) who are treated with the appropriate maintenance therapies.
Interleukin (IL)-5 Antagonists – Commercial and Healthcare Reform	8/9/2019	Revised quantity limit to 1 syringe per 28 days. An override is available for EGPA to allow 3 syringes per 28 days.
Katerzia (amlodipine benzoate) – Commercial and Healthcare Reform	9/20/2019	New policy created for Katerzia (amlodipine benzoate) to require diagnosis of hypertension and is 6 years of age or older or diagnosis of coronary artery disease and is 18 years of age or older. Member has tried and failed amlodipine besylate tablets and has an inability to swallow tablets. Reauthorization criteria attesting positive clinical response and continues to have an inability to swallow tablets.
Lotronex (alosetron) – Commercial and Healthcare Reform	1/1/2020	New policy created to ensure appropriate use of Lotronex (alosetron) in adult female patients with irritable bowel syndrome with diarrhea (IBS-D) who have experienced therapeutic failure or intolerance to 2 of the following or all are contraindicated: loperamide, cholestyramine, colestipol, dicyclomine, hyoscyamine, tricyclic antidepressants (e.g. amitriptyline, nortriptyline), and selective serotonin reuptake inhibitors (e.g. sertraline).
Tretinoin Therapy – Commercial	TBD	New policy created for Commercial line of business. Policy revised to include an additional step for brand Tazorac and generic tazarotene through at least 2 topical medications for acne vulgaris and one topical corticosteroid for plaque psoriasis.
Vyleesi (bremelanotide) – Commercial and Healthcare Reform	9/20/2019	New policy created to ensure appropriate use of Vyleesi (bremelanotide) in premenopausal women with acquired, generalized hypoactive sexual desire (HSDD) that causes marked distress or interpersonal difficulty and is not due to a co-existing medical or psychiatric problem, problems with the relationship, or the effects of a medication or drug substance.
Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) – Commercial and Healthcare Reform	8/9/2019	New policy created to ensure appropriate use of Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) in adults 18 years of age or older with a diagnosis of wild type or hereditary transthyretin-

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		mediated amyloidosis with cardiomyopathy (ATTR-CM), New York Heart Association Class I, II, or III, and that immunohistochemistry, mass spectrometry, or scintigraphy has ruled out light chain amyloidosis. Prescribed by or in consultation with a cardiologist or physician who specializes in ATTR-CM. Reauthorization documenting disease improvement or delayed disease progression.
Xpovio (selinexor) – Commercial and Healthcare Reform	9/20/2019	New policy created to ensure appropriate use of Xpovio (selinexor) for relapsed or refractory multiple myeloma, in patients aged >18 years, in combination with dexamethasone, who have failed 5 prior agents.
Evoxac (cevimeline) – Healthcare Reform 2020	1/1/2020	Policy revised to include step through generic cevimeline before obtaining brand Evoxac.
Fertility – Pennsylvania Healthcare Reform Individual Plans	1/1/2020	Policy revised to require trial and failure of Follistim AQ (follitropin beta) for approval of Gonal-F (follitropin alfa).
Fertility – Select Healthcare Reform Plans	1/1/2020	Policy revised to remove criteria for Healthcare Reform plans from Commercial plans and to require trial and failure of Follistim AQ (follitropin beta) for approval of Gonal-F (follitropin alfa).
Vusion – Healthcare Reform	1/1/2020	In addition to the generic, brand Vusion will require a PA to ensure appropriate diagnosis and prior therapy with alternatives.

