SPECIAL eBULLETIN

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OCTOBER/DECEMBER 2020; JANUARY 2021 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

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

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

HIGHMARK

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IMPORTANT DRUG SAFETY UPDATES

03/31/2021 – Studies show increased risk of heart rhythm problems with seizure and mental health medicine lamotrigine (Lamictal) in patients with heart disease. FDA now requiring studies to evaluate heart risk across the drug class.

On March 31, 2021, the FDA announced a review of study findings showed a potential increased risk of heart rhythm problems, called arrhythmias, in patients with heart disease who are taking the seizure and mental health medication lamotrigine (Lamictal). In addition, safety studies on other medicines in the same drug class are being required, and the public will be updated when additional information becomes available. Lamotrigine has been approved and on the market for more than 25 years, but in some cases, problems including chest pain, loss of consciousness, and cardiac arrest occurred. It is important to know that all medicines have side effects even when used correctly as prescribed, and people respond differently to all medicines.

Lamotrigine is used alone or with other medications to treat seizures in patients 2 years of age and older, and it may also be used as maintenance treatment in patients with the mental health condition bipolar disorder to help delay the occurrence of mood episodes such as depression, mania, or hypomania. Patients should not stop taking lamotrigine without first talking to your prescriber, as doing so can lead to uncontrolled seizures, or new or worsening mental health problems. They should contact their health care professional or go an emergency room if they experience an abnormal heart rate or irregular rhythm, or symptoms such as a racing heartbeat, skipped or slow heartbeat, shortness of breath, dizziness, or fainting. Health care professionals should assess whether the potential benefits of lamotrigine outweigh the potential risk of arrhythmias for each patient. Side effects involving lamotrigine or other medications should be reported to the FDA MedWatch program.

03/25/2021 – FDA warns that abuse and misuse of the nasal decongestant propylhexedrine causes serious harm. This includes heart and mental health problems or death.

On March 25, 2021, the FDA issued a warning that the abuse and misuse of the OTC nasal decongestant propylhexedrine, which is currently only marketed under the brand name Benzedrex, can lead to serious harm such as heart and mental problems. Complications include fast or abnormal heart rhythm, high blood pressure, and paranoia, all of which could lead to hospitalization, disability, or death. Propylhexedrine is used short term to temporarily relieve nasal congestion due to colds, hay fever, or other upper respiratory allergies and works by reducing swelling and inflammation of the mucous membrane lining of the nose. It is safe and effective when used as directed, which is two inhalations in each nostril not more often than every 2 hours for adults and children older than 6 years of age. It should not be used for more than 3 days at a time because prolonged use may cause nasal congestion to recur or worsen.

The FDA is requesting that all manufacturers of OTC propylhexedrine inhalers consider product design changes that support its safe use. Consumers should only use the product by inhalation and seek medication attention by calling 911 or poison control at 1-800-222-1222 if they experience severe anxiety or agitation, confusion, hallucinations, or paranoia; rapid heartbeat or abnormal heart rhythm; or chest pain or tightness. Health care professionals should be aware that some individuals are abusing or misusing propylhexedrine, particularly by using it by routes other than nasal inhalation,

which can result in serious cardiac and psychiatric adverse events or death. There is no specific reversal agent in cases of acute propylhexedrine intoxication, so management is symptomatic and supportive. Side effects involving propylhexedrine or other medications should be reported to the FDA MedWatch program.

10/15/2020 - FDA recommends avoiding use of NSAIDs in pregnancy at 20 weeks or later because they can result in low amniotic fluid

On October 15, 2020, the FDA issued a warning that use of NSAIDs around 20 weeks or later in pregnancy can lead to serious kidney problems in the unborn baby. NSAID are commonly used to treat pain and reduce fevers from different medication conditions such as arthritis, headaches, colds, flu, and menstrual cramps. NSAIDs include medications such as ibuprofen, naproxen, aspirin, diclofenac, and celecoxib. The FDA is requiring changes to the prescribing information to detail the risk of kidney problems that may result in low amniotic fluid. NSAIDs should be avoided at 20 weeks or later in pregnancy rather than the 30 weeks currently described in the prescribing information. If NSAID treatment is necessary, the lowest effective dose should be used. Healthcare professionals should consider ultrasound monitoring of amniotic fluid if NSAID treatment extends beyond 48 hours. Pregnant women should talk with their healthcare professionals about the benefits and risks of NSAIDs before using them. Alternative medications such as acetaminophen may be used to treat pain and fever during pregnancy. Patients should talk with their prescriber before choosing which medication is best. Adverse effects involving NSAIDs should be reported to the FDA MedWatch program.

09/24/2020 - FDA warns about serious problems with high doses of the allergy medicine diphenhydramine (Benadryl)

On September 24, 2020, the FDA issued a warning that taking higher than recommended doses of the common over-the-counter allergy medicine diphenhydramine can lead to serious heart problems, seizures, coma, or death. Diphenhydramine is an antihistamine used to temporarily relieve symptoms due to hay fever, upper respiratory allergies, or symptoms of the common cold. There have been reports of teenagers participating in a social media Benadryl challenge leading to emergency room visits or deaths. Social media networks have been contacted to remove current videos and any future videos that may be posted promoting the Benadryl challenge. The FDA recommends diphenhydramine to be stored and locked to prevent misuse by teens and accidental poisonings. Healthcare professionals should be aware of the Benadryl challenge and should alert their patients. In the cases of overdose, diphenhydramine should be suspected. Adverse effects involving diphenhydramine should be reported to the FDA MedWatch program.

09/23/2020 - FDA requiring Boxed Warning updated to improve safe use of benzodiazepine drug class

On September 23, 2020, the FDA required a Boxed Warning update to improve the safe use of benzodiazepine drug class. Benzodiazepines are widely prescribed in the United States and are used to treat conditions such as anxiety, insomnia, and seizures. The prescribing information currently did not provide adequate warnings about serious risks and harms associated with benzodiazepine use even when taken at the recommended doses. Abuse and dependence can occur when benzodiazepines are taken for several days to weeks, even when taken as prescribed. Stopping

benzodiazepines abruptly or reducing the dosage too quickly can lead to withdrawal reactions, including seizures which can be life-threatening.

The FDA is requiring the Boxed Warning and patient Medication guides to be updated describing the risks of abuse, misuse, addiction, physical dependence, and withdrawal reactions consistent with benzodiazepines. Patients on benzodiazepines should communicate with their prescriber about any over the counter medication they are taking or any substances they are using including alcohol. Patients taking benzodiazepines should not stop suddenly without planning to discuss with a healthcare professional for slowly decreasing the dose and the frequency. Healthcare professionals should decide whether the benefits of benzodiazepines outweigh the risks before prescribing the medications. Adverse effects involving benzodiazepines should be reported to the FDA MedWatch program.

NP Thyroid by Acella Pharmaceuticals: Recall – Sub Potency

On September 17th, 2020, Acella Pharmaceuticals recalled the above product. The affected product was recalled due to sub potency, or amounts of NP Thyroid less than specified.

Patients being treated for hypothyroidism (underactive thyroid), who receive sub potent NP Thyroid®, may experience signs and symptoms of hypothyroidism (underactive thyroid) which may include, fatigue, increased sensitivity to cold, constipation, dry skin, puffy face, hair loss, slow heart rate, depression, swelling of the thyroid gland and/or unexplained weight gain or difficulty losing weight. There is reasonable risk of serious injury in newborn infants or pregnant women with hypothyroidism including early miscarriage, fetal hyperthyroidism, and/or impairments to fetal neural and skeletal development. In elderly patients and patients with underlying cardiac disease toxic cardiac manifestations of hyperthyroidism may occur, such as cardiac pain, palpitations or cardiac arrhythmia. To date, Acella has received four reports of adverse events for these lot numbers possibly related to this recall.

Enoxaparin Sodium Injection 100 mg/mL and Enoxaparin Sodium Injection 150 mg/mL by Apotex Corp: Recall – Packaging Error

On February 3rd, 2020, Apotex Corp. recalled the above product. The affected product was recalled due to a packaging error that resulted in some syringe barrels containing 150 mg/mL markings (corresponding to 120 mg/0.8mL strength) instead of 100 mg/mL markings (corresponding to 100 mg/mL strength) on the syringe barrel and vice versa.

Incorrect syringe barrel marking could lead to miscalculation and inaccurate dose administration to patients. In one recalled batch (batch CS008, strength 100 mg/mL), if a consumer used a 150 mg/mL concentration packaged in a barrel corresponding to a l00 mg/mL concentration, patients could receive 3.75 mg of Enoxaparin, instead of 3 mg of Enoxaparin. In another recalled batch (batch CT003, strength 120 mg/0.8mL), if a consumer used a 100 mg/mL concentration packaged in a barrel corresponding to a 150 mg/mL concentration, patients would receive 2 mg of Enoxaparin rather than 2.5 mg of Enoxaparin. Accidental overdosage following administration of enoxaparin sodium injection may lead to bleeding complications. Alternatively, if the dose administered is less than prescribed, the patient may be subject to developing some blood clotting conditions. To date, Apotex has not received any reports of adverse events related to use of these two batches.

Sildenafil 100mg Tablets and Trazodone 100mg Tablets by AvKARE: Recall – Product Mix-up

On December 9th, 2020, AvKARE recalled the above products. The affected products were recalled due to a product mix-up of the listed two separate products inadvertently packaged together during bottling at a 3rd party facility.

Unintentional consumption of sildenafil may pose serious health risks to consumers with underlying medical issues. For example, sildenafil may interact with nitrates found in some prescription drugs (such as nitroglycerin) lowering blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, or heart disease often take nitrates. Unintended intake of trazodone may result in adverse health consequences such as somnolence/sedation, dizziness, constipation, and blurred vision. These adverse events may be more concerning in elderly patients due to a subsequent increased risk for falls and driving impairment. To date, AvKARE has not received any reports of adverse events related to this recall.

Ketorolac Tromethamine Injection, USP, 30 mg / mL, 1 mL fill in a 2 mL amber vial by Fresenius Kabi: Recall – Presence of particulate matter

On January 8th, 2021, Fresenius Kabi USA recalled the above product. The affected product was recalled due to the presence of particulate matter.

Administration of products containing particulate matter could obstruct blood vessels and result in local irritation of blood vessels, swelling at the site of injection, a mass of tissue that could become inflamed and infected, blood clots traveling to the lung, scarring of the lung tissues, and allergic reactions that could lead to life-threatening consequences. No adverse event reports have been received for the recalled lot, which was produced and sold in 2019.

Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg by Marksans Pharma Limited: Recall – Detection of N-Nitrosodimethylamine (NDMA)

On October 2nd, 2020, Marksans Pharma Limited recalled the above products. The affected products were recalled due to the detection of NDMA over the acceptable daily limit.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant found in water and foods, including meats, dairy products and vegetables. Marksans Pharma Limited has not received any reports of adverse events that have been related to this recall.

Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg by Nostrum Laboratories, Inc.: Recall – Detection of N-Nitrosodimethylamine (NDMA)

On November 2nd, 2020, January 4th, 2021, and January 25th 2021, Nostrum Laboratories, Inc. recalled the above products. The affected products were recalled due to the detection of NDMA over the acceptable daily limit.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables. Nostrum Laboratories, Inc. has not received any reports of adverse events related to this recall.

RIOMET ER™ (Metformin Hydrochloride for Extended-Release Oral Suspension), 500 mg per 5 mL by Sun Pharmaceutical Industries, Inc.: Recall – Detection of N-Nitrosodimethylamine (NDMA)

On September 23rd, 2020, Sun Pharmaceuticals recalled the above product. The affected product was recalled due to the detection of NDMA over the acceptable daily limit.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables. To date, SUN PHARMA has not received any reports of adverse events related to this recall.

Anagrelide Capsules, USP, 1 mg by Torrent Pharmaceuticals Limited: Recall – Dissolution Test Failure

On December 9th, 2020, Torrent Pharmaceuticals Limited recalled the above product. The affected product was recalled due to dissolution test failure detected during routine quality testing.

Failed dissolution can result in a slower rate and extent of drug release leading to less anagrelide available in the body. For seriously ill patients with elevated platelet counts, less available anagrelide could increase the risk of clotting (blood coagulation) and clotting or bleeding events such as a heart attack or stroke which could be life-threatening. To date, Torrent Pharmaceuticals Limited has not received any reports of adverse events related to this recall.

HIGHMARK FORMULARY UPDATE – OCTOBER AND DECEMBER 2020 – JANUARY 2021

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
- Highmark Comprehensive Healthcare Reform Formulary

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

Table 1. Products Added (All products added to the formulary effective upon completion of internal review and implementation, unless otherwise noted.)

Brand Name	Generic Name	Comments
Cystadrops ophthalmic solution	cysteamine ophthalmic solution	Corneal Cystine Crystal Deposits
Omnipod DASH	Omnipod DASH	Diabetes Mellitus
V-Go 20, V-Go 30, V-Go 40	V-Go 20, V-Go 30, V-Go 40	Diabetes Mellitus
Xtandi film-coated tablet	enzalutamide film-coated tablet	Prostate Cancer
Xeljanz oral solution	tofacitinib oral solution	Chronic Inflammatory Diseases
Cequr Simplicity (insulin delivery patch)	Cequr Simplicity (insulin delivery patch)	Diabetes Mellitus
Sutab (sodium sulfate/magnesium sulfate/potassium chloride)	Sutab (sodium sulfate/magnesium sulfate/potassium chloride)	Bowel Preparation
Xofluza (baloxavir marboxil) oral suspension	Xofluza (baloxavir marboxil) oral suspension	Influenza

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Breztri Aerosphere	budesonide/formoterol/glycopyrrolate	Trelegy Ellipta
Kesimpta	ofatumumab	dimethyl fumarate
Qdolo oral solution	tramadol oral solution	Tramadol HCL 50 mg tablet
Sogroya	somapacitan-beco	Genotropin, Humatrope, Norditropin
Winlevi	clascoterone	tretinoin cream (gram); tretinoin 0.025 % gel (gram); adapalene 0.3 % gel (gram)
Wynzora	calcipotriene/betamethasone dipriopionate	calcipotriene topical cream; calcipotriene scalp solution; betamethasone dipropionate topical cream; betamethasone dipropionate topical lotion; betamethasone dipropionate topical ointment
Xeglyze	abametapir	Malathion
Xywav	calcium/magnesium/potassium/sodium oxybates	Modafinil
Enspryng	satralizumab-mwge	Provider Discretion
Gavreto	pralsetinib	Provider Discretion
Lampit	nifurtimox	Provider Discretion
Onureg	azacitidine	Provider Discretion
Upneeq ophthalmic solution	oxymetazoline ophthalmic solution	Provider Discretion
Alkindi sprinkle oral granules	hydrocortisone oral granules	Hydrocortisone oral tablet
Bronchitol	mannitol	Sodium chloride vial, nebulizer
Eysuvis 0.25% ophthalmic suspension	loteprednol etabonate 0.25% ophthalmic suspension	Fluorometholone
Gemtesa	vibegron	oxybutynin chloride tablet; oxybutynin chloride ER, tolterodine tartrate
Impeklo	clobetasol 0.05% lotion in metered dose pump	clobetasol propionate cream (gram); clobetasol propionate gel (gram); fluocinonide 0.05% cream (gram)
Klisyri	tirbanibulin	fluorouracil cream (gram) 5%; fluorouracil solution, non-oral 2%; imiquimod cream in packet (ea) 5%
RediTrex	methotrexate	methotrexate sodium vial (ml)
Thyquidity 100 mcg/5 mL oral solution	levothyroxine sodium 100 mcg/5 mL oral solution	Levothyroxine sodium tablet, Euthyrox, Unithroid
Hetlioz LQ oral solution	tasimelteon oral solution	Provider Discretion
Imcivree	setmelanotide	Provider Discretion
Orgovyx	relugolix	Provider Discretion

Brand Name	Generic Name	Preferred Alternatives
Orladeyo	berotralstat	Provider Discretion
Zokinvy	lonafarnib	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
Cystadrops ophthalmic solution	cysteamine ophthalmic solution
Xtandi film-coated tablet	enzalutamide film-coated tablet
Enspryng	satralizumab-mwge
Gavreto	pralsetinib
Kesimpta	ofatumumab
Onureg	azacitidine
Sogroya	somapacitan-beco
Wynzora	calcipotriene/betamethasone dipriopionate
Xywav	calcium/magnesium/potassium/sodium oxybates
Xeljanz oral solution	tofacitinib oral solution
Alkindi sprinkle oral granules	hydrocortisone oral granules
Bronchitol	mannitol
Hetlioz LQ oral solution	tasimelteon oral solution
Imcivree	setmelanotide
Orgovyx	relugolix
Orladeyo	berotralstat
Zokinvy	lonafarnib

Table 4 Products to Be Removed or Shifted to Higher Tier— Effective by dates below

Brand name	Generic Name	Preferred Alternatives
Only Healthcare Reform Comprehensive products (effective October 2020)		
adapalene 0.1%	adapalene	Tretinoin, Differin gel OTC
Cimetidine	Cimetidine	Cimetidine OTC, famotidine
Diphenhydramine HCL	Diphenhydramine HCL	Diphenhydramine OTC, children's allergy relief OTC
Fexofenadine HCL	Fexofenadine HCL	Fexofenadine OTC

Brand name	Generic Name	Preferred Alternatives
Glydo	Lidocaine HCL	Pain relief with lidocaine OTC, aspercreme with lidocaine OTC
Levocarnitine	Levocarnitine (with sugar)	Levocarnitine OTC
Lidocaine 5% ointment	Lidocaine	Lidocaine 5% cream OTC, topicaine 5% gel OTC
Lidocaine 5% patch	Lidocaine	Lidocaine pain relief patch OTC, aspercreme patch OTC.
Lidocaine HCL 2% jelly	Lidocaine	Pain relief with lidocaine OTC, aspercreme with lidocaine OTC
Lidocaine HCL 3% lotion	Lidocaine	Lidocaine 3% cream OTC
Lido-K	Lidocaine	Lidocaine 3% cream OTC
Lidozion	Lidocaine	Lidocaine 3% cream OTC
Metformin HCL ER	Metformin HCL	Metformin HCL ER (generic glucophage XR)
Niacin Er	Niacin	Niacin ER OTC, slo-niacin OTC
Phenazopyridine HCL	Phenazopyridine HCL	Azo urinary pain relief OTC
Ranitidine HCL	Ranitidine HCL	Cimetidine OTC, famotidine
Only Commercial Comprehensive products (effective October 2020)		
Loprox	Ciclopirox/skin cleanser no.40	Ciclopirox
All Commercial & Healthcare Reform Comprehensive products (effective October 2020)		
Advair Diskus	Fluticasone propion/salmeterol	Fluticasone-salmeterol, Wixela Inhub
Afinitor	Everolimus	Everolimus
Apriso	Mesalamine	Mesalamine ER
Carafate	Sucralfate	Sucralfate
Daraprim	Pyrimethamine	Pyrimethamine
Depen	Penicillamine	Penicillamine
Diastat	Diazepam	Diazepam
Differin	adapalene	Tretinoin, Differin gel OTC
Dyrenium	triamterene	Triamterene
Heparin sodium in 0.45% nacl	Heparin sod, pork in 0.45% nacl	Heparin sodium in 0.45% NaCl
Lido-sorb	Lidocaine HCl	Lidocaine 3% cream OTC
Manganese sulfate	Manganese sulfate	Provider discretion
Nebupent	Pentamidine isethionate	Pentamidine isethionate
Nuvaring	Etonogestrel/ethinyl estradiol	Eluryng, etonogestrel-ethinyl estradiol
Orfadin	Nitisinone	Nitisinone
Proair HFA	albuterol sulfate	albuterol sulfate HFA
Samsca	Tolvaptan	Tolvaptan
Transderm-scop	Scopolamine	Scopolamine
Travatan z	Travoprost	Travoprost

Brand name	Generic Name	Preferred Alternatives
Only Healthcare Reform Comprehensive products (effective January 2021)		
Atripla	efavirenz/ emtricitabine/ tenofovir disoproxil fumarate	efavirenz/ emtricitabine / tenofovir disoproxil fumarate
Bidil	Isosorbide dinit/hydralazine	Isosorbide dinitrate, hydralazine HCL
Ciprodex	ciprofloxacin HCl/dexamethasone	ciprofloxacin-dexamethasone
Colcrys	Colchicine	Colchicine
Demser	Metyrosine	Metyrosine
Kaletra	Lopinavir/ritonavir	Provider Discretion
K-tab	Potassium chloride	Potassium chloride
Pancreaze	Lipase/protease/amylase	Creon, Zenpep
Truvada 200-300 mg	emtricitabine/tenofovir disoproxil	emtricitabine/tenofovir disoproxil
Tykerb	lapatinib	lapatinib
Atripla	Efavirenz/emtricit/tenofovr df	Efavirenz-emtric-tenofov disop
All Commercial & Healthcare Reform Comprehensive products (effective January 2021)		
Bidil	Isosorbide dinit/hydralazine	Isosorbide dinitrate, hydralazine HCL
Ciprodex	Ciprofloxacin hcl/dexameth	Ciprofloxacin-dexamethasone
Colcrys	Colchicine	Colchicine
Demser	Metyrosine	Metyrosine
Kaletra	Lopinavir/ritonavir	provider discretion
K-tab	Potassium chloride	Potassium chloride
Truvada 200-300 mg	emtricitabine/tenofovir disoproxil	emtricitabine/tenofovir disoproxil
Tykerb	Lapatinib ditosylate	Lapatinib

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
- Highmark Healthcare Reform Progressive Formulary

Table 1. Formulary Updates (All products added to the formulary effective upon completion of internal review and implementation, unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below are preferred products			
Omnipod DASH	Omnipod DASH	2 - Preferred Brand	Diabetes Mellitus
V-Go 20, V-Go 30, V-Go 40	V-Go 20, V-Go 30, V-Go 40	2 - Preferred Brand	Diabetes Mellitus
Cystadrops ophthalmic solution	cysteamine ophthalmic solution	3 - Preferred Specialty	Corneal Cystine Crystal Deposits
Xtandi film-coated tablet	enzalutamide film-coated tablet	3 - Preferred Specialty	Prostate Cancer
Xeljanz oral solution	tofacitinib oral solution	3 – Preferred Specialty	Chronic Inflammatory Diseases
Cequr Simplicity	insulin delivery patch	2 - Preferred Brand	Diabetes Mellitus
Sutab	sodium sulfate/magnesium sulfate/potassium chloride	2 - Preferred Brand	Bowel Preparation
Xofluza oral suspension	baloxavir marboxil oral suspension	2 - Preferred Brand	Influenza
Items listed below are non-preferred products			
Breztri Aerosphere	budesonide/formoterol/glycopyrrolate	3 - Nonpreferred Brand	Trelegy Ellipta
Qdolo oral solution	tramadol oral solution	3 - Nonpreferred Brand	Tramadol HCL 50 mg tablet
Winlevi	clascoterone	3 - Nonpreferred Brand	tretinoin cream (gram); tretinoin 0.025 % gel (gram); adapalene 0.3 % gel (gram)
Xeglyze	abametapir	3 - Nonpreferred Brand	Spinosad
Kesimpta	ofatumumab	4 - Nonpreferred Specialty	dimethyl fumarate
Sogroya	somapacitan-beco	4 - Nonpreferred Specialty	Genotropin, Humatrope, Norditropin
Wynzora	calcipotriene/betamethasone dipriopionate	4 - Nonpreferred Specialty	calcipotriene scalp solution; betamethasone dipropionate topical cream; betamethasone dipropionate topical lotion; betamethasone dipropionate topical ointment
Xywav	calcium/magnesium/potassium/sodium oxybates	4 - Nonpreferred Specialty	Modafinil; Armodafinil
Lampit	nifurtimox	3 - Nonpreferred Brand	Provider Discretion

Upneeq ophthalmic solution	oxymetazoline ophthalmic solution	3 - Nonpreferred Brand	Provider Discretion
Enspryng	satralizumab-mwge	4 - Nonpreferred Specialty	Provider Discretion
Gavreto	pralsetinib	4 - Nonpreferred Specialty	Provider Discretion
Onureg	azacitidine	4 - Nonpreferred Specialty	Provider Discretion
Eysuvis 0.25% ophthalmic suspension	loteprednol etabonate 0.25% ophthalmic suspension	3 - Nonpreferred Brand	fluorometholone
Alkindi sprinkle oral granules	hydrocortisone oral granules	4 - Nonpreferred Specialty	hydrocortisone oral tablet
Bronchitol	mannitol	4 - Nonpreferred Specialty	Sodium chloride vial, nebulizer
Gemtesa	vibegron	3 - Nonpreferred Brand	oxybutynin chloride tablet; oxybutynin chloride ER, tolterodine tartrate
Impeklo	clobetasol 0.05% lotion in metered dose pump	3 - Nonpreferred Brand	clobetasol propionate cream (gram); clobetasol propionate gel (gram); fluocinonide 0.05% cream (gram)
Klisyri	tirbanibulin	3 - Nonpreferred Brand	fluorouracil cream (gram) 5%; fluorouracil solution, non-oral 2%; imiquimod cream in packet (ea) 5%
RediTrex	methotrexate	3 - Nonpreferred Brand	methotrexate sodium vial
Thyquidity 100 mcg/5 mL oral solution	levothyroxine sodium 100 mcg/5 mL oral solution	3 - Nonpreferred Brand	Levothyroxine sodium tablet, Euthyrox, Unithroid
Hetlioz LQ oral solution	tasimelteon oral solution	4 - Nonpreferred Specialty	Provider Discretion
Imcivree	setmelanotide	4 - Nonpreferred Specialty	Provider Discretion
Orgovyx	relugolix	4 - Nonpreferred Specialty	Provider Discretion
Orladeyo	berotralstat	4 - Nonpreferred Specialty	Provider Discretion
Zokinvy	lonafarnib	4 - Nonpreferred Specialty	Provider Discretion

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
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 by January 2021

Brand Name	Generic Name	Preferred Alternatives
Only Healthcare Reform Progressive products		
adapalene 1%	Adapalene	Tretinoin,differin gel OTC
Apriso	Mesalamine	Mesalamine ER
Benzepro	Benzoyl peroxide	Benzoyl peroxide OTC
Benzoyl peroxide	Benzoyl peroxide	Benzoyl peroxide OTC
BPO	Benzoyl peroxide	Benzoyl peroxide OTC
Cimetidine	Cimetidine	Cimetidine OTC, famotidine
Clotrimazole	Clotrimazole	Lotrimin AF OTC, clotrimazole OTC
Depen	Penicillamine	Penicillamine
Diclofenac sodium	Diclofenac sodium	Fluorouracil
Diphenhydramine hcl	Diphenhydramine HCL	Diphenhydramine OTC,children's allergy relief OTC
Glydo	Lidocaine HCL	Pain relief with lidocaine OTC, aspercreme with lidocaine OTC
Levocarnitine	Levocarnitine(with sugar)	Levocarnitine OTC
Levocetirizine dihydrochloride	Levocetirizine dihydrochloride	Xyzal OTC
Lidocaine 5% ointment	Lidocaine	Lidocaine 5% cream OTC, topicaine 5% gel OTC
Lidocaine HCL 2% jel urojet AC	Lidocaine	Pain relief with lidocaine OTC, aspercreme with lidocaine OTC
Lidocaine HCL 2% jelly	Lidocaine	Pain relief with lidocaine OTC, aspercreme with lidocaine OTC
Lidocaine HCL 3% lotion	Lidocaine	Lidocaine 3% cream OTC
Lido-k	Lidocaine HCL	Lidocaine 3% cream OTC
Lido-sorb	Lidocaine HCL	Lidocaine 3% cream OTC
Lidozion	Lidocaine HCL	Lidocaine 3% cream OTC
Loperamide HCL	Loperamide HCL	Imodium a-d OTC, loperamide HCL OTC
Metformin HCL ER	Metformin HCL	Metformin HCL ER (generic glucophage XR)
Nebupent	Pentamidine isethionate	Pentamidine isethionate
Niacin ER	Niacin	Niacin ER OTC, slo-niacin OTC
Omeppi	Omeprazole/sodium bicarbonate	Zegerid OTC
Orphenadrine-aspirin-caffeine	Orphenadrine/aspirin/caffeine	Chlorzoxazone, cyclobenzaprine HCL
Phenazopyridine HCL	Phenazopyridine HCL	Azo urinary pain relief OTC
Pseudoephedrine HCL	Pseudoephedrine HCL	Pseudoephedrine HCL OTC
Ranitidine HCL	Ranitidine HCL	Cimetidine OTC, famotidine
Samsca	Tolvaptan	Tolvaptan
Transderm-scop	Scopolamine	Scopolamine
Atripla	efavirenz/emtricitabine/tenofovir disoproxil	efavirenz/emtricitabine/tenofovir disoproxil

Brand Name	Generic Name	Preferred Alternatives
Colcrys	Colchicine	Colchicine
Kuvan	Sapropterin dihydrochloride	Sapropterin dihydrochloride
Truvada 200-300 mg	emtricitabine/tenofovir disoproxil	emtricitabine/tenofovir disoproxil
Tykerb	Lapatinib ditosylate	Lapatinib

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 here.