*For policies that require step therapy, an exception may be made for commercial and HCR members enrolled in a West Virginia plan. For additional details, refer to pharmacy policy bulletin J-513 (West Virginia – Step Therapy Override Exception).
**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
Migraine Therapies – Healthcare Reform	9/17/2019	Policy terminated due to being combined into J-790 Acute Migraine Therapies - Healthcare Reform
Buprenorphine Non-Opioid Dependence Use – Commercial and Healthcare Reform	8/9/2019	Policy revised to change duration of authorization to one year.
Extavia (interferon beta-1b) – Commercial and Select Healthcare Reform	8/27/2019	Policy revised to allow for use in members who have experienced a first clinical episode with MRI features consistent with multiple sclerosis (MS).
Lyrica (pregabalin) & Lyrica CR (pregabalin ER) – Commercial and Healthcare Reform	TBD	Policy revised for Lyrica (pregabalin) and Lyrica CR (pregabalin ER) to allow members to try and fail two of three drug classes for the treatment of neuropathic pain (serotonin-norepinephrine reuptake inhibitors, antiepileptic drugs, or tricyclic antidepressants). Removed age edit for the treatment of partial-onset seizures. Member must try and fail generic pregabalin immediate-release if the request is for brand Lyrica or Lyrica CR. Member must also have an inability to swallow capsules to obtain Lyrica (pregabalin) oral solution. Decreased authorization duration from lifetime to 12 months.
Vimovo (naproxen/esomeprazole) – Commercial, Healthcare Reform and Commercial National Select	8/9/2019	Added reauthorization or prescriber attestation of positive clinical response to therapy as well as administrative changes.
Non-preferred Generic NSAIDs – Healthcare Reform Essential Formulary	8/9/2019	Added reauthorization criteria of prescriber attestation of positive clinical response to therapy.
Bystolic (nebivolol) – Healthcare Reform Essential	8/9/2019	Policy revised for Bystolic (nebivolol) to add reauthorization criteria attesting clinical response.
Edarbi (azilsartan) – Healthcare Reform Essential Formulary	8/9/2019	Policy revised for Edarbi (azilsartan) to add reauthorization criteria attesting clinical response.
Antiviral Therapies – Healthcare Reform	8/9/2019	Added reauthorization criteria attesting clinical response.
Leukotriene Modifiers (Accolate, Zyflo, Zyflo CR) – Healthcare Reform	8/9/2019	Policy revised to include reauthorization criteria and automatic approval criteria updated to reflect failure, contraindication or intolerance to montelukast, zafirlukast and zileuton ER.
Picato (ingenol mebutate) – Healthcare Reform Essential	8/9/2019	Policy revised to update the authorization duration from 12 months to 1 month.
Opioid Dependence Step Therapy – Healthcare Reform Essential Formulary	10/2/2019	Policy terminated due to legislative requirement for removal of prior authorization on Medication Assisted Therapy.
Antiviral Therapies – Commercial	8/9/2019	Added reauthorization criteria attesting clinical response.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Rayos (prednisone) – Commercial and Healthcare Reform	9/17/2019	Policy revised to have the prescriber provide documentation as to why the patient experienced a therapeutic failure to generic, immediate release prednisone, remove reauthorization criteria and limit authorization duration to 1 year.
Atypical Antipsychotics – Commercial and Healthcare Reform	9/17/2019	Policy revised to include new indication for Vraylar (Cariprazine) (depression associated with bipolar I), revised formatting of criteria from indications to individual drugs
Viibryd (vilazodone) and Trintellix (vortioxetine) – Commercial and Healthcare Reform	8/9/2019	Policy revised to remove any reference to Brintellix (vortioxetine), removed all ICD-9 and ICD-10 codes, added reauthorization criteria, and changed authorization duration from "lifetime" to 2 years.
Epinephrine Auto Injectors – Commercial and Healthcare Reform	8/21/2019	Policy revised to include Symjepi 0.15 mg (epinephrine) as a preferred product; this strength is newly available.
Doxycycline Products – Commercial and Healthcare Reform	8/9/2019	Policy revised to include a new product, Doxycycline Hyclate 80 mg (vibramycin) as well as background information and criteria for bacterial infections; also added reauthorization criteria for both bacterial infections and acne vulgaris.
Acute Migraine Therapies – Commercial	9/17/2019	Policy revised for acute migraine therapies to add prophylactic migraine medication alternatives alpha-agonists and angiotensin-converting-enzyme inhibitors or angiotensin II receptor blockers and changed selective-serotonin reuptake inhibitors to serotonin-norepinephrine reuptake inhibitors.
Acute Migraine Therapies – Healthcare Reform	9/17/2019	Policy revised to add step therapy for non-preferred medications previously located in J-4 Migraine Therapies - Healthcare Reform. For acute migraine therapies, added prophylactic migraine medication alternatives alpha-agonists and angiotensin-converting-enzyme inhibitors or angiotensin II receptor blockers and changed selective-serotonin reuptake inhibitors to serotonin-norepinephrine reuptake inhibitors.
Topical Acne Medications – Commercial	10/2/2019	Policy revised for topical acne medications to remove step alternatives dapsone, erythromycin/benzoyl peroxide, metronidazole, and sulfacetamide/sulfur.
Consensi (amlodipine/celecoxib) – Commercial and Healthcare Reform	8/9/2019	Policy revised for Consensi (amlodipine/celecoxib) to add reauthorization criteria attesting clinical response.
Duobrii (halobetasol propionate/tazarotene) – Commercial and Healthcare Reform	10/2/2019	New policy created to ensure appropriate use of Duobrii (halobetasol/tazarotene) lotion for plaque psoriasis in those have tried and failed one other generic topical corticosteroid and generic tazarotene cream.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Nayzilam (midazolam) – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use of Nayzilam (midazolam) in patients with acute repetitive seizures and seizure clusters who have experienced a therapeutic failure, intolerance or contraindication to diazepam rectal gel.
Norgesic Forte and Orphengesic Forte (orphenadrine citrate, aspirin and caffeine) – Commercial and Healthcare Reform	10/2/2019	Policy created for Norgesic Forte and Orphengesic Forte (orphenadrine citrate, aspirin, and caffeine). Member is 12 years of age or older with mild to moderate pain of acute musculoskeletal disorder(s). The member has tried and failed orphenadrine in combination with aspirin and caffeine, chlorzoxazone 500 mg, cyclobenzaprine, and methocarbamol. Reauthorization criteria of positive clinical response and continues to experience mild to moderate pain of acute musculoskeletal disorder(s).
Picato (ingenol mebutate) – Commercial and Healthcare Reform	1/1/2020	Policy created to ensure appropriate use of Picato (ingenol mebutate) in members that have a diagnosis of actinic keratosis and have experienced therapeutic failure or intolerance to both generic imiquimod cream and fluorouracil cream or solution.
Qternmet XR (dapagliflozin and saxagliptin and metformin ER) – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use of Qternmet XR (dapagliflozin and saxagliptin and metformin ER) in patients with type 2 diabetes who have tried and failed a preferred metformin product, a preferred sodium-glucose cotransporter inhibitor, and a preferred dipeptidyl peptidase-4 inhibitor.
Carbinoxamine 6 mg – Healthcare Reform	1/1/2020	New policy created for carbinoxamine 6 mg tablets to ensure appropriate use in members with seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods, mild, uncomplicated allergic skin manifestations of urticaria and angioedema, dermatographism, anaphylactic reactions after acute manifestations have been controlled adjunctive to epinephrine and other standard measures, or hypersensitivity reactions to blood or plasma who are 2 years of age or older. The member has experienced therapeutic failure, contraindication, or intolerance to carbinoxamine 4 mg tablets and to two (2) different antihistamines. Reauthorization criteria includes prescriber attestation that member is experiencing a positive clinical response to therapy. Authorization duration of up to 12 months.
Doxepin 5% Cream – Healthcare Reform	1/1/2020	Updated approval criteria to include trial of topical and oral antihistamines.
Herpetic Keratitis – Commercial and Healthcare Reform 2020	1/1/2020	New policy created to ensure appropriate use of Avaclyr (acyclovir) ophthalmic ointment, Viroptic

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		(trifluridine) ophthalmic solution, and Zirgan (ganciclovir) ophthalmic gel for the treatment of acute herpetic keratitis in patients who have tried and failed trifluridine 1% eye drops.
Non-Preferred Erectile Dysfunction Therapy – Healthcare Reform	1/1/2020	Policy revised to include Cialis as a target drug.
Topical Corticosteroids – Healthcare Reform	1/1/2020	New policy created to step select non-preferred topical corticosteroids through preferred alternative topical corticosteroids. To receive a non-preferred low- to medium-potency topical corticosteroid, a member must try and fail two preferred low to medium potency topical corticosteroids. To receive a non-preferred high-potency topical corticosteroid, a member must try and fail two preferred high-potency topical corticosteroids.
Brand Statins – Healthcare Reform	1/1/2020	Policy revised to include brand Crestor as a target for strep through, requiring trial and failure of at least one generic statin alternative.
Generic Step Therapy Edit – Healthcare Reform	1/1/2020	Policy revised to include brand Crestor as a target for strep through, requiring trial and failure of at least one generic statin alternative.
Fibrates – Healthcare Reform	1/1/2020	New policy developed to step select non-preferred fibrates through preferred alternative fibrate therapies.
Methotrexate Injectables – Healthcare Reform	1/1/2020	New policy developed which will require the step through generic methotrexate injectable prior to use of Rasuvo and Otrexup. Additionally, prior to use of Otrexup the member must try Rasuvo.
Topical Psoriasis Treatments – Healthcare Reform	1/1/2020	New policy which requires that preferred topical steroid and generic calciptriene be tried prior to use of Dovonex, Vectical (calcitriol), or Sorilux.
Ranexa – Healthcare Reform	1/1/2020	New policy developed which requires that preferred alternatives be tried prior to Ranexa (ranolazine).

For policies that require step therapy, an exception may be made for Commercial and HCR members enrolled in a West Virginia plan. For additional details, refer to pharmacy policy bulletin J-513 (West Virginia – Step Therapy Override Exception).
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.

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
AirDuo Digihaler (fluticasone propionate/salmeterol)*	2 inhalers per lifetime	2 inhalers per lifetime
Corlanor (ivabradine) oral solution	3 cartons (84 ampules) per 28 days	9 cartons (252 ampules) per 84 days
Dexcom (blood glucose meter; continuous)	Receiver: 1 pack per 365 days; Transmitter: 1 pack per 90 days; Sensor: 3 pack per 30 days	Receiver: 1 pack per 365 days; Transmitter: 1 pack per 90 days; Sensor: 9 pack (3 x 3-pack) per 90 days
Emgality (galcanezumab) 100 mg syringe	3 syringes per 30 days	9 syringes per 90 days
Eticovo (etanercept-ykro)*	4 prefilled syringes per 28 days	12 prefilled syringes per 84 days
Evenity (romosozumab-aqqg)	24 syringes per 720 days	24 syringes/720 days
Freestyle (blood glucose meter; continuous)	Reader: 1 pack per 365 days; Sensor: 2 packs per 28 days	Reader: 1 pack per 365 days; Sensor: 6 packs per 84 days
Katerzia (amlodipine benzoate)	2 bottles (300 ml) per 30 days	6 bottles (900 ml) per 90 days
Nucala (mepolizumab) syringe & auto-injector	1 syringe per 28 days	3 syringes per 84 days
Onfi 2.5 mg/mL suspension*	4 bottles per 30 days	12 bottles per 90 days
Picato (ingenol lebutate) 0.015% gel, 0.05% gel*	1 carton per 28 days	3 cartons per 83 days
Piqray 250 mg/day, 300 mg/day	56 tablets per 28 days	168 tablets per 84 days
Piqray 200 mg/day	28 tablets per 28 days	84 tablets per 84 days
Sprix (ketorolac tromethamine) nasal spray	5 bottles per 90 days	5 bottles per 90 days
Vyleesi (bremelanotide)	4 autoinjectors per 30 days	12 autoinjectors per 90 days
Xpovio (selinexor) 60 mg/week	12 tablets per 28 days	36 tablets per 84 days
Xpovio (selinexor) 80 mg/week	16 tablets per 28 days	48 tablets per 84 days
Xpovio (selinexor) 100 mg/week	20 tablets per 28 days	60 tablets per 84 days
Xpovio (selinexor) 160 mg/week	32 tablets per 28 days	96 tablets per 84 days

*Effective date to be determined.

Drug Name	Age Restriction	Retail Edit Limit	Mail Edit Limit
Engerix-B (Hepatitis B Virus Vaccine/Pf)*	19 years of age or older	4 doses per lifetime	4 doses per lifetime
Gardasil (human papillomavirus vaccine, QVAL/PF) / Gardasil 9	Up to 26 years of age		

Drug Name	Age Restriction	Retail Edit Limit	Mail Edit Limit
(human papillomavirus vaccine, QVAL/PF)			
Heplisav-B (hepatitis B vaccine/CPG1018/PF)*	19 years of age or older	4 doses per lifetime	4 doses per lifetime
Influenza virus vaccines	19 years of age or older	1 dose per 185 days	1 dose per 185 days
Pediarix (hepatitis B vaccine/Dp(A)T-Polio/PF)*	19 years of age or older	4 doses per lifetime	4 doses per lifetime
Pneumovax 23 (pneumococcal 23-val p-sac vac)*	19 years of age or older	2 doses per 365 days	2 doses per 365 days
Prevnar 13 (pneumoc 13-val conj-dip CRM/PF)*	19 years of age or older	1 dose per 365 days	1 dose per 365 days
Recombivax hb (hepatitis B virus vaccine/PF)*	19 years of age or older	4 doses per lifetime	4 doses per lifetime
Shingrix (varicella-zoster GE/AS01B/PF)	50 years of age or older		
Twinrix (hepatitis A and B vaccine/PF)*	19 years of age or older	4 doses per lifetime	4 doses per lifetime
Zostavax (zoster vaccine live/PF)	60 years of age or older		

*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
Duobrii (halobetasol propionate/tazarotene)	1 tube (100 g) per dispensing event	3 tubes (300 g) per dispensing event
Nayzilam (midazolam) nasal spray*	2 sprays units per dispensing event	2 sprays units per dispensing event

*Effective date to be determined.
Quantity per dispensing event limits the quantity of medication that can be dispensed per each fill. If the submitted day supply on a claim is 34 days or less, the retail limit will apply. If the submitted day supply on a claim is greater than 34 days, the mail limit will apply.