Table 1. Formulary Updates
(All formulary effective upon completion of internal review and implementation unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Omnipod DASH	Omnipod DASH	3	Diabetes Mellitus
V-Go 20, V-Go 30, V-Go 40	V-Go 20, V-Go 30, V-Go 40	3	Diabetes Mellitus
Cystadrops ophthalmic solution	cysteamine ophthalmic solution	4	Corneal Cystine Crystal Deposits
Xtandi film-coated tablet	enzalutamide film-coated tablet	4	Prostate Cancer
Xeljanz oral solution	tofacitinib oral solution	4	Chronic Inflammatory Diseases
Cequr Simplicity	insulin delivery patch	3	Diabetes Mellitus
Sutab	sodium sulfate/magnesium sulfate/potassium chloride	3	Bowel Preparation
Xofluza oral suspension	baloxavir marboxil oral suspension	3	Influenza
Items listed below were not added to the formulary			
Breztri	budesonide/formoterol/glycopyrrolate	NF	Trelegy Ellipta
Kesimpta	ofatumumab	NF	dimethyl fumarate
Qdolo oral solution	tramadol oral solution	NF	Tramadol HCL 50 mg tablet
Sogroya	somapacitan-beco	NF	Genotropin, Humatrope, Norditropin

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Winlevi	clascoterone	NF	tretinoin cream (gram); tretinoin 0.025 % gel (gram); adapalene 0.3 % gel (gram)
Wynzora	calcipotriene/betamethasone dipriopionate	NF	betamethasone dipropionate topical cream; betamethasone dipropionate topical lotion; betamethasone dipropionate topical ointment
Xeglyze	abametapir	NF	Malathion; Spinosad
Xywav	calcium/magnesium/potassium/sodium oxybates	NF	Modafinil; Armodafinil
Enspryng	satralizumab-mwge	NF	Provider Discretion
Gavreto	pralsetinib	NF	Provider Discretion
Lampit	nifurtimox	NF	Provider Discretion
Onureg	azacitidine	NF	Provider Discretion
Upneeq ophthalmic solution	oxymetazoline ophthalmic solution	NF	Provider Discretion
Alkindi sprinkle oral granules	hydrocortisone oral granules	NF	hydrocortisone oral tablet
Bronchitol	mannitol	NF	Sodium chloride vial, nebulizer
Eysuvis 0.25% ophthalmic suspension	loteprednol etabonate 0.25% ophthalmic suspension	NF	fluorometholone
Gemtesa	vibegron	NF	oxybutynin chloride tablet; oxybutynin chloride ER, tolterodine tartrate
Impeklo	clobetasol 0.05% lotion in metered dose pump	NF	clobetasol propionate cream (gram); clobetasol propionate gel (gram); fluocinonide 0.05% cream (gram)
Klisyri	tirbanibulin	NF	fluorouracil cream (gram) 5%; fluorouracil solution, non-oral 2%; imiquimod cream in packet (ea) 5%
RediTrex	methotrexate	NF	methotrexate sodium vial (ml)
Thyquidity 100 mcg/5 mL oral solution	levothyroxine sodium 100 mcg/5 mL oral solution	NF	Levothyroxine tablet, Euthyrox, Unithroid
Hetlioz LQ oral solution	tasimelteon oral solution	NF	Provider Discretion
Imcivree	setmelanotide	NF	Provider Discretion
Orgovyx	relugolix	NF	Provider Discretion
Orladeyo	berotralstat	NF	Provider Discretion
Zokinvy	lonafarnib	NF	Provider Discretion

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

Table 2. Products to Be Removed or Shifted to Higher Tier – Effective by January 2021

Brand Name	Generic Name	Preferred Alternatives
All Healthcare Reform Essential Products		
Afinitor	Everolimus	Everolimus
Daraprim	Pyrimethamine	Pyrimethamine
Diastat	Diazepam	Diazepam
Dyrenium	Triamterene	Triamterene
Halog	Halcinonide	Halcinonide
Moxeza	Moxifloxacin HCL	Moxifloxacin HCL
Naftin	Naftifine HCL	Naftifine HCL
Nebupent	Pentamidine isethionate	Pentamidine isethionate
Noxafil	Posaconazole	Posaconazole
Nuvaring	Etonogestrel/ethinyl estradiol	Eluryng, etonogestrel-ethinyl estradiol
Orfadin	Nitisinone	Nitisinone
Samsca	Tolvaptan	Tolvaptan
Taclonex	Calcipotriene/betamethasone	Calcipotriene-betamethasone
Transderm-scop	Scopolamine	Scopolamine
Travatan z	Travoprost	Travoprost
Zortress	Everolimus	Everolimus
Atripla	efavirenz/emtricitabine/tenofovir disoproxil	Efavirenz/emtricitabine/tenofovir disoproxil
Ciprodex	Ciprofloxacin hcl/dexameth	Ciprofloxacin-dexamethasone
Kaletra	Lopinavir/ritonavir	provider discretion
K-tab	Potassium chloride	Potassium chloride
Kuvan	Sapropterin dihydrochloride	Sapropterin dihydrochloride
Moviprep	PEG3350/sodium sulfate/NaCl/KCl/sodium ascorbate/ ascorbic acid	PEG3350/sodium sulfate/NaCl/KCl/sodium ascorbate/ ascorbic acid
Noxafil	Posaconazole	Posaconazole
Pepcid AC	Famotidine	Famotidine
Truvada 200-300 mg	emtricitabine/tenofovir disoproxil	emtricitabine/tenofovir disoproxil
Tykerb	Lapatinib ditosylate	Lapatinib

D. Changes to the Highmark Core Formulary

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

Table 1. Formulary Updates
(All formulary changes effective upon completion of internal review and implementation, unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Omnipod DASH	Omnipod DASH	3	Diabetes Mellitus
V-Go 20, V-Go 30, V-Go 40	V-Go 20, V-Go 30, V-Go 40	3	Diabetes Mellitus
Cystadrops ophthalmic solution	cysteamine ophthalmic solution	4	Corneal Cystine Crystal Deposits
Xtandi film-coated tablet	enzalutamide film-coated tablet	4	Prostate Cancer
Xeljanz oral solution	tofacitinib oral solution	4	Chronic Inflammatory Diseases
Cequr Simplicity	insulin delivery patch	3	Diabetes Mellitus
Sutab	sodium sulfate/magnesium sulfate/potassium chloride	3	Bowel Preparation
Xofluza oral suspension	baloxavir marboxil oral suspension	3	Influenza
Items listed below were not added to the formulary			
Breztri	budesonide/formoterol/glycopyrrolate	NF	Trelegy Ellipta
Kesimpta	ofatumumab	NF	dimethyl fumarate
Qdolo oral solution	tramadol oral solution	NF	Tramadol HCL 50 mg tablet
Sogroya	somapacitan-beco	NF	Humatrope, Norditropin
Winlevi	clascoterone	NF	tretinoin cream (gram); tretinoin 0.025 % gel (gram); adapalene 0.3 % gel (gram)
Wynzora	calcipotriene/betamethasone dipriopionate	NF	betamethasone dipropionate topical cream; betamethasone dipropionate topical lotion
Xeglyze	abametapir	NF	Malathion; Spinosad
Xywav	calcium/magnesium/potassium/sodium oxybates	NF	Modafinil
Enspryng	satralizumab-mwge	NF	Provider Discretion
Gavreto	pralsetinib	NF	Provider Discretion
Lampit	nifurtimox	NF	Provider Discretion
Onureg	azacitidine	NF	Provider Discretion
Upneeq ophthalmic solution	oxymetazoline ophthalmic solution	NF	Provider Discretion
Alkindi sprinkle oral granules	hydrocortisone oral granules	NF	hydrocortisone oral tablet
Bronchitol	mannitol	NF	Sodium chloride vial, nebulizer

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Eysuvis 0.25% ophthalmic suspension	loteprednol etabonate 0.25% ophthalmic suspension	NF	fluorometholone
Gemtesa	vibegron	NF	oxybutynin chloride tablet; oxybutynin chloride ER, tolterodine tartrate
Impeklo	clobetasol 0.05% lotion in metered dose pump	NF	clobetasol propionate cream (gram); clobetasol propionate gel (gram); fluocinonide 0.05% cream (gram)
Klisyri	tirbanibulin	NF	fluorouracil cream (gram) 5%; fluorouracil solution, non-oral 2%; imiquimod cream in packet (ea) 5%
Orladeyo	berotralstat	NF	Takhzyro
RediTrex	methotrexate	NF	methotrexate sodium vial (ml)
Thyquidity 100 mcg/5 mL oral solution	levothyroxine sodium 100 mcg/5 mL oral solution	NF	Levothyroxine sodium tablet, Euthyrox, Unithroid
Hetlioz LQ oral solution	tasimelteon oral solution	NF	Provider Discretion
Imcivree	setmelanotide	NF	Provider Discretion
Orgovyx	relugolix	NF	Provider Discretion
Zokinvy	lonafarnib	NF	Provider Discretion

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

Table 2. Products to Be Removed or Shifted to Higher Tier – Effective by January 2021

Brand Name	Generic Name	Preferred Alternatives
All Core Products		
Adapalene	Adapalene	Tretinoin, differin gel OTC
Afinitor	Everolimus	Everolimus
Apriso	Mesalamine	Mesalamine ER
Bacitracin/polymyxin	Bacitracin zinc/polymyxin b	Bacitracin/polymyxin OTC
Poly bacitracin	Bacitracin zinc/polymyxin b	Bacitracin/polymyxin OTC
Depen	Penicillamine	Penicillamine
Kenalog	Triamcinolone acetonide	Triamcinolone acetonide
Lido-sorb	Lidocaine HCL	Lidocaine 3% cream OTC
Nebupent	Pentamidine isethionate	Pentamidine isethionate
Nuvaring	Etonogestrel/ethinyl estradiol	Eluryng, etonogestrel-ethinyl estradiol
Orphenadrine-aspirin-caffeine	Orphenadrine/aspirin/caffeine	Chlorzoxazone, cyclobenzaprine HCL
Proglycem	Diazoxide	Diazoxide
Samsca	Tolvaptan	Tolvaptan

Silvadene	Silver sulfadiazine	Silver sulfadiazine
Tazorac	Tazarotene	Tazarotene
Zortress	Everolimus	Everolimus
Atripla	efavirenz/emtricitabine/tenofovir disoproxil	efavirenz/emtricitabine/tenofovir disoproxil
Cytomel	Liothyronine sodium	Liothyronine sodium
Dilantin	Phenytoin	Phenytoin
Kaletra	Lopinavir/ritonavir	provider discretion
K-tab	Potassium chloride	Potassium chloride
Kuvan	Sapropterin dihydrochloride	Sapropterin dihydrochloride
Moviprep	PEG3350/sodium sulfate/NaCl/KCl/sodium ascorbate/ ascorbic acid	PEG3350/sodium sulfate/NaCl/KCl/sodium ascorbate/ ascorbic acid
Noxafil	Posaconazole	Posaconazole
Truvada 200-300 mg	emtricitabine/tenofovir disoproxil	emtricitabine/tenofovir disoproxil
Tykerb	Lapatinib	Lapatinib
Venlafaxine HCL ER tablet	Venlafaxine HCL	Venlafaxine HCL ER capsule
WP thyroid	Thyroid,pork	Nature-throid

E. Changes to the Highmark National Select Formulary

The National Select Formulary is an incentive formulary with a non-formulary drug list to manage products in therapeutic categories for which preferred alternatives are available. The National Select Formulary is available for select Commercial self-funded (ASO) plans. A list of drugs included on the National Select Formulary, listed by therapeutic class, is available here.

Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (preferred)			
Breztri Aerosphere	budesonide/formoterol/glycopyrrolate	2	Chronic obstructive pulmonary disease (COPD)
Enspryng	satralizumab-mwge	2	neuromyelitis optica spectrum disorder (NMOSD)
Omnipod DASH	Omnipod DASH	2	Diabetes Mellitus
V-Go 20, V-Go 30, V-Go 40	V-Go 20, V-Go 30, V-Go 40	2	Diabetes Mellitus
Xtandi film-coated tablet	enzalutamide film-coated tablet	2	Prostate Cancer
Xeljanz oral solution	tofacitinib oral solution	2	Chronic Inflammatory Diseases

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Xywav	calcium/magnesium/potassium/sodium oxybates	2	Narcolepsy
Gavreto	pralsetinib	2	Non-small cell lung cancer (NSCLC); Thyroid cancer
Kesimpta	ofatumumab	2	Multiple Sclerosis
Items listed below were added to the formulary (non-preferred)			
Eysuvis 0.25% ophthalmic suspension	loteprednol etabonate 0.25% ophthalmic suspension	3	loteprednol etabonate
Bronchitol	mannitol	3	Provider Discretion
Cequr Simplicity (insulin delivery patch)	Cequr Simplicity (insulin delivery patch)	3	Provider Discretion
Imcivree	setmelanotide	3	Provider Discretion
Orladeyo	berotralstat	3	Takhzyro
Xofluza (baloxavir marboxil) oral suspension	Xofluza (baloxavir marboxil) oral suspension	3	oseltamivir
Zokinvy	lonafarnib	3	Provider Discretion
Hetlioz LQ oral solution	tasimelteon oral solution	3	Provider Discretion
Xeglyze	abametapir	3	Provider Discretion
Sogroya	somapacitan-beco	3	Genotropin, Norditropin Flexpro
Gemtesa	vibegron	3	oxybutynin chloride ER, tolterodine tartrate ER, Myrbetriq
Items listed below were not added to the formulary			
Lampit	nifurtimox	NF	benznidazole
Onureg	azacitidine	NF	Provider discretion
Upneeq ophthalmic solution	oxymetazoline ophthalmic solution	NF	Provider discretion
Impeklo	clobetasol 0.05% lotion in metered dose pump	NF	clobetasol propionate, fluocinonide, betamethasone dipropionate
Orgovyx	relugolix	NF	Eligard, Firmagon
Sutab (sodium sulfate/magnesium sulfate/potassium chloride)	Sutab (sodium sulfate/magnesium sulfate/potassium chloride)	NF	PEG 3350-electrolyte, PEG3350-SOD SUL-NaCl-KCl-ASB-C
Thyquidity 100 mcg/5	levothyroxine sodium 100 mcg/5 mL oral solution	NF	levothyroxine sodium, Euthyrox, Unithroid

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
mL oral solution			
Wynzora	calcipotriene/betamethasone dipriopionate	NF	calcipotriene-betamethasone, Enstilar
Winlevi	clascoterone	NF	clindamycin phosphate, erythromycin, Amzeeq
Qdolo	tramadol oral solution	NF	tramadol tablet
Alkindi Sprinkle	hydrocortisone oral granules	NF	hydrocortisone tablet
Reditrex	methotrexate	NF	Rasuvo
Klisyri	tirbanibulin	NF	fluorouracil, imiquimod, Picato
Cystadrops ophthalmic solution	cysteamine ophthalmic solution	NF	Cystaran

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

Table 2. Additions to the Specialty Tier Copay Option
(Effective upon completion of internal review and implementation unless otherwise noted.)

Brand Name	Generic Name
Cystadrops ophthalmic solution	cysteamine ophthalmic solution
Xtandi film-coated tablet	enzalutamide film-coated tablet
Enspryng	satralizumab-mwge
Gavreto	pralsetinib
Kesimpta	ofatumumab
Onureg	azacitidine
Sogroya	somapacitan-beco
Wynzora	calcipotriene/betamethasone dipriopionate
Xywav	calcium/magnesium/potassium/sodium oxybates
Xeljanz oral solution	tofacitinib oral solution
Alkindi sprinkle oral granules	hydrocortisone oral granules
Bronchitol	mannitol
Hetlioz LQ oral solution	tasimelteon oral solution
Imcivree	setmelanotide
Orgovyx	relugolix
Orladeyo	berotralstat
Zokinvy	lonafarnib

Table 3. Products to Be Removed or Shifted to Higher Tier – Effective by January 2021

Brand Name	Generic Name	Preferred Alternatives
All National Select Products		
Acanya	Clindamycin phos/benzoyl perox	Clindamycin-benzoyl peroxide

Aggrenox	Aspirin/dipyridamole	Aspirin-dipyridamole ER
Airduo Respiclick	Fluticasone propion/salmeterol	Wixela Inhub, Advair HFA
Amitiza	Lubiprostone	Linzess, Trulance
Androgel	Testosterone	Testosterone
Aptiom	Eslicarbazepine acetate	Vimpat, oxcarbazepine
Atralin	Tretinoin	Tretinoin
Avastin	Bevacizumab	Provider discretion
Aveed	Testosterone undecanoate	Provider discretion
Bunavail	Buprenorphine HCL/naloxone HCL	buprenorphine-naloxone, Zubsolv
Calquence	Acalabrutinib	Imbruvica, Venclexta
Carac	Fluorouracil	Picato
Ciloxan	Ciprofloxacin HCL	Ciprofloxacin HCL, ofloxacin
Clindagel	Clindamycin phosphate	Clindamycin phosphate, Amzeeq
Clindamycin phosphate	Clindamycin phosphate	Clindamycin phosphate, Amzeeq
Concerta	Methylphenidate HCL	Methylphenidate ER
Cosentyx 150mg	Secukinumab	Taltz, Humira
Cosentyx 300mg	Secukinumab	Taltz, Humira
Crinone	Progesterone, micronized	Endometrin
Cutaquig	Immun glob g(igg)-hipp/maltose	Provider discretion
Doral	Quazepam	Quazepam
Duragesic	Fentanyl	Fentanyl
Ecoza	Econazole nitrate	Econazole nitrate, ketoconazole
Elelyso	Taliglucerase alfa	Provider discretion
Elestrin	Estradiol	Divigel
Epiduo	Adapalene/benzoyl peroxide	Adapalene-benzoyl peroxide
Epiduo forte	Adapalene/benzoyl peroxide	Adapalene-benzoyl peroxide
Estrace	Estradiol	Estradiol
Estrostep FE	Norethindrone-e.estradiol-iron	Tri-legest FE
Firazyr	Icatibant acetate	Icatibant
Firdapse	Amifampridine phosphate	Ruzurgi
Firvanq	Vancomycin HCL	Vancomycin HCL
Fluticasone-salmeterol	Fluticasone propion/salmeterol	Wixela Inhub, Advair HFA
Gammaked	Immune globul g/gly/iga avg 46	Provider discretion
Generess FE	Noreth-ethinyl estradiol/iron	Norethin-eth estra ferrous fum
Herceptin	Trastuzumab	Provider discretion
Herceptin Hylecta	Trastuzumab-hyaluronidase-oysk	Provider discretion
Hizentra	Immun glob g(igg)/pro/iga 0-50	Provider discretion

Inderal XL	Propranolol HCL	Propranolol HCL ER
Innopran XL	Propranolol HCL	Propranolol HCL ER
Intrarosa	Prasterone (dhea)	Estring, premarin
Jentadueto	Linagliptin/metformin HCL	Janumet
Jentadueto XR	Linagliptin/metformin HCL	Janumet XR
Kevzara	Sarilumab	Actemra, humira
Korlym	Mifepristone	Lysodren, signifor
Lastacaft	Alcaftadine	Zerviate
Letairis	Ambrisentan	Ambrisentan
Lialda	Mesalamine	Mesalamine
Locoid	Hydrocortisone butyrate	Hydrocortisone butyrate
Locoid lipocream	Hydrocortisone butyrate/emoll	Hydrocortisone butyrate
LoSeasonique	L-norgest/e.estradiol-e.estrad	Camrese Lo
Lotronex	Alosetron HCL	Alosetron HCL
Mestinon	Pyridostigmine bromide	Pyridostigmine bromide
Minivelle	Estradiol	Estradiol
Mircette	Desog-e.estradiol/e.estradiol	Desogestr-eth estrad eth estra
Moviprep	PEG3350/sodium sulfate/NaCl/KCl/sodium ascorbate/ ascorbic acid	PEG3350/sodium sulfate/NaCl/KCl/sodium ascorbate/ ascorbic acid
Mytesi	Crofelemer	Diphenoxylate w/atropine, loperamide
Natroba	Spinosad	Spinosad
Neulasta	Pegfilgrastim	Fulphila, Ziextenzo
Nexium Rx	Esomeprazole magnesium	Esomeprazole magnesium
Noxafil	Posaconazole	Posaconazole
Nucynta	Tapentadol HCL	Tramadol HCL
Ogivri	Trastuzumab-dkst	Provider discretion
Osmoprep	Sod phosphate mbas/sod phos,di	Prepopik, Suprep
Otrexup	Methotrexate/pf	Rasuvo
Pazeo	Olopatadine HCL	Zerviate
Percocet	Oxycodone hcl/acetaminophen	Oxycodone w/acetaminophen
Pregenna	Pnv no.163/iron/folate no.10	Prenatal plus, Preplus
Primlev	Oxycodone HCL/acetaminophen	Prolate
Proair HFA	Albuterol sulfate	Albuterol sulfate HFA
Proair respiclick	Albuterol sulfate	Albuterol sulfate HFA
Proctofoam-hc	Hydrocortisone/pramoxine	Hc pramoxine, pramoxine HCL w/hydrocortisone
Procysbi	Cysteamine bitartrate	Cystagon
Pylera	Bismuth/metronid/tetracycline	Lansoprazol-amoxicil-clarithro, talicia
Qtern	Dapagliflozin/saxagliptin HCL	Glyxambi, Steglujan

Quartette	L-norgest/e.estradiol-e.estrad	Rivelsa
Quazepam	Quazepam	Quazepam
Ranexa	Ranolazine	Ranolazine ER
Retin-A micro	Tretinoin microspheres	Tretinoin microsphere
Retin-A micro pump	Tretinoin microspheres	Tretinoin microsphere
Rituxan	Rituximab	Provider discretion
Rituxan hycela	Rituximab/hyaluronidase,human	Provider discretion
Rozerem	Ramelteon	Ramelteon
Safyral	Drospir/eth estra/levomefolca	Drospirenone-eth estra-levomef
Seasonique	L-norgest/e.estradiol-e.estrad	Camrese
Sensipar	Cinacalcet HCL	Cinacalcet HCL
Targretin	Bexarotene	Bexarotene
Tavalisse	Fostamatinib disodium	Doptelet, promacta
Tazorac	Tazarotene	Tazarotene
Tekturna	Aliskiren hemifumarate	Aliskiren
Toprol XL	Metoprolol succinate	Metoprolol succinate
Tradjenta	Linagliptin	Januvia
Transderm-scop	Scopolamine	Scopolamine
Travatan Z	Travoprost	Travoprost
Trelstar	Triptorelin pamoate	Provider discretion
Treximet	Sumatriptan succ/naproxen sod	Sumatriptan succ-naproxen sod
Trinaz	Pnv no.162/iron glu/folic acid	Prenatal plus, preplus
Truxima	Rituximab-abbs	Provider discretion
Udenyca	Pegfilgrastim-cbqv	Fulphila, ziextenzo
Uloric	Febuxostat	Febuxostat
Vanos	Fluocinonide	Fluocinonide
Ventolin HFA	Albuterol sulfate	Albuterol sulfate HFA
Vesicare	Solifenacin succinate	Solifenacin succinate
Welchol	Colesevelam HCL	Colesevelam HCL
Wellbutrin XL	Bupropion HCL	Bupropion HCL XL
Ximino	Minocycline HCL	Minocycline HCL ER
Xolegel	Ketoconazole	Econazole nitrate, ketoconazole
Zelapar	Selegiline HCL	Rasagiline mesylate, selegiline HCL
Zohydro ER	Hydrocodone bitartrate	Hydrocodone bitartrate
Zovirax	Acyclovir	Acyclovir
Only Tier Changes		
Alrex	Loteprednol etabonate	Zerviate
Bepreve	Bepotastine besilate	Zerviate
First-lansoprazole	Lansoprazole	Lansoprazole, esomprazole magnesium
First-mouthwash blm	Mag&al/sim/diphenhyd/lidocaine	Provider discretion

First-omeprazole	Omeprazole	Lansoprazole, esomeprazole magnesium
Ilevro	Nepafenac	Bromfenac sodium
Oracea	Doxycycline monohydrate	Doxycycline monohydrate
Privigen	Immun glob g(igg)/pro/iga 0-50	Gammagaro liquid
Prolensa	Bromfenac sodium	Bromfenac sodium
Qbrexza	Glycopyrronium tosylate	Certain dri OTC

F. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors – Commercial and Healthcare Reform	10/20/2020	Policy revised for Nexletol (bempedoic acid) and Nexlizet (bempedoic acid/ezetimibe) to include statin intolerance criteria that is supported by skeletal muscle symptoms or increase in lab values (creatinine kinase, liver function tests), or hospitalization.
Anti Obesity - Commercial and Healthcare Reform	10/20/2020	Policy revised to remove Belviq (lorcaserin) and Belviq XR (lorcaserin extended-release).
Anti-Angiogenesis and VEGF Kinase Inhibitors - Commercial and Healthcare Reform	10/20/2020	Policy revised for Lenvima (lenvatinib) in combination with pembrolizumab for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.
Arakoda and Krintafel (tafenoquine) - Commercial and Healthcare Reform	10/21/2020	Policy revised to include contraindication in breastfeeding for some patients under Limitations of Coverage
CaroSpir (spironolactone) - Commercial and Healthcare Reform	10/22/2020	Policy revised to require heart failure "with reduced ejection fraction."
CFTR Modulators - Commercial and Healthcare Reform	10/26/2020	Policy revised to change minimum patient age requirement for Kalydeco (ivacaftor) from 6 months of age to 4 months of age.
Chronic Inflammatory Diseases - Commercial and Healthcare Reform	10/14/2020	Policy revised to include expanded indication for Stelara (ustekinumab) for the treatment of patients 6 years of age or