Table 3. Maximum Daily Quantity Limits – Commercial and Healthcare Reform Plans

Drug Name	Daily Limit
Cablivi (caplacizumab-yhdp)*	1 single-dose vial per day
Drizalma Sprinkle (duloxetine)*	1 capsule per day
Norgesic Forte (orphenadrine citrate/aspirin/caffeine)	4 tablets per day
Nubeqa (darolutamide)	4 tablets per day
Onfi (clobazam) 10 mg, 20 mg tablet*	2 tablets per day
Orphengesic Forte (orphenadrine citrate/aspirin/caffeine)	4 tablets per day
Qternmet XR (dapagliflozin/saxagliptin/metformin ER)*	1 tablet per day
Risperdal/risperidone 0.25 mg, 0.5 mg, 1 mg, 2 mg	2 tablets per day
Ruzurgi (amifampridine)	10 tablets per day
Selzentry 25 mg, 75 mg, 150 mg tablet	2 tablets per day
Selzentry 300 mg tablet	4 tablets per day
Seroquel/quetiapine 25 mg, 50 mg, 100 mg, 200 mg	3 tablets per day
Thiola EC (tiopronin) 300 mg	6 tablets per day
Thiola EC (tiopronin) 100 mg	20 tablets per day
Turalio (pexidartinib)	4 capsules per day
Vyndamax (tafamidis)	1 capsule per day
Vyndaqel (tafamidis meglumine)	4 capsules per day

*Effective date to be determined.

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 at:

Performance Formulary*:*https://client.formularynavigator.com/Search.aspx?siteCode=1349658900
Venture Formulary: https://client.formularynavigator.com/Search.aspx?siteCode=1347236614
Incentive Formulary*:* https://client.formularynavigator.com/Search.aspx?siteCode=1344627998

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

Brand Name	Generic Name	Comments
Dengvaxia	dengue vaccine	--

Table 2. Non-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	Preferred Alternatives
Corlanor oral solution	ivabradine	Provider discretion
Qternmet XR	dapagliflozin/saxagliptin/ metformin ER	Provider discretion
Nayzilam nasal spray	midazolam	Provider discretion
Slynd	drospirenone	Provider discretion
Myxredlin	insulin (human)/sodium chloride	Provider discretion
Katerzia	amlodipine benzoate	Provider discretion
AirDuo Digihaler	fluticasone propionate/salmeterol	Provider discretion
Drizalma Sprinkle	duloxetine	Provider discretion

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: https://client.formularynavigator.com/Search.aspx?siteCode=1349658900
Venture Formulary: https://client.formularynavigator.com/Search.aspx?siteCode=1347236614
Incentive Formulary: https://client.formularynavigator.com/Search.aspx?siteCode=1344627998

Table 1. Preferred Products

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

Brand Name	Generic Name	Comments
Dengvaxia	dengue vaccine	Provider discretion

Table 2. Non-Preferred Products

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

Brand Name	Generic Name	Preferred Alternatives
Nayzilam nasal spray	midazolam	diazepam kit
Drizalma Sprinkle	duloxetine	Provider 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
Corlanor oral solution	ivabradine	metoprolol succinate, carvedilol
Eticovo	etanercept-ykro	Enbrel
Qternmet XR	dapagliflozin/saxagliptin/ metformin ER	metformin tablet extended release 24 HR, Januvia, Jardiance
Slynd	drospirenone	Camila, Errin
AirDuo Digihaler	fluticasone propionate/ salmeterol	fluticasone/salmeterol, Breo Ellipta
Myxredlin	insulin (human)/sodium chloride	Provider discretion
Katerzia	amlodipine benzoate	Provider discretion

*Physicians may request coverage of these products using the Prescription Drug Medication Request Form, which can be accessed online in Highmark's Provider Resource Center. Under **Forms**, select **Miscellaneous Forms**, and select the form titled **Request for Non-Formulary Drug Coverage**.

C. Additions to the Specialty Tier

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

Brand Name	Generic Name
Eticovo	etanercept-ykro
Duobrii	halobetasol propionate/tazarotene
Vyndaqel	tafamidis meglumine
Vyndamax	tafamidis
Ruzurgi	amifampridine
Zolgensma	onasemnogene abeparvovec-xioi
Piqray	alpelisib
Nucala	mepolizumab
Polivy	polatuzumab vedotin-piiq
Kanjinti	trastuzumab-anns
Zirabev	bevacizumab-bvzr
Thiola EC	tiopronin
Xembify	immune globulin, human-klhw
Xpovio	selinexor
Recarbrio	imipenem/cilastatin/relebactam
Nubeqa	darolutamide
Turalio	pexidartinib

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Testosterone (Androgens) – Medicare	10/1/2019	Policy revised to include criteria that the documentation of testosterone levels is not necessary if the prescriber attests that the member is not producing any testosterone.
Miscellaneous Immunomodulators – Medicare	MedD	Policy revised to include expanded FDA-approved indication for Revlimid (lenalidomide) in the treatment of previously treated follicular lymphoma (FL), in combination with a rituximab product; and previously treated marginal zone lymphoma (MZL), in combination with a rituximab product.
Miscellaneous Immunomodulators – Medicare 2020	1/1/2020	Policy revised to reflect Thalomid's (thalidomide) FDA-approved indications in the package insert. Limitation of coverage added to deny coverage of Thalomid for use as monotherapy for erythema nodosum leprosum (ENL) treatment in the presence of moderate to severe neuritis; and for Revlimid to deny coverage for the treatment of patients with chronic lymphocytic leukemia (CLL).
Kalydeco (ivacaftor) – Medicare	8/1/2019	Policy revised to include expanded indication for patients 6 months of age and older.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Homozygous Familial Hypercholesterolemia – Medicare 2020	1/1/2020	Policy revised for Homozygous Familial Hypercholesterolemia to include reauthorization criteria that member has experienced a reduction in LDL-C from baseline.
Immediate Release Fentanyl Citrate – Medicare	MedD	Policy revised to take all items listed under limitations of coverage and place under background; remove statement concerning "more units needed…" and place it also, under background.
Gilenya (fingolimod) – Medicare	MedD	Policy revised to move prescriber attestation of certain clinical parameters (e.g., absence of bradycardia) from criteria to limitations of coverage.
Hepatitis C Oral Agents – Medicare	MedD	Policy revised to include Mavyret's pediatric indication, background added to clarify the definition between acute and chronic HCV, and administrative changes.
Hepatitis C Oral Agents – Medicare 2020	1/1/2020	Policy revised to appropriate display preferred agents including Harvoni/ Harvoni authorized generic (AG), Epclusa/Epclusa AG and Mavyret.
Antipsychotics – Medicare	MedD	Revised authorization duration to 12 months. Noted that policy only applies to new starts only. Requires documentation of diagnosis, and for MDD—adjunctive treatment and an adequate trial of 1 alternate antidepressant. Added new indication for Vraylar. Removed indication of agitation associated with schizophrenia or bipolar mania.
H.P. Acthar Gel (repository corticotropin injection) – Medicare	1/1/2020	Policy revised to include reauthorization criteria for the approval of additional courses of H.P. Acthar (repository corticotropin injection).
Viibryd (vilazodone) and Trintellix (vortioxetine) – Medicare	7/1/2019	Policy revised to decrease required trial and failure from two antidepressants to one antidepressant.
Programmed Death Receptor Therapies – Medicare	MedD	Policy revised to include expanded FDA-approved indication for Bavencio (avelumab) in combination with Inlyta (axitinib) for first-line advanced renal cell carcinoma; and expanded FDA-approved indications for Keytruda (pembrolizumab) for head and neck squamous cell cancer; small cell lung cancer; and esophageal cancer.
Gattex (teduglutide) – Medicare	MedD	Policy revised to add criteria for the approval of Gattex (teduglutide) in pediatric patients with a diagnosis of Short Bowel Syndrome who are dependent on parenteral nutrition.
Corlanor (ivabradine) – Medicare	MedD	Policy revised for Corlanor (ivabradine) to include treatment of symptomatic heart failure due to dilated cardiomyopathy in pediatrics with clinical documentation of normal sinus rhythm and resting heart rate greater than or equal to 70 bpm. For adults and pediatrics requesting Corlanor oral solution, member has an inability to swallow tablets. Removed adult age criteria.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
PCSK9 Inhibitors – Medicare 2020	1/1/2020	Policy revised for PCSK9 Inhibitors to remove prescriber specialty.
Lonsurf (trifluridine/tipiracil) – Medicare 2020	1/1/2020	Policy revised to add age limitation for use of Lonsurf (trifluridine-tipiracil) in members 18 years of age or older; criteria was added for coverage of gastric or gastroesophageal junction adenocarcinoma per FDA-approved indications; and reauthorization criteria was removed.
Darzalex (daratumumab) – Medicare	MedD	Policy revised to include expanded FDA-approved indication for Darzalex in combination with lenalidomide and dexamethasone for patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
Viberzi (eluxadoline) – Medicare	MedD	Policy revised to move the majority of the Limitations of Coverage to the Background section by only leaving "severe (Child-Pugh C) hepatic impairment" in the Limitations of Coverage.
Interleukin (IL)-5 Antagonists – Medicare	8/9/2019	Policy title revised to drug class vs. indication as the medications are approved for more than eosinophilic asthma. Administrative changes made to facilitate better policy flow.
Interleukin (IL)-5 Antagonists – Medicare	MedD	Revised quantity limit to 1 syringe per 28 days. An override is available for EGPA to allow 3 syringes per 28 days.
Venclexta (venetoclax) – Medicare	MedD	Policy revised to remove criteria for 17p deletion status and at least one prior therapy to reflect updated FDA-approved indication.
Nuplazid (pimavanserin) – Medicare	MedD	Policy revised to clarify background, and as per CMS guidelines require member to be at 18 years of age, as well as clarifying that the policy applies only to new starts.
Dupixent (dupilumab) – Medicare	MedD	Policy revised to include expanded indication for chronic rhinosinusitis with nasal polyposis.
Emflaza (deflazacort) – Medicare	MedD	Policy revised to reflect newly approved expanded indications to include use in members 2 years of age and older. Also added prescribing information concerning immunizations and adverse effects with use of the suspension.
Chronic Inflammatory Diseases – Medicare	MedD	Policy revised to include expanded indication of Behçet's Disease for Otezla (apremilast) that requires members to step through a triamcinolone topical product and colchicine. The maintenance therapy quantity limit was updated for Humira (adalimumab) to allow use of four prefilled syringes every four weeks when there is clinical documentation that treatment with two prefilled syringes every four weeks was ineffective for plaque psoriasis and ulcerative colitis indications. The induction therapy quantity limit was updated for Humira (adalimumab) to allow for six