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		older (instead of 12 years of age or older) with moderate to severe plaque psoriasis.
Cystadrops and Cystaran (cysteamine ophthalmic solution) - Commercial and Healthcare Reform	11/27/2020	New policy created for Cystadrops and Cystaran (cysteamine ophthalmic solution) to require diagnosis of cystinosis and prescriber attestation that corneal cystine crystals have accumulated.
Diclofenac Containing Products - Commercial and Healthcare Reform	10/26/2020	Policy revised to require an age edit of 18 years and older for Pennsaid (diclofenac sodium) and Zorvolex (diclofenac), specified prescription for the generic diclofenac gel requirement. Policy revised to include Benefits in header. Policy revised to include reauthorization criteria for a diclofenac-containing product.
Drugs for Chagas Disease - Commercial and Healthcare Reform	11/27/2020	Policy revised to include a new medication, Lampit (nifurtimox). Member must be between the ages of birth to less than 18 years of age, weigh at least 2.5 kg, and have a diagnosis of Chagas Disease. Name of policy also revised to reflect more than one medication in policy.
Elidel (pimecrolimus) and Protopic (tacrolimus) - Commercial	10/26/2020	Policy revised to include age requirement for Elidel (pimecrolimus), Protopic (tacrolimus) ointment 0.03%, and Protopic (tacrolimus) ointment 0.1% and step through generic topical tacrolimus or pimecrolimus.
Enspryng (satralizumab-mwge) - Commercial and Healthcare Reform	10/26/2020	New policy created for Enspryng (satralizumab-mwge) requiring age of 18 years or older, a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) anti-aquaporin-4 (AQP4) antibody positive, prescribed in consultation with a neurologist, and documentation of baseline NMOSD relapses. Reauthorization criteria for prescriber to attest the member has experienced a decrease from baseline in the number of NMOSD relapse(s).
Epidiolex (cannabidiol solution) - Commercial and Healthcare Reform	10/28/2020	Policy revised to include expanded FDA labeled indication of Tuberous Sclerosis Complex and to revise age requirement to 1 year of age or older.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Galafold (migalastat) - Commercial and Healthcare Reform	10/28/2020	Policy revised for Galafold (migalastat) reauthorization to verify that the member is not receiving concomitant enzyme replacement therapy (ERT) such as Fabrazyme.
Gilenya (fingolimod) - Commercial and Healthcare Reform	10/28/2020	Policy revised to remove requirement for baseline documentation of electrocardiogram, liver transaminases and bilirubin, ophthalmologic evaluation, and complete blood count. These criteria were moved to limitations of coverage.
Hereditary Angioedema - Commercial and Healthcare Reform	10/28/2020	Policy revised to add expanded indication for Haegarda [C1 Esterase Inhibitor (Human)] in patients 6 years of age or older.
Human Growth Hormone - Commercial and Healthcare Reform	10/28/2020	Policy revised to include the glucagon stimulation test in the adult growth hormone deficiency section.
Human Growth Hormone - Delaware Commercial and Healthcare Reform	10/29/2020	Policy revised to include the glucagon stimulation test in the adult growth hormone deficiency section.
Interleukin (IL)-5 Antagonists - Commercial and Healthcare Reform	10/29/2020	Policy revised for Nucala (mepolizumab) to add criteria for a new indication: hypereosinophilic syndrome (HES)
Kesimpta (ofatumumab) - Commercial and Healthcare Reform	10/29/2020	New policy for Kesimpta (ofatumumab) requiring age of 18 years or older and diagnosis of a relapsing form of multiple sclerosis.
Kuvan (sapropterin) - Commercial and Healthcare Reform	10/29/2020	Policy revised for Kuvan (sapropterin) to include a step through the generic formulation if trying to access the brand formulation and to confirm member is not concomitantly utilizing Palynziq injection.
Market Watch Programs - DE - Commercial and Healthcare Reform	11/23/2020	Policy revised to add Qdolo (tramadol hydrochloride) oral solution to list of High Cost Low Value medications with generic tramadol hydrochloride tablets being a therapeutic alternative.
Market Watch Programs - PA and WV - Commercial and Healthcare Reform	11/23/2020	Policy revised to add Qdolo (tramadol hydrochloride) oral solution to list of High Cost Low Value medications with generic tramadol hydrochloride tablets being a therapeutic alternative.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Mavenclad (cladribine) - Commercial and Healthcare Reform	11/02/2020	Policy revised to require the member to be at least 18 years of age (previously "adult") and to remove documentation requirements that Mavenclad will not be used in combination with other disease modifying therapies and for baseline cancer screening, liver function tests, infection screening, and complete blood count. The latter two criteria were moved to limitations of coverage.
Mayzent (siponimod) - Commercial and Healthcare Reform	11/03/2020	Policy revised to remove requirement for baseline documentation of cardiac evaluation, liver function tests, ophthalmologic evaluation, and complete blood count. These criteria were moved to limitations of coverage.
Nascobal (cyanocobalamin) - Commercial	11/02/2020	Policy revised to require member age 18 years and older and member to have vitamin B12 level > 300 pg/mL following intramuscular (IM) vitamin B12 therapy or vitamin B12 level ≤ 300 pg/mL and member is not a candidate for continued IM therapy. Criteria removed regarding Schilling test requirement and documented malabsorption or structural damage to stomach or ileum.
Nascobal (cyanocobalamin) - Healthcare Reform	11/02/2020	Policy revised to require member age 18 years and older and member to have vitamin B12 level > 300 pg/mL following intramuscular (IM) vitamin B12 therapy or vitamin B12 level ≤ 300 pg/mL and member is not a candidate for continued IM therapy. Criteria removed regarding Schilling test requirement and documented malabsorption or structural damage to stomach or ileum.
Natpara (parathyroid hormone) - Commercial and Healthcare Reform	11/02/2020	Policy revised to update the total serum calcium level requirement for reauthorization with the upper limit revised from 9.5 mg/dL to 10.6 mg/dL.
Nityr and Orfadin (nitisinone) - Commercial and Healthcare Reform	11/03/2020	Policy revised to update Orfadin (nitisinone) criteria to include generic nitisinone capsules as an option for step therapy. Revised Orfadin (nitisinone) suspension criteria for the member to experience therapeutic failure or

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		intolerance to Nityr (nitisinone) tablets and generic nitisinone capsules.
Oral Hypomethylating Agents - Commercial and Healthcare Reform	11/03/2020	Policy revised to add Onureg (azacitidine) criteria for use in members 18 years of age or older with acute myeloid leukemia (AML) after the member has achieved complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy; and for prescriber attestation that the member is unable to complete intensive curative therapy.
RET Kinase Inhibitors - Commercial and Healthcare Reform	11/27/2020	Policy revised to include Gavreto (pralsetinib) with criteria of age 18 years or older and diagnosis of metastatic non-small cell lung cancer classified as RET (rearranged during transfection) fusion-positive as detected by an FDA approved test.
Spinraza (nusinersen) - Commercial and Healthcare Reform	11/03/2020	Policy revised to require the member to not have previously received gene replacement therapy for the treatment of spinal muscular atrophy (SMA) or for the member to have experienced a declination of clinical status since receipt of gene replacement therapy. Policy revised to accept baseline documentation for additional approved motor function tests.
Valchlor (mechlorethamine) - Commercial and Healthcare Reform	11/03/2020	Policy revised for Valchlor (mechlorethamine) for members with Stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma after receiving at least one of the following skin-directed therapies: topical corticosteroids, topical chemotherapy (e.g. carmustine), local radiation, topical retinoids (e.g. bexarotene, tazarotene), phototherapy, topical imiquimod, total skin electron beam radiation (TSEBT).
Vimpat (lacosamide) - Healthcare Reform	11/03/2020	Policy revised for Vimpat (lacosamide) to change FDA labeled diagnosis to partial-onset seizures and remove requirement of monotherapy or adjunctive therapy.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		Policy revised to change reauthorization criteria to reduction in seizure frequency from baseline.
Vivlodex (meloxicam) - Commercial and Healthcare Reform	11/03/2020	Policy revised to update the authorization duration from 6 months to 12 months.
Xuriden (uridine triacetate) - Commercial and Healthcare Reform	11/03/2020	Policy revised for Xuriden (uridine triacetate) reauthorization to ask if the member's urinary orotic acid levels have decreased from baseline. All authorization durations now up to 12 months (reauthorization duration was previously up to 24 months).
Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates) - Commercial and Healthcare Reform	11/27/2020	Policy for Xyrem (sodium oxybate) revised to include new medication Xywav (calcium, magnesium, potassium, and sodium oxybates). In order to obtain Xywav (calcium, magnesium, potassium, and sodium oxybates), member must step through Xyrem (sodium oxybate) or be sensitive to sodium intake because of heart failure, hypertension, or impaired renal function. Name of policy now includes Xywav (calcium, magnesium, potassium, and sodium oxybates).
Zeposia (ozanimod) - Commercial and Healthcare Reform	11/03/2020	Policy revised to remove requirement for baseline documentation of electrocardiogram, liver transaminases and bilirubin, ophthalmologic evaluation, and complete blood count. These criteria were moved to limitations of coverage.
Adalimumab BIOSIMILARS - Commercial and Healthcare Reform	TBD	Policy revised to include updated reauthorization criteria to ensure that the prescriber attests that the member has demonstrated a disease stability or beneficial response to therapy.
Afinitor (everolimus) - Commercial and Healthcare Reform	12/09/2020	Policy revised for Afinitor (everolimus) to remove criteria for renal cell carcinoma classified as "clear cell" and "non-clear cell," and to remove criteria for combination use with Lenvima (lenvatinib) to reflect FDA-labeled indications, and to remove criteria regarding generic step through of everolimus for inability to swallow tablets.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Alkindi Sprinkle (hydrocortisone) - Commercial and Healthcare Reform	12/15/2020	New policy created for Alkindi Sprinkle (hydrocortisone) to ensure that members have a diagnosis of adrenocortical insufficiency, are 17 years of age or younger, and have experienced therapeutic failure or intolerance to generic hydrocortisone tablets. If the member is one year or younger, the prescriber attests that the dose is being titrated at least every 4 months.
Austedo (deutetrabenazine) - Commercial and Healthcare Reform	12/14/2020	Policy revised for reauthorization criteria of prescriber attestation that the member continues to be not actively suicidal to apply to Huntington's chorea only.
Cerdelga (eliglustat) - Commercial and Healthcare Reform	01/12/2021	Policy revised for Cerdelga (eliglustat) to add reauthorization criteria requiring members to utilize an appropriate quantity based on their CYP2D6 metabolizer status. Limitations of coverage criteria revised to move criteria detailing instances when Cerdelga (eliglustat) should not be used to the Background section.
Cholbam (cholic acid) - Commercial and Healthcare Reform	12/14/2020	Policy revised for Cholbam (cholic acid) to confirm member has one of six specific single enzyme defects.
Chronic Inflammatory Diseases - Commercial and Healthcare Reform	01/01/2021	Policy revised to include expanded indication of psoriatic arthritis for Tremfya (guselkumab) in members 18 years of age or older with a step through at least two of the following products: Cosentyx (secukinumab), Humira (adalimumab), Otezla (apremilast), Stelara (ustekinumab), Xeljanz/Xeljanz XR (tofacitinib), and Enbrel (etanercept). Policy revised to include newly FDA-approved Xeljanz (tofacitinib) oral solution and Xeljanz oral tablet in members 2 years of age or older with a diagnosis of juvenile idiopathic arthritis with a step through at least one non-biologic disease-modifying antirheumatic drug and at least two of the following products: Enbrel (etanercept), Humira (adalimumab), and Actemra (tocilizumab). Policy revised to include step through Humira

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		(adalimumab), Remicade (infliximab), Inflectra (infliximab-dyyb), Entyvio (vedolizumab), or Simponi (golimumab) for Stelara (ustekinumab) for ulcerative colitis.
Conjupri (levamlodipine) - Commercial and Healthcare Reform	12/15/2020	Policy revised for Conjupri (levamlodipine) to require member is 6 years of age and older.
Cystic Fibrosis Inhaled Medications - Commercial and Healthcare Reform	03/10/2021	Policy revised to add Bronchitol (mannitol inhalation powder). Criteria includes member's age 18 years and older, diagnosis of cystic fibrosis, attestation by the prescriber that the member passed a Bronchitol Tolerance Test, attestation by the prescriber that the member will be using Bronchitol in conjunction with standard therapies, trial and failure of inhaled hypertonic saline.
Cystic Fibrosis Inhaled Medications - Commercial National Select	03/10/2021	Policy revised to add Bronchitol (mannitol inhalation powder). Criteria includes member's age 18 years and older, diagnosis of cystic fibrosis, attestation by the prescriber that the member passed a Bronchitol Tolerance Test, attestation by the prescriber that the member will be using Bronchitol in conjunction with standard therapies, trial and failure of inhaled hypertonic saline.
Endari (L-glutamine) - Commercial and Healthcare Reform	12/14/2020	Policy revised for Endari (L-glutamine) to clarify indication to include "acute" complications.
Etanercept BIOSIMILARS - Commercial and Healthcare Reform	TBD	Policy revised to include expanded indication for Erelzi (etanercept-szzs) in members 4 years of age or older for the treatment of plaque psoriasis and updated reauthorization criteria to ensure that the prescriber attests that the member has demonstrated a disease stability or beneficial response to therapy. Policy revised to include updated reauthorization criteria to ensure that the prescriber attests that the member has demonstrated a disease stability or beneficial response to therapy.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Fumarate Products - Commercial and Healthcare Reform	12/09/2020	Policy revised to require a step through generic dimethyl fumarate for brand Tecfidera (dimethyl fumarate), Bafiertam (monomethyl fumarate), and Vumerity (diroximel fumarate).
Hepatitis C Oral Agents - Commercial and Healthcare Reform	12/09/2020	Policy revised to clarify Harvoni (ledipasvir/sofobuvir) 12 week vs. 8 week prescribing. For 12 weeks members must meet one of the following criteria: HCV (hepatitis C virus) RNA > 6 million IU/mL, HIV-infected, cirrhosis, prior liver transplant or prescriber attests that 8 weeks of therapy would be inappropriate. For Harvoni (ledipasvir/sofobuvir) 8 weeks of therapy the member must meet all the following criteria: HIV-uninfected, HCV RNA < 6 million IU/mL, and no cirrhosis.
Hepatitis C Oral Agents - Commercial Core	12/15/2020	Policy revised to clarify Harvoni (ledipasvir/sofobuvir) 12 week vs. 8 week prescribing. For 12 weeks members must meet one of the following criteria: HCV (hepatitis C virus) RNA > 6 million IU/mL, HIV-infected, cirrhosis, prior liver transplant or prescriber attests that 8 weeks of therapy would be inappropriate. For Harvoni (ledipasvir/sofobuvir) 8 weeks of therapy the member must meet all the following criteria: HIV-uninfected, HCV RNA < 6 million IU/mL, and no cirrhosis.
Hepatitis C Oral Agents - Commercial National Select	12/15/2020	Policy revised to clarify Harvoni (ledipasvir/sofobuvir) 12 week vs. 8 week prescribing. For 12 weeks members must meet one of the following criteria: HCV (hepatitis C virus) RNA > 6 million IU/mL, HIV-infected, cirrhosis, prior liver transplant or prescriber attests that 8 weeks of therapy would be inappropriate. For Harvoni (ledipasvir/sofobuvir) 8 weeks of therapy the member must meet all the following criteria: HIV-uninfected, HCV RNA < 6 million IU/mL, and no cirrhosis.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Homozygous Familial Hypercholesterolemia - Commercial and Healthcare Reform	12/15/2020	Policy revised to remove treated LDL-C levels ≥ 300 mg/dL in homozygous familial hypercholesterolemia (HoFH). Added that member has a LDL-C > 100 mg/dL despite use with a maximally tolerated statin or member is statin intolerant. If member is statin intolerant member must show rhabdomyolysis or skeletal-related muscle symptoms while receiving at least two (2) separate trials of different statins which resolved upon discontinuation of the statins or one (1) of the following: creatinine kinase increase to 10 times upper limit of normal, liver function tests increase to 3 times upper limit of normal, or hospitalization due to severe statin-related adverse event.
Horizant (gabapentin enacarbil) - Commercial and Healthcare Reform	12/09/2020	Policy revised to require that the member is 18 years of age or older for both post-herpetic neuralgia and restless leg syndrome indications.
Ilumya (tildrakizumab-asmn) - Commercial and Healthcare Reform 2021	01/01/2021	Policy revised to exclude Commercial National Select formulary, step through at least two (2) of the following products for the treatment of plaque psoriasis: Cosentyx (secukinumab), Humira (adalimumab), Otezla (apremilast), Skyrizi (risankizumab), Stelara (ustekinumab), Tremfya (guselkumab), and Enbrel (etanercept), and include updated reauthorization criteria to ensure that the prescriber attests that the member has demonstrated disease stability or a beneficial response to therapy.
Ilumya (tildrakizumab-asmn) - Commercial National Select 2021	01/01/2021	New policy created for Ilumya (tildrakizumab-asmn) for National Select formulary to ensure appropriate use in members 18 years of age or older with a diagnosis of moderate-to-severe plaque psoriasis with a step through phototherapy or systemic therapy. The member must step through at least two (2) of the following products: Taltz (ixekizumab), Humira (adalimumab), Otezla (apremilast), Skyrizi (risankizumab), Stelara (ustekinumab),

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		Tremfya (guselkumab), and Enbrel (etanercept). Reauthorization criteria ensures the prescriber attests that the member has demonstrated disease stability or a beneficial response to therapy.
Market Watch Programs - Delaware	12/31/2020	Policy revised to add Alkindi Sprinkle (hydrocortisone) to the High-Cost Low-Value table with the alternative of hydrocortisone tablets.
Market Watch Programs - Pennsylvania and West Virginia	12/31/2020	Policy revised to add Alkindi Sprinkle (hydrocortisone) to the High-Cost Low-Value table with the alternative of hydrocortisone tablets.
Ofev (nintedanib) and Esbriet (pirfenidone) - Commercial and Healthcare Reform	12/14/2020	Moved concomitant use of Ofev and Esbriet from approval criteria to limitations of coverage. Moved limitation of coverage regarding PFTs to background.
PCSK9 Inhibitors - Commercial and Healthcare Reform	03/04/2021	Policy revised to remove treated LDL-C levels ≥ 300 mg/dL in homozygous familial hypercholesterolemia (HoFH) or LDL-C levels ≥ 160 mg/dL in heterozygous familial hypercholesterolemia (HeFH) prior to starting a PCSK9 inhibitor. For all indications, revised previous statin criteria to member has a LDL-C > 100 mg/dL in HeFH and HoFH or LDL-C > 70 in hypercholesterolemia with atherosclerotic cardiovascular disease and primary hyperlipidemia despite use with a maximally tolerated statin or member is statin intolerant. If member is statin intolerant member must show rhabdomyolysis or skeletal-related muscle symptoms while receiving at least two (2) separate trials of different statins which resolved upon discontinuation of the statins or one (1) of the following: creatinine kinase increase to 10 times upper limit of normal, liver function tests increase to 3 times upper limit of normal, or hospitalization due to severe statin-related adverse event. Removed criteria of concurrent statin therapy.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Testosterone (Androgens) - Commercial and Healthcare Reform	01/01/2021	Policy revised to remove step for brand Testost as product no longer on market. For double orchidectomy, removed Testost and added Xyosted for step through topical testosterone. For vulvar dystrophies clarified it can be a testosterone propionate ointment or cream. For hypogonadism, documentation of lab values expanded to include a set cut off or the laboratory reference range. For total testosterone level is < 300 ng/dL (10.4 nmol/L) or below the normal range per the laboratory reference range. For free testosterone, level is < 65 pg/mL (225 pmol/L) or below the normal range per the laboratory reference range.
Testosterone (Androgens) - Healthcare Reform	001/01/2021	Policy terminated as it was combined into J-0197 (Commercial).
Wakix (pitolisant) - Commercial and Healthcare Reform	12/09/2020	Policy revised to include expanded indication of cataplexy in adult patients with narcolepsy. Addition of requirement of documentation of baseline cataplexy episodes. Reauthorization criteria revised to require prescriber attestation of a decrease in cataplexy episodes compared to baseline or a decrease in daytime sleepiness as proven by improvement on the Epworth Sleepiness Scale or Maintenance of Wakefulness Test compared to baseline.
Adcirca and Alyq (tadalafil) - Healthcare Reform Essential	02/03/2021	Policy terminated as criteria now in J-0016.
Aldara and Zyclara (imiquimod) - Commercial and Healthcare Reform	02/03/2021	Policy revised to remove Efudex (fluorouracil) as a targeted agent. Criteria for Aldara (imiquimod) and Zyclara (imiquimod) revised to remove "generic" from fluorouracil 5% topical cream and topical solution step therapy for the diagnosis of actinic keratosis and superficial basal cell carcinoma. Actinic keratosis and superficial basal cell carcinoma criteria updated to require the member is 18 years of age or older. Authorization duration for Zyclara

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		(imiquimod) changed from 2 weeks (actinic keratosis) and 8 weeks (external genital warts) to 16 weeks for both actinic keratosis and external genital warts.
Aldara and Zyclara (imiquimod) - Healthcare Reform	02/03/2021	Policy terminated as criteria is now in J-0212.
Anti-Obesity - Commercial and Healthcare Reform	02/09/2021	Policy revised to include new adolescent indication for Saxenda (liraglutide). For Saxenda (liraglutide) for adults, criteria was added to allow patients who initiated therapy before age 18 to continue on therapy as long as they have received at least a 1% weight loss from baseline. Authorization duration of 3 months was added for patients 12 years to less than 18 years of age. Criterion requiring documentation of height, weight, and BMI from 12 months previously removed throughout the policy.
Aubagio (teriflunomide) - Commercial and Healthcare Reform	TBD	Policy revised to include criteria that the member has experienced therapeutic failure, contraindication, or intolerance to generic dimethyl fumarate or the member is currently stable on Aubagio (teriflunomide).
Austedo (deutetrabenazine) - Commercial and Healthcare Reform	02/03/2021	Policy revised for Austedo (deutetrabenazine) to move certain criteria to limitations of coverage. Reauthorization criteria updated to remove requirement if the member has a diagnosis of Huntington's chorea, the prescriber attests that the member continues not to be actively suicidal. Quantity Level Limits revised to remove the prescriber documents clinical rationale why the lower dose would not be appropriate for the patient.
Benlysta (belimumab) - Commercial and Healthcare Reform	02/09/2021	Policy revised to include expanded indication for Benlysta (belimumab) subcutaneous for members 18 years of age or older for active lupus nephritis. The prescriber submits documentation of positive anti-nuclear antibody (ANA) titer (≥1:80) or anti-double-stranded DNA antibody (anti-dsDNA) ≥ 30 IU/mL. The

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		member has experienced therapeutic failure, contraindication, intolerance, or insufficient response while on two (2) standard of care drug classes: corticosteroids, antimalarials, and immunosuppressives. The will to continue to receive concomitant standard of care which includes corticosteroids with one (1) of the following: mycophenolate for induction followed by mycophenolate for maintenance or cyclophosphamide for induction followed by azathioprine for maintenance.
BTK Inhibitors - Commercial and Healthcare Reform	02/18/2021	Policy revised for Imbruvica (ibrutinib) to add a step through Imbruvica (ibrutinib) 140 mg capsules for either Imbruvica (ibrutinib) 140 mg tablets or Imbruvica (ibrutinib) 280 mg tablets.
CFTR Modulators - Commercial and Healthcare Reform	02/03/2021	Policy revised to include updated examples of cystic fibrosis transmembrane conductance regulator (CFTR) gene mutations that produce CFTR proteins and are responsive to Symdeko (tezacaftor-ivacaftor), and Kalydeco (ivacaftor) and Trikafta (elexacaftor/tezacaftor/ivacaftor).
Chronic Inflammatory Diseases - Commercial and Healthcare Reform	02/10/2021	Policy revised to include expanded indication for Kineret (anakinra) in members with a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) and the member has experienced therapeutic failure or intolerance to at least one (1) corticosteroid, or all corticosteroids are contraindicated. The recommended starting dose is 1-2 mg/kg daily. Documentation of member weight and prescribed Kineret dose consistent with dosing below is required: The dose can be individually adjusted to a maximum of 8 mg/kg daily. Kineret may be divided into twice daily dosing.
Chronic Inflammatory Diseases - Commercial National Select Formulary	02/10/2021	Policy revised to include expanded indication for Kineret (anakinra) in members with a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) and the member has experienced

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		therapeutic failure or intolerance to at least one (1) corticosteroid, or all corticosteroids are contraindicated. The recommended starting dose is 1-2 mg/kg daily. Documentation of member weight and prescribed Kineret dose consistent with dosing below is required: The dose can be individually adjusted to a maximum of 8 mg/kg daily. Kineret may be divided into twice daily dosing.
EGFR Kinase Inhibitors - Commercial and Healthcare Reform	05/04/2021	Criteria updated for Gilotrif (afatinib), Iressa (gefitinib), Tagrisso (osimertinib), Tarceva (erlotinib), and Vizimpro (dacomitinib) for use in members 18 years of age or older. Criteria added for Tagrisso (osimertinib) for use as adjuvant therapy for non-small cell lung cancer after tumor resection with an epidermal growth factor receptor (EGFR) exon 19 deletion or EGFR exon 21 L858 mutation.
Gilenya (fingolimod) - Commercial and Healthcare Reform	TBD	Policy revised to include criteria that the member has experienced therapeutic failure, contraindication, or intolerance to generic dimethyl fumarate or the member is currently stable on Gilenya (fingolimod) or the prescriber attests that the patient has highly active Multiple Sclerosis.
Hepatitis C Oral Therapy - Commercial and Healthcare Reform	02/03/2021	Policy revised for Hepatitis C preferred products HCV Genotype 1, 4, 5, and 6 with prior liver transplant and compensated cirrhosis status to update from Harvoni (ledipasvir/sofosbuvir) + ribavirin x 12 weeks to Harvoni ledipasvir/sofosbuvir) x 12 weeks.
Hepatitis C Oral Therapy - Commercial Core	02/03/2021	Policy revised for Hepatitis C preferred products HCV Genotype 1, 4, 5, and 6 with prior liver transplant and compensated cirrhosis status to update from Harvoni (ledipasvir/sofosbuvir) + ribavirin x 12 weeks to Harvoni ledipasvir/sofosbuvir) x 12 weeks.
Hepatitis C Oral Therapy - Commercial National Select Formulary	02/03/2021	Policy revised for Hepatitis C preferred products HCV Genotype 1, 4, 5, and 6 with prior liver transplant and compensated cirrhosis status to update from Harvoni (ledipasvir/sofosbuvir) +

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		ribavirin x 12 weeks to Harvoni ledipasvir/sofosbuvir) x 12 weeks.
Hereditary Angioedema - Commercial and Healthcare Reform	02/12/2021	Policy revised to include newly FDA-approved Orladeyo (berotralstat) for members 12 years of age or older for prophylactic management against angioedema attacks of HAE. Policy includes requirement of C4 or C1INH laboratory values and a family history of HAE or FXII mutation.
Hetlioz and Hetlioz LQ (tasimelteon) - Commercial and Healthcare Reform	03/24/2021	Policy revised to add criteria for new product and new indication: Also added new criteria for Hetlioz capsules for the treatment of nighttime sleep disturbances in SMS in patients 16 years of age and older.
Imcivree (setmelanotide) – Commercial and Healthcare Reform	02/12/2021	New policy created for Imcivree (setmelanotide) to require age is 6 years or older, obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency supported by genetic testing, baseline and current age/height/weight/BMI, and weight is considered obese. For continuation therapy, member has experienced at least a 5% reduction from baseline body weight or BMI for those with growth potential. For maintenance of therapy, member has maintained weight loss from baseline. Authorization duration initially 4 months and then 12 months thereafter.
Interferons - Commercial and Healthcare Reform	02/04/2021	Policy revised for Actimmune (interferon gamma-1B recombinant) to require the prescriber attests the member will be using Actimmune (interferon gamma-1B recombinant) to reduce the frequency and severity of infections for a diagnosis of chronic granulomatous disease (CGD) and the prescriber attests the member will be using Actimmune (interferon gamma-1B recombinant) to delay the time to disease progression for severe malignant osteopetrosis (SMO).