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		prefilled syringes within the first four weeks of therapy to mirror the quantity limit in place for Crohn's disease.
Chronic Inflammatory Diseases – Medicare 2020	1/1/2020	Policy revised to include exception criteria for members that may require initial biologic therapy for juvenile idiopathic arthritis and revise step through two immunosuppressants to one corticosteroid for severe ulcerative colitis.
Hetlioz (tasimelteon) – Medicare	MedD	Policy revised to require daily sleep logs for at least 14 days rather than 1 month.
Xolair (omalizumab) – Medicare	MedD	Policy revised to include reauthorization criteria in the appropriate section of the document.
Megace (megestrol acetate) – Medicare	8/9/2019	Policy revised to include "Tablets only: applies to new starts only" in the Additional Restrictions section. Policy revised to include current FDA-approved indications.
Symdeko (tezacaftor/ivacaftor) – Medicare	10/1/2019	Policy revised to include the expanded indication of patients 6 years of age or older.
Endari (L-glutamine) – Medicare	MedD	Policy revised to remove failure of over-the-counter L-glutamine product and decrease the number of sickle cell complications.
CGRP Inhibitors – Medicare	MedD	Policy revised to include coverage criteria for Emgality (galcanezumab) in adult members with cluster headache who are experiencing attack frequency at least once every other day during a cluster period. Policy revised to add prophylactic migraine medication alternatives alpha-agonists and angiotensin-converting-enzyme inhibitors or angiotensin II receptor blockers and changed selective-serotonin reuptake inhibitors to serotonin-norepinephrine reuptake inhibitors.
Jynarque (tolvaptan) – Medicare 2020	1/1/2020	Policy revised for Jynarque (tolvaptan) by adding reauthorization criteria for attestation that decline in the member's kidney function (e.g., total kidney volume, estimated glomerular filtration rate) has slowed.
Doptelet (avatrombopag) and Mulpleta (lusutrombopag) – Medicare	10/1/2019	Policy revised for Doptelet (avatrombopag) to include new indication of chronic immune thrombocytopenia in members 18 years of age or older. Member has tried and failed corticosteroid therapy, immunoglobulin therapy, or splenectomy. Member has documented platelet count of < 50 x 10^9/L with risk factor or platelet count ≤ 30 x 10^9/L.
Daytrana (methylphenidate) patch – Medicare	1/1/2020	Authorization criteria updated to include double step through two of the following: atomoxetine, methylphenidate, amphetamine/dextroamphetamine.
Thiola and Thiola EC (tiopronin) – Medicare	10/1/2019	Policy revised for Thiola (tiopronin) to add Thiola EC (tiopronin delayed-release). Policy revised to include approval for members that weight 20 kg or greater and lowered urine alkalization goal to a pH of 6.5 to 7. The 24-

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		hour urine collection with urinary cysteine excretion lowered to > 400 mg/day.
Epidiolex (cannabidiol) solution – Medicare	MedD	Policy revised to remove specific preferred alternatives. Members must simply try and fail two standard-of-care alternatives before approval of Epidiolex (cannabidiol).
PI3K Inhibitors – Medicare	9/1/2019	Policy revised to include FDA-approved Piqray (alpelisib) in combination with fulvestrant for males or postmenopausal women with advanced or metastatic breast cancer that is HR-positive, HER2-negative, PI3K-mutation positive, after disease progression with an endocrine-based regimen.
PI3K Inhibitors – Medicare 2020	1/1/2020	Policy revised to add age limitation for use of Copiktra (duvelisib) in members 18 years of age or older.
Tibsovo (ivosidenib) – Medicare	MedD	Policy revised to include expanded indication for newly-diagnosed acute myeloid leukemia (AML) with a susceptible IDH1 mutation, as detected by an FDA-approved test, in patients who are at least 75 years old or who have comorbidities that preclude the use of intensive induction chemotherapy.
Tibsovo (ivosidenib) – Medicare 2020	1/1/2020	Policy revised with updated authorization criteria to reflect indications in the package insert; limitation of coverage was added to deny coverage for use as monotherapy for erythema nodosum leprosum (ENL) treatment in the presence of moderate to severe neuritis.
Ruzurgi (amifampridine) and Firdapse (amifampridine) – Medicare	MedD	Policy revised to include new agent Ruzurgi (amifampridine). Members requesting Firdapse (amifampridine) must step through Ruzurgi.
EGFR Kinase Inhibitors – Medicare 2020	1/1/2020	Policy revised to add limitation of coverage for Iressa (gefitinib) for tumors with epidermal growth factor receptor (EGFR) mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.
BCR-ABL Kinase Inhibitors – Medicare 2020	1/1/2020	Policy revised to add age limitation of 18 years or older to Bosulif (bosutinib) and Iclusig (ponatinib); Limitation of coverage added for Iclusig.
Bruton's Tyrosine Kinase inhibitors – Medicare 2020	1/1/2020	Policy revised to add age limitation of 18 years or older for Calquence (acalabrutinib).
Anti-Angiogenesis and VEGF Kinase Inhibitors – Medicare 2020	1/1/2020	Policy revised for Nexavar (sorafenib) criteria for documentation of diagnosis; and for locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment. Policy revised for Inlyta (axitinib) criteria for diagnosis of advanced renal cell carcinoma and treatment with at least one prior systemic therapy. Policy revised for Sutent (sunitinib) for advanced renal cell carcinoma, member age of at least 18 years old, previous nephrectomy, and use in adjuvant treatment.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
FLT3 Kinase Inhibitors – Medicare 2020	1/1/2020	Policy revised to add age limitation for use of Rydapt (midostaurin) in members 18 years of age or older; limitation of coverage added for Rydapt, as it is not indicated as a single-agent induction therapy for the treatment of patients with AML.
PARP Kinase Inhibitors – Medicare	MedD	Policy revised to reflect FDA-approved indication of Talzenna (talazoparib) for deleterious or suspected deleterious gBRCAm, HER2-negative locally advanced or metastatic breast cancer; and Talzenna (talazoparib) criteria was removed for previous treatment with chemotherapy in the neoadjuvant, adjuvant and/or metastatic setting.
PARP Kinase Inhibitors – Medicare 2020	1/1/2020	Policy revised to reflect changes effective 1/1/2020 for updated Talzenna (talazoparib) criteria in adult members with FDA-approved diagnosis.
JAK Inhibitors – Medicare	MedD	Policy revised to include expanded FDA-approved indication for Jakafi (ruxolitinib) in the treatment of steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older.
Evenity (romosozumab-aqqg) – Medicare	MedD	Policy revised to include criteria limiting members to a maximum of 12 monthly doses.
AirDuo Digihaler (fluticasone propionate and salmeterol) – Medicare	MedD	New policy created to reserve use of AirDuo Digihaler (fluticasone propionate and salmeterol) for members who have experienced an inadequate response to a non-digitized asthma combination inhaler containing an inhaled corticosteroid and a long-acting beta2-adrengergic agonist.
Brand ADHD Step Therapy – Medicare	1/1/2020	New policy created to ensure brand attention-deficit/hyperactivity disorder (ADHD) medications are used for a medically accepted indication. For the diagnosis ADHD a trial and failure of 2 of the following generic medications is required: methylphenidate, dextroamphetamine/amphetamine and atomoxetine.
Brineura (cerliponase alfa) – Medicare	MedD	Policy revised to remove requirement to be symptomatic, prescribed by or in consultation with a neurologist and that intent of treatment is to prevent loss of ambulation.
Drizamla Sprinkle (duloxetine) – Medicare	MedD	New policy created to ensure use of Drizalma Sprinkle (duloxetine) for FDA-approved indications in members who have the inability to swallow capsules.
Katerzia (amlodipine benzoate) – Medicare	MedD	New policy created for Katerzia (amlodipine benzoate) to require diagnosis of hypertension and is 6 years of age or older or diagnosis of coronary artery disease and is 18 years of age or older. Member meets one of the following: has tried and failed amlodipine besylate tablets or has an inability to swallow tablets.
Nayzilam (midazolam) – Medicare	MedD	New policy created to ensure appropriate use of Nayzilam (midazolam) in patients with acute repetitive seizures and seizure clusters who have experienced a therapeutic