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Interleukin (IL)-5 Antagonists - Commercial and Healthcare Reform	02/04/2021	Policy revised for Nucala (mepolizumab) to require the member to be 12 years of age or older. Criteria for Nucala (mepolizumab) and Fasenra (benralizumab) updated to require a diagnosis of severe asthma evidence by one (1) of the following: pretreatment forced expiratory volume in 1 second (FEV1) less than 80% predicted; or FEV1 reversibility of at least 12% and 200 milliliters (mL) after albuterol (salbutamol) administration. Reauthorization criteria for Nucala (mepolizumab) and Fasenra (benralizumab) updated for the prescriber to submit attestation that the member has one (1) of the following: decreased rescue medication or oral corticosteroid use; decrease in frequency of severe asthma exacerbations; increase in pulmonary function from baseline (e.g. FEV1); or reduction in reported asthma related symptoms.
Klisyri (tirbanibulin) – Commercial and Healthcare Reform	03/03/2021	New policy created for Klisyri (tirbanibulin) for the member to be 18 years of age and older, have a diagnosis of actinic keratosis of the face or scalp, and experienced therapeutic failure or intolerance to two of the following agents: generic imiquimod 5% cream, fluorouracil 5% topical cream, and fluorouracil topical solution. Authorization duration for 4 weeks (1 month).
Korlym (mifepristone) - Commercial and Healthcare Reform	02/04/2021	Policy revised for Korlym (mifepristone) to remove therapeutic failure or not a candidate for radiotherapy as an option to obtain drug.
Market Watch Programs – Delaware	03/03/2021	Policy revised to add Impeklo (clobetasol propionate 0.05% topical lotion in metered-dose pump) to the High-Cost Low-Value table with the alternatives of clobetasol propionate 0.05% cream, clobetasol propionate 0.05% gel, clobetasol propionate 0.05% lotion, and fluocinonide 0.05% cream. Also, meloxicam capsule (generic drug of Vivlodex) is added with alternatives of

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		ibuprofen, meloxicam tablets, and naproxen. Also, Thyquidity (levothyroxine) oral solution is added with alternatives of Euthyrox (levothyroxine), Levothyroxine tablet, and Unithroid (levothyroxine).
Market Watch Programs - PA and WV	03/03/2021	Policy revised to add Impeklo (clobetasol propionate 0.05% topical lotion in metered-dose pump) to the High-Cost Low-Value table with the alternatives of clobetasol propionate 0.05% cream, clobetasol propionate 0.05% gel, clobetasol propionate 0.05% lotion, and fluocinonide 0.05% cream. Also, meloxicam capsule (generic drug of Vivlodex) is added with alternatives of ibuprofen, meloxicam tablets, and naproxen. Also, Thyquidity (levothyroxine) oral solution is added with alternatives of Euthyrox (levothyroxine), Levothyroxine tablet, and Unithroid (levothyroxine).
Mavenclad (cladribine) - Commercial and Healthcare Reform	TBD	Policy revised to include criteria that the member has experienced therapeutic failure, contraindication, or intolerance to generic dimethyl fumarate or the member is currently stable on Mavenclad (cladribine).
Mayzent (siponimod) - Commercial and Healthcare Reform	TBD	Policy revised to include criteria that the member has experienced therapeutic failure, contraindication, or intolerance to generic dimethyl fumarate or the member is currently stable on Mayzent (siponimod).
Myalept (metreleptin) - Commercial and Healthcare Reform	02/05/2021	Policy revised for Myalept (metreleptin) to remove documentation for all of the following: baseline HbA1c, fasting triglyceride level, and plasma glucose level. Added criteria that member has experienced therapeutic failure to one (1) previous therapy for diabetes or hypertriglyceridemia.
Nuplazid (pimavanserin) - Commercial and Healthcare Reform	02/24/2021	Policy revised to add criteria requiring members to be 18 years of age or older for approval of Nuplazid (pimavanserin).
Orgovyx (relugolix) - Commercial and Healthcare Reform	02/12/2021	Policy created for Orgovyx (relugolix) for adult patients with advanced prostate

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		cancer who meet one of the following criteria: biochemical or clinical relapse following local primary intervention, newly diagnosed castration-sensitive metastatic disease or advanced localized disease.
Parathyroid Hormone Analogs - Commercial and Healthcare Reform	02/02/2021	Policy revised for Forteo (teriparatide) and Tymlos (abaloparatide) to remove age of 50 years or older when providing result of Fracture Risk Assessment (FRAX) Tool and member is not taking requested drug with other parathyroid hormone analogs, RANKL inhibitors, or sclerostin inhibitors. Criteria revised for Forteo (teriparatide) that member is 40 years of age or older in those with a history of glucocorticoid use.
Parathyroid Hormone Analogs - Commercial National Select Formulary	02/02/2021	Policy revised for Forteo (teriparatide) and Tymlos (abaloparatide) to remove age of 50 years or older when providing result of Fracture Risk Assessment (FRAX) Tool and member is not taking requested drug with other parathyroid hormone analogs, RANKL inhibitors, or sclerostin inhibitors. Criteria revised for Forteo (teriparatide) that member is 40 years of age or older in those with a history of glucocorticoid use.
Parathyroid Hormone Analogs - Healthcare Reform	02/02/2021	Policy terminated as this was added to J-0681 Parathyroid Hormone Analogs - Commercial and Healthcare Reform.
Prolia (denosumab) and Evenity (romosozumab-aqqg) - Commercial and Healthcare Reform	02/02/2021	Policy revised for Prolia (denosumab) and Evenity (romosozumab-aqqg) to clarify that history of fracture is singular and remove age of 50 years or older when providing result of Fracture Risk Assessment (FRAX) Tool and member is not taking requested drug with other parathyroid hormone analogs, RANKL inhibitors, or sclerostin inhibitors. For Prolia (denosumab) criteria revised that member is 40 years of age or older in those with a history of glucocorticoid use. For Evenity (romosozumab-aqqg) removed history of glucocorticoid use as approvable criteria.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Pulmonary Hypertension	02/04/2021	Policy revised for pulmonary hypertension agents. For Adcirca/Alyq (tadalafil) and Letairis (ambrisentan) member has tried and failed its own generic and generic sildenafil. For Revatio (sildenafil) member has tried and failed its generic. For Tyvaso (inhaled treprostinil), Uptravi (selexipag), or Ventavis (inhaled iloprost), member has tried and failed either generic sildenafil or generic ambrisentan. For Tracleer (bosentan) exception to right heart catheterization may be allowed in pediatric patients if risk outweighs the benefit. If right heart catheterization is not performed, submission of alternative study is to be provided. For all drugs, mean pulmonary arterial pressure (mPAP) changed to > 20 mm Hg at rest from ≥ 25 mmHg and pulmonary vascular resistance (PVR) changed to ≥ 3 Wood units from > 3 Wood units. Clarified for all drugs that functional class symptoms can use either the New York Heart Association or World Health Organization functional classification.
RET Kinase Inhibitors - Commercial and Healthcare Reform	02/16/2021	Policy revised to add criteria for new indications for Gavreto (pralsetinib): treatment of adult and pediatric patients 12 years of age and older with either advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy or advanced or metastatic RET fusion positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
Signifor (pasireotide) - Commercial and Healthcare Reform	02/05/2021	Policy revised for Signifor (pasireotide) that urinary free cortisol level meets one of the following: < 100 mcg/24 hours, < 276 nmol/day, or normal range per the laboratory reference range for reauthorization criteria.
Sympazan (clobazam) - Commercial and Healthcare Reform	02/05/2021	Policy revised to update reauthorization criteria to include prescriber attestation of a reduction in seizure frequency from baseline.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Syprine (trientine) & Cuprimine, Depen (penicillamine) - Commercial and Healthcare Reform	02/05/2021	Policy revised to add Clovique (trientine hydrochloride) to policy and numerous edits made regarding step through agents: 1) Generic penicillamine capsule now requires step through both generic penicillamine tablet and either Brand Depen tablet or Brand D-penamine tablet; 2) Brand Cuprimine capsule now requires additional steps through generic penicillamine tablet and generic penicillamine capsule; 3) Generic trientine hydrochloride and Clovique now requires step through generic penicillamine tablet, Brand Depen tablet, or Brand D-penamine tablet; 4) Brand Syprine now requires additional step through generic penicillamine tablet, Brand Depen tablet, or Brand D-penamine tablet.
Talicia (omeprazole/amoxicillin/rifabutin) - Commercial and Healthcare Reform	02/05/2021	Policy revised for Talicia (omeprazole, amoxicillin, and rifabutin) to update step therapy for the member to be previously treated with a first-line treatment regimen including all the following products: lansoprazole OR omeprazole; amoxicillin OR metronidazole; and clarithromycin; unless the member has a penicillin allergy, clarithromycin allergy, or prior exposure to macrolide therapy. Step therapy requiring prior treatment with Pylera updated to allow the step requirement to be met if the member has an allergy, intolerance, or contraindication to any components of Pylera (i.e. bismuth subcitrate, metronidazole, or doxycycline).
Thiola and Thiola EC (tiopronin) - Commercial and Healthcare Reform	02/21/2021	Criteria revised to require failure on 4 liters of fluid intake daily (increased from 3), and urinary alkalinization with

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		potassium citrate to achieve a urinary pH of 7.0 specifically.
Urea Cycle Disorder Medications - Commercial and Healthcare Reform	02/18/2021	Policy revised to update criteria for Carbaglu (carglumic acid) for the adjunctive treatment of hyperammonemia revised to include due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS).
Vimpat (lacosamide) - Healthcare Reform	02/05/2021	Policy revised to include expanded indication of adjunctive treatment of primary generalized tonic-clonic seizures for patients 4 years of age or older.
Xcopri (cenobamate) - Commercial and Healthcare Reform	02/05/2021	Policy revised for Xcopri (cenobamate) to require therapeutic failure or intolerance to at least two (2) other anti-epileptic drugs (AEDs) indicated for partial-onset seizures or all are contraindicated. Reauthorization criteria revised to require prescriber attestation that the member has experienced a reduction in seizure frequency from baseline.
Xenazine (tetrabenazine) - Commercial and Healthcare Reform	02/05/2021	Policy revised for Xenazine (tetrabenazine) to move criteria to limitations of coverage stating patients with a diagnosis of comorbid depression should not be actively suicidal and have controlled depression with an active antidepressant medication in their prescription medication profile. Reauthorization criteria created for the prescriber to attest the member has experienced positive clinical response to therapy. Revised limitations of coverage to remove exceptions may be made for a diagnosis of tardive dyskinesia.
Xpovio (selinexor) - Commercial and Healthcare Reform	TBD	Policy revised for Xpovio (selinexor) to add criteria for use in members 18 years of age or older with multiple myeloma, for use in combination with both bortezomib and dexamethasone after the member has received at least one prior therapy for multiple myeloma.
Zavesca (miglustat) - Commercial and Healthcare Reform	02/05/2021	Policy revised for Zavesca (miglustat) to require a step through generic miglustat if brand Zavesca is being requested.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Zeposia (ozanimod) - Commercial and Healthcare Reform	TBD	Policy revised to include criteria that the member has experienced therapeutic failure, contraindication, or intolerance to generic dimethyl fumarate or the member is currently stable on Zeposia (ozanimod).
Zokinvy (lonafarnib) - Commercial and Healthcare Reform	02/02/2021	New policy created for Zokinvy (lonafarnib) to require diagnosis of HGPS with a mutation in the LMNA gene OR processing-deficient PL with heterozygous LMNA mutation and progerin-like protein accumulation OR processing-deficient PL with either homozygous ZMPSTE24 mutations or compound heterozygous ZMPSTE24 mutations. Regardless of diagnosis, patient must also be 12 months of age or older and have a BSA of 0.39m2 or above, and quantity requested must be appropriate based on dosing regimen table provided in FDA-approved package insert.

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

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Additional Antibiotic Quantities - Commercial and Healthcare Reform	10/20/2020	Policy revised to change approval criteria for vancomycin to a recurrence of clostridium difficile diarrhea (previously was a second recurrence).
Brand and Extended Release Metformin - Commercial and Healthcare Reform	10/21/2020	Policy revised to require therapeutic failure, intolerance, or contraindication to generic metformin hydrochloride extended-release (generic of Fortamet) for approval of Glumetza (metformin hydrochloride extended-release). Policy revised to require therapeutic failure, intolerance, or contraindication to generic metformin hydrochloride oral solution and metformin hydrochloride immediate release tablets for approval of Riomet oral solution (metformin hydrochloride orral solution).

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Duaklir Pressair (aclidinium bromide and formoterol fumarate) – Commercial and Healthcare Reform	10/26/2020	Policy revised for Duaklir Pressair (aclidinium bromide and formoterol fumarate) to require member age 18 years and older.
Glycate (glycopyrrolate) - Commercial and Healthcare Reform	10/28/2020	Policy revised for Glycate (glycopyrrolate) to require reauthorization criteria that member has experienced positive response and require additional courses of treatment.
Leukotriene Modifiers (Accolate, Zyflo, zileuton ER) - Healthcare Reform	11/02/2020	Policy revised to have automatic approval criteria lookback period of 365 days for all lookback periods that were previously 360 days. Policy title revised to include zileuton ER.
Leukotriene Modifiers (Accolate, Zyflo, zileuton ER) - Commercial	11/02/2020	Policy revised to have automatic approval criteria lookback period of 365 days for all lookback periods that were previously 360 days. Policy title revised to include zileuton ER.
Nuedexta (dextromethorphan-quinidine) - Commercial and Healthcare Reform	12/11/2020	Policy revised to include all Multiple Sclerosis medications in automatic approval criteria.
Opioid Management - Commercial	12/11/2020	Policy revised to add Qdolo (tramadol hydrochloride) oral solution to the list of short-acting opioids requiring prior authorization.
Opioid Management - Healthcare Reform	12/11/2020	Policy revised to add Qdolo (tramadol hydrochloride) oral solution to the list of short-acting opioids requiring prior authorization.
Paroxetine - Commercial and Healthcare Reform	04/01/2021	Policy revised to change automatic approval criteria; member must have at least one claim within the past 12 months for a preferred paroxetine medication.
Ryvent (carbinoxamine) 6 mg - Healthcare Reform	12/11/2020	Policy revised for Ryvent (carbinoxamine) 6 mg to stipulate the step therapy is through generic carbinoxamine 4 mg tablets. Additional dual step therapy through specific therapeutic alternatives changed to two different, generic, antihistamine tablets or capsules.
Topical Acne Products - Commercial	02/12/2021	Policy revised to include Winlevi (clascoterone) that member has diagnosis of acne and tried and failed 3 preferred topical agents. Step therapy for other acne agents changed from double-step to triple-step along with removal of cindamycin phosphate/benzoyl peroxide as an alternative option.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Topical Acne Products - Healthcare Reform	2/12/2021	Policy revised to include Winlevi (clascoterone) that member has diagnosis of acne and tried and failed 3 preferred topical agents. Step therapy for other acne agents changed from double-step to triple-step along with removal of cindamycin phosphate/benzoyl peroxide as an alternative option.
Topical Antifungals - Commercial and Healthcare Reform	12/11/2020	Policy revised to include quantity limit override language for 8 mL bottle. Automatic approval criteria removed.
Topical Psoriasis Treatments - Commercial	12/16/2020	Policy revised to include newly FDA-approved Wynzora (calcipotriene/betamethasone dipropionate) topical cream and to step through one prescription high-potency generic topical corticosteroid.
Topical Psoriasis Treatments - Healthcare Reform	12/16/2020	Policy revised to include newly FDA-approved Wynzora (calcipotriene/betamethasone dipropionate) topical cream and to step through one prescription high-potency generic topical corticosteroid.
Topiramate ER - Commercial and Healthcare Reform	04/01/2021	Policy revised to reflect updated benefit change for Commercial to step therapy and automatic approval criteria revised to include a claim for generic topiramate IR, topiramate ER, Trokendi XR, or Qudexy XR in the member's prescription drug claims history within the previous 180 days.
Additional Antibiotic Quantities - Commercial and Healthcare Reform	01/12/2021	Policy revised to change the quantity of vancomycin in the automatic approval criteria to take into account the first and second incidence of *Clostridium Difficile* Associated Diarrhea.
Doxepin 5% Cream - Commercial	12/15/2020	Policy revised for doxepin hydrochloride 5% cream to add an alternate step therapy if the member has experienced therapeutic failure, intolerance, or contraindication to generic topical tacrolimus or pimecrolimus in the past 180 days if the member has atopic dermatitis with facial or anogenital involvement.
Eysuvis (loteprednol) - Commercial and Healthcare Reform	01/12/2021	New policy created for Eysuvis (loteprednol) for the member to have a diagnosis of dry eye disease and therapeutic failure or intolerance to an artificial tears product and generic loteprednol 0.5%.
Horizant (gabapentin enacarbil) - Commercial and Healthcare Reform	12/09/2020	Policy revised to require that the member is 18 years of age or older for both post-herpetic neuralgia and restless leg syndrome indications.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Non-Preferred Tramadol Products - Commercial and Healthcare Reform	01/12/2021	Policy revised for new drug Qdolo (tramadol hydrochloride) to be added to existing Tramadol Hydrochloride 100 mg policy. Criteria added for Qdolo (tramadol hydrochloride) to require a diagnosis of pain, therapeutic failure or intolerance to tramadol hydrochloride 50mg, and documented inability to swallow tablets. Reauthorization added for Qdolo (tramadol hydrochloride) to require prescriber attestation for positive clinical response to therapy and member still unable to swallow oral tablets. Authorization duration updated from 6 months to 3 months.
Tirosint-SOL - Commercial and Healthcare Reform	12/15/2020	Policy revised for Tirosint-SOL (levothyroxine sodium) to remove initial authorization criteria allowing members to receive the product if they are unable to swallow tablets or have a GI condition that affects the way the body dissolves traditional levothyroxine tablets. Initial authorization criteria requiring members to step through generic levothyroxine tablets plus one other oral tablet form of levothyroxine revised to require members to step through generic levothyroxine tablets plus one (1) of the following specific products: Euthyrox or Unithroid. Reauthorization criteria revised to remove criteria requiring members to be unable to swallow tablets. Limitations of coverage criteria revised to move criteria detailing instances when Tirosint-SOL (levothyroxine sodium) should not be used to the Background section.
Topical Antifungals - Commercial National Select	12/11/2020	Policy revised to add member age requirement of 18 years or older and remove automatic approval criteria.
Gemtesa (vibegron) - Commercial and Healthcare Reform	03/17/2021	New policy created for Gemtesa (vibegron) to require the member to be 18 years of age or older, have a diagnosis of overactive bladder, meet one of the following criteria: tried and failed Myrbetriq, or Myrbetriq is inappropriate for the member because of high blood pressure or drug interaction(s) with Myrbetriq, and meet one of the following: tried and failed one of the three agents (oxybutynin, tolterodine, trospium), or antimuscarinics (e.g. oxybutynin, trospium, tolterodine) are inappropriate because of the side effects (e.g. dry mouth, constipation, drowsiness, blurred vision, delirium, risk of dementia, or cognitive impairment). Reauthorization criterion was created to require

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		attestation that the member has experienced positive clinical response to therapy.
Gout Therapy - Commercial and Healthcare Reform	03/17/2021	Policy revised to include that the member is 18 years of age or older for Uloric (febuxostat). Policy revised to include that the member is 18 years of age or older and step through generic colchicine tablets for Mitigare (colchicine). Policy revised to include criteria for colchicine capsules (authorized generic) to ensure that the member is using colchicine capsules for the prevention or treatment of gout attacks or treatment of familial Mediterranean fever (FMF) and has experienced therapeutic failure and intolerance to allopurinol and generic colchicine tablets.
Lubiprostone - Commercial and Healthcare Reform	02/12/2021	New policy created for lubiprostone (authorized generic only) for members 18 years of age or older with a diagnosis of chronic idiopathic constipation (CIC), opioid-induced constipation (OIC), or irritable bowel syndrome with constipation (IBS-C). The member has experienced therapeutic failure or contraindication to brand Amitiza. The reauthorization criteria ensures that the prescriber attests that the member has experienced positive clinical response to therapy.
Methotrexate Injections - Commercial	03/17/2021	Policy revised to include recently-launched RediTrex (methotrexate) to ensure use for an FDA-approved indication. The member has experienced therapeutic failure or intolerance to generic methotrexate solution for injection.
Methotrexate Injections - Healthcare Reform	03/17/2021	Policy revised to include recently-launched RediTrex (methotrexate) to ensure use for an FDA-approved indication. The member has experienced therapeutic failure or intolerance to generic methotrexate solution for injection.
Tazarotene Products - Commercial	02/11/2021	Policy revised to remove clindamycin phosphate/benzoyl peroxide as an alternative step option and to count either clindamycin phosphate or clindamycin phosphate/benzoyl peroxide as meeting one of the two steps for automatic authorization logic.
Tazarotene Products - Healthcare Reform	02/11/2021	Policy revised to remove clindamycin phosphate/benzoyl peroxide as an alternative step option and to count either clindamycin phosphate or clindamycin phosphate/benzoyl peroxide as

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		meeting one of the two steps for automatic authorization logic.
Tirosint SOL and Thyquidity (levothyroxine sodium) - Commercial and Healthcare Reform	TBD	Policy revised to include new drug, Thyquidity (levothyroxine) oral solution with requirements of FDA labeled diagnosis, therapeutic failure or intolerance to generic levothyroxine oral tablets, and therapeutic failure or intolerance to Euthyrox (levothyroxine) or Unithroid (levothyroxine).
Topical Corticosteroids - Commercial	02/18/2021	Policy revised to add Impeklo 0.05% (clobetasol propionate) lotion (brand only), remove Diprolene AF 0.05% (betamethasone dipropionate) cream and lotion (brand only), remove generic 0.25% desoximetasone cream, and remove Ultravate X 0.05%-10% (halobetasol/lactic acid) on the list of high potency topical corticosteroids.
Topical Corticosteroids - Healthcare Reform	02/18/2021	Policy revised to add Impeklo 0.05% (clobetasol propionate) lotion (brand only), remove Diprolene AF 0.05% (betamethasone dipropionate) cream and lotion (brand only), remove generic 0.25% desoximetasone cream, and remove Ultravate X 0.05%-10% (halobetasol/lactic acid) on the list of high potency topical corticosteroids.
Topical Lidocaine Products – Healthcare Reform	02/09/2021	Policy terminated as criteria is now in J-0760.

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

3. Formulary Program

No changes at this time.

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

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

Drug Name	Retail Edit Limit	Mail Edit Limit
Cystadrops (cysteamine) ophthalmic solution	20 mL (4 vials) per 28 days	60 mL (12 vials) per 84 days
Cystaran (cysteamine) ophthalmic solution	60 mL (4 bottles) per 28 days	180 mL (12 bottles) per 84 days

Drug Name	Retail Edit Limit	Mail Edit Limit
Enspryng (satralizumab-mwge)	1 syringe per 28 days	3 syringes per 84 days
Helidac	224 tablets/capsules (14 blister cards) per 365 days	224 tablets/capsules (14 blister cards) per 365 days
Jynarque (tolvaptan) 15/15MG Blister Card	4 blister cards (56 tablets) per 28 days	12 blister cards (168 tablets) per 84 days
Jynarque (tolvaptan) 30/15 MG Blister Card	4 blister cards (56 tablets) per 28 days	12 blister cards (168 tablets) per 84 days
Kesimpta (ofatumumab)	1 pen per 28 days	3 pens per 84 days
Omnipod DASH	10 pods per 30 days	30 pods per 90 days
Onureg (azacitidine)	14 tablets per 28 days	42 tablets per 84 days
Sogroya (somapacitan-beco)	4 pens per 28 days	12 pens per 84 days
Trulicity (dulaglutide) 3 mg/0.5 mL	2 mL per 21 days	6 mL per 63 days
Trulicity (dulaglutide) 4.5 mg/0.5 mL	2 mL per 21 days	6 mL per 63 days
V-Go 20, V-Go 30, V-Go 40	30 devices per 30 days	90 devices per 90 days
Xyrem (sodium oxybate)	540 mL per 30 days	1620 mL per 90 days
Xywav (calcium/magnesium/potassium/sodium oxybates)	540 mL per 30 days	1620 mL per 90 days
Bronchitol (mannitol)	1 pack per lifetime	1 pack per lifetime
COVID-19 vaccine	2 doses per 720 days	2 doses per 720 days
Eysuvis (loteprednol etabonate) 0.25% ophthalmic suspension	6 bottles per 365 days	6 bottles per 365 days
Firvanq 25 mg/mL and 50 mg/mL	2100 mL per 180 days	2100 mL per 180 days
Vancocin (vancomycin) capsule	141 capsules per 180 days	141 capsules per 180 days
Xeljanz (tofacitinib) oral solution	240 mL per 18 days	740 mL per 54 days
Cequr Simplicity (insulin delivery patch)	10 patches per 30 days	30 patches per 90 days
Eliquis (apixaban) 5 mg	74 tablets per 30 days	194 tablets per 90 days
Hetlioz LQ (tasimelteon) oral solution	1 bottle (158 mL) per 30 days	3 bottles (474 mL) per 90 days
Imcivree (setmelanotide)	10 vials (100 mg or 10 ml) per 30 days	30 vials (300 mg or 30 ml) per 90 days
Klisyri (tirbanibulin)	5 packets (1.25 g) per 60 days	5 packets (1.25 g) per 60 days
Orgovyx (relugolix)	1 blister card per lifetime	1 blister card per lifetime

*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
Breztri Aerosphere (budesonide/formoterol/glycopyrrolate)	10.7 g (1 cannister)	32.1 g (3 cannisters)
Santyl Ointment	3 x 30 gm tubes OR 1 x 90 gm tube	9 x 30 gm tubes or 3 x 90 gm tubes
Winlevi (clascoterone)	One 60 gram tube	Three 60 gram tubes
Xeglyze (abametapir)	210 mL (1 bottle)	210 mL (1 bottle)
Bronchitol (mannitol)	1 pack	3 packs
Eysuvis (loteprednol etabonate) 0.25% ophthalmic suspension	1 bottle	1 bottle
Impeklo (clobetasol 0.05% lotion in metered dose pump)	68 mL (one bottle)	68 mL (one bottle)
Xofluza (baloxavir marboxil) oral suspension	2 bottles (40 mL)	2 bottles (40 mL)

*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
Gavreto (pralsetinib)	4 capsules per day
Xtandi (enzalutamide) film-coated tablet	40 mg: 3 tablets per day, 80 mg tabs: 2 tabs per day
Alkindi Sprinkle (hydrocortisone) oral granules	3 capsules per day
Cerdelga (eliglustat) - Commercial and Healthcare Reform	1 tablet per day
Cuprimine (penicillamine) Capsule 250 mg AND Depen (penicillamine) Tablet 250 mg	8 capsules/tablets per day
D-penamine (penicillamine) Tablet 125 mg	16 tablets per day
Gemtesa (vibegron)	1 tablet per day
Orgovyx (relugolix)	1 tablet per day
Orladeyo (berotralstat)	1 capsule per day
Syprine (trientine hydrochloride) Capsule 250 mg (includes branded generic Clovique)	8 capsules per day
Zokinvy (lonafarnib)	2 capsules per day

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

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

SECTION II. Highmark Medicare Part D Formularies

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

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

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

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

Brand Name	Generic Name	Comments
Inmazeb	atoltivimab/maftivimab/odesivimab-ebgn	Zaire Ebolavirus
Alkindi Sprinkle oral granules	hydrocortisone oral granules	Adrenal Insufficiency
Bronchitol	mannitol	Cystic Fibrosis
Xeljanz oral solution	tofacitinib	Chronic Inflammatory Diseases
Ebanga	ansuvimab-zykl	Zaire Ebolavirus Infection
Xofluza oral suspension	baloxavir marboxil oral suspension	Influenza
Danyelza	naxitamab-gqgk	Neuroblastoma
Hetlioz LQ oral solution	tasimelteon oral solution	Smith-Magenis Syndrome
Margenza	margetuximab-cmkb	Breast Cancer
Orgovyx	relugolix	Prostate Cancer
Orladeyo	berotralstat	Hereditary Angioedema Prophylaxis
Oxlumo	lumasiran	Primary hyperoxaluria type 1
Riabni	rituximab-arrx	Leukemias/Lymphomas
Zokinvy	lonafarnib	Hutchinson-Gilford Progeria Syndrome; Processing-Deficient Progeroid Laminopathies

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
Breztri Aerosphere	budesonide/formoterol/glycopyrrolate	Trelegy Ellipta
Olinvyk	oliceridine	Hydromorphone Hcl Injection; Morphine Sulfate Intravenous; Morphine Sulfate Injection
Qdolo oral solution	tramadol oral solution	Tramadol HCL 50 mg tablet

Brand Name	Generic Name	Preferred Alternatives
Winlevi	clascoterone	Adapalene Gel (Gram); Tretinoin Cream (Gram); Clindamycin-Benzoyl Peroxide Gel (Gram)
Xeglyze	abametapir	Malathion
Lampit	nifurtimox	Provider Discretion
Upneeq ophthalmic solution