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		failure, intolerance, or contraindication to diazepam rectal gel.
Polivy (polatuzumab) – Medicare	MedD	New policy created for Polivy (polatuzumab) use in combination with bendamustine and a rituximab product, in patients 18 years of age and older with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, after at least two prior therapies.
Probuphine (buprenorphine) – Medicare	8/9/2019	Archive this policy; Probuphine (buprenorphine) does not have a MedD indicator, policy is not needed.
Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) – Medicare	10/1/2019	New policy created for Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) to require a diagnosis of wild type or hereditary transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) supported by amyloid deposits in cardiac biopsy or scintigraphy with heart to contralateral > 1.5. The member is 18 years of age or older and has cardiac involvement seen by cardiac magnetic resonance, echocardiography, or serum cardiac biomarker. Immunohistochemistry, mass spectrometry, or scintigraphy has ruled out light chain amyloidosis. Reauthorization documenting disease improvement or delayed disease progression from one of the following: 6-minute walk test, cardiac function, Kansas City Cardiomyopathy Questionnaire-Overall Summary, number of cardiovascular-related hospitalizations, or serum cardiac biomarker. Authorization duration of 12 months.
Xpovio (selinexor) – Medicare	10/1/2019	New policy created to ensure appropriate use of Xpovio (selinexor) for relapsed or refractory multiple myeloma, in patients aged>18 years, in combination with dexamethasone, who have failed 5 prior agents.
Celebrex (celecoxib) Step Therapy – Medicare	1/1/2020	New policy created to ensure Celebrex (celecoxib) is used for a medically accepted indication and a trial/failure, intolerance, or contraindication to 2 generic nonsteroidal anti-inflammatory drug (NSAIDs) is required.
Chronic Inflammatory Diseases – Medicare	1/1/2020	Policy revised to make Humira (adalimumab), Enbrel (etanercept), Actemra (tocilizumab), Cosentyx (secukinumab), Xeljanz (tofacitinib), Stelara (ustekinumab), and Otezla (apremilast) all preferred products. All non-preferred products will require a double step through preferred products.
Inbrija (levodopa) – Medicare	1/12020	Policy revised to remove the requirement for members to try and fail two alternative therapies or be unable to swallow tablets. Members must be experiencing at least 2 hours of off episodes per day.
Ocrevus (ocrelizumab) – Medicare	1/1/2020	Policy revised to require attestation that members will not be using Ocrevus (ocrelizumab) in combination with another disease modifying therapy.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
2020 Benlysta (belimumab) – Medicare	TBD	Policy revised to add reauthorization criteria to ensure patients are stable or improving on therapy.

*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
Egrifta (tesamorelin) – Medicare	MedD	Policy revised to remove age restriction.
Lyrica (pregabalin) & Lyrica CR (pregabalin ER) – Medicare	MedD	Policy revised for Lyrica (pregabalin) and Lyrica CR (pregabalin ER) to try and fail generic pregabalin immediate-release if the request is for brand Lyrica or Lyrica CR.
Lyrica (pregabalin) & Lyrica CR (pregabalin ER) – Medicare 2020	1/1/2020	Policy revised for Lyrica (pregabalin) and Lyrica CR (pregabalin ER) that member must have an inability to swallow capsules to obtain Lyrica (pregabalin) oral solution. Policy revised to remove coverage of non-FDA approved indications for Lyrica CR.
Namenda (memantine) and Namzaric (memantine/donepezil) – Medicare	MedD	Policy revised to clarify FDA-approved indications and added information about Namzaric (memantine/donepezil) to background.
Combination Prescription Drug Safety – Medicare	MedD	Policy revised to correct spelling of hydrocodone and add buprenorphine buccal film and benzhydrocodone/apap under drug products, and as per CMS guidelines, add information to skeletal muscle relaxant criteria, as well as a requirement for attestation and an intent to monitor throughout the criteria. Again as per CMS guidelines, authorization duration has been added for opiate agonist with a substance abuse medication, and automatic approval criteria have been added.
Buprenorphine Step Therapy – Medicare	8/9/2019	Policy revised to clarify products included in policy as well as some formatting issue.
Buprenorphine Transdermal Patch and Buccal Film – Medicare	MedD	Policy revised as per CMS guidelines to require documentation of moderate to severe chronic pain.
Latuda (lurasidone) – Medicare	8/9/2019	Policy revised to clarify background and approval criteria. In addition, as per CMS guidelines, added that this policy applies to new starts only
Duobrii (halobetasol propionate/tazarotene) – Medicare	9/1/2019	New policy created to ensure appropriate use of Duobrii (halobetasol/tazarotene) lotion for plaque psoriasis in those have tried and failed one other generic topical corticosteroid and generic tazarotene cream.
Norgesic Forte and Orphengesic Forte (orphenadrine citrate, aspirin and caffeine) – Medicare	MedD	Policy created for Norgesic Forte and Orphengesic Forte (orphenadrine citrate, aspirin, and caffeine). Member is 12 years of age or older with mild to moderate pain of acute musculoskeletal disorder(s). The member has tried and failed orphenadrine and one other antispasmodic skeletal muscle relaxant.

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria
Qternmet XR (dapagliflozin and saxagliptin and metformin ER) – Medicare	MedD	New policy created to ensure appropriate use of Qternmet XR (dapagliflozin and saxagliptin and metformin ER) in patients with type 2 diabetes who have tried and failed a preferred metformin product and either a preferred sodium-glucose cotransporter inhibitor or a preferred dipeptidyl peptidase-4 inhibitor.
Briviact (brivaracetam) – Medicare	1/1/2020	New policy created for Briviact (brivaracetam) requiring trial and failure of two other anticonvulsants. Members requesting the oral solution must be unable to tolerate oral tablets.
Carbinoxamine 6 mg – Medicare	1/1/2020	New policy created for carbinoxamine 6 mg tablets to ensure appropriate use in members with seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods, mild, uncomplicated allergic skin manifestations of urticaria and angioedema, dermatographism, anaphylactic reactions after acute manifestations have been controlled adjunctive to epinephrine and other standard measures, or hypersensitivity reactions to blood or plasma who are 2 years of age or older. The member has experienced therapeutic failure, contraindication, or intolerance to carbinoxamine 4 mg tablets and to two (2) different antihistamines. Reauthorization criteria includes prescriber attestation that member is experiencing a positive clinical response to therapy. Authorization duration of up to 12 months.

*Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria.

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)
AirDuo Digihaler (fluticasone propionate/salmeterol)	2 inhalers per 365 days	2 inhalers per 365 days
Albuterol Sulfate HFA (albuterol sulfate)	2 inhalers	6 inhalers
Bosentan 62.5 mg, 125 mg	62 tablets	180 tablets
Cinacalcet HCL 30 mg, 60 mg	62 tablets	180 tablets
Cinacalcet HCL 90 mg	124 tablets	360 tablets
Corlanor (ivabradine) oral solution	3 cartons per 28 days	9 cartons per 84 days
Detrol 1 mg	62 tablets	180 tablets
Diclegis 10 mg-10 mg	124 tablets	360 tablets
Doxylamine Succinate-Pyridoxine HCL 10 mg-10 mg	124 tablets	360 tablets
Drizalma Sprinkle (duloxetine)	20 mg: 3 capsules per day, 30 mg: 2 capsules per day, 40 mg: 1 capsule per day, 60 mg: 1 capsule per day	20 mg: 3 capsules per day, 30 mg: 2 capsules per day, 40 mg: 1 capsule per day, 60 mg: 1 capsule per day
Duobrii (halobetasol propionate/tazarotene)	1 tube	3 tubes
Emgality (galcanezumab) 100 mg syringe	3 syringes	9 syringes
Eticovo (etanercept-ykro)	4 prefilled syringes	12 prefilled syringes
Fentanyl Citrate 100 mcg, 200 mcg	124 tablets	360 tablets
Fentanyl Citrate 400 mcg	119 tablets	346 tablets
Fentanyl Citrate 600 mcg	79 tablets	230 tablets
Fentanyl Citrate 800 mcg	59 tablets	172 tablets
Icatibant 30 mg/3 mL	18 mL per 30 days	54 mL
Ingrezza initiation pack 40 mg-80 mg	56 tablets (2 initiation packs) per 365 days	56 tablets (2 initiation packs) per 365 days
Kalydeco 25 mg	62 packets	180 packets
Katerzia (amlodipine benzoate)	2 bottles	6 bottles
Mavenclad 10 mg	40 tablets per 365 days	40 tablets per 365 days
Mayzent 0.25 mg	155 tablets	450 tablets
Lexapro (escitalopram) 10 mg tablet	1.5 tablets per day	1.5 tablets per day
Nayzilam (midazolam) nasal spray	2 spray units	6 spray units
Norgesic Forte (orphenadrine citrate/aspirin/caffeine)	4 tablets per day	4 tablets per day
Nubeqa (darolutamide)	124 tablets	360 tablets
Nucala (mepolizumab)	1 syringe	3 syringes
Orphengesic Forte (orphenadrine citrate/aspirin/caffeine)	4 tablets per day	4 tablets per day

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Piqray 200 mg/day (200 mg X 1) tablet	1 tablet per day	1 tablet per day
Piqray 250 mg/day (200 mg X 1-50 mg X 1) tablet	2 tablets per day	2 tablets per day
Piqray 300 mg/day (150 mg X 2) tablet	2 tablets per day	2 tablets per day
Pregabalin 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg	93 capsules	270 capsules
Pregabalin 225 mg, 300 mg	62 capsules	180 capsules
Pregabalin 20 mg/mL	930 mL	2700 mL
Qternmet XR (dapagliflozin/saxagliptin/ metformin ER)	1 tablet per day	1 tablet per day
Ruzurgi (amifampridine)	10 tablets per day	10 tablets per day
Sildenafil Citrate 10 mg/mL	224 mL	672 mL
solifenacin succinate 5 and 10 mg tablets	1 tablet per day	1 tablet per day
Symdeko 50 mg-75 mg	56 tablets per 28 days	168 tablets per 84 days
Thiola EC (tiopronin) 300 mg	6 tablets per day	6 tablets per day
Thiola EC (tiopronin) 100 mg	20 tablets per day	20 tablets per day
Turalio (pexidartinib)	124 capsules	124 capsules
Vyndamax (tafamidis)	1 capsule per day	1 capsule per day
Vyndaqel (tafamidis meglumine)	124 capsules	124 capsules
Xpovio (selinexor) 60 mg/week	12 tablets per 28 days	36 tablets per 84 days
Xpovio (selinexor) 80 mg/week	16 tablets per 28 days	48 tablets per 84 days
Xpovio (selinexor) 100 mg/week	20 tablets per 28 days	60 tablets per 84 days
Xpovio (selinexor) 160 mg/week	32 tablets per 28 days	96 tablets per 84 days

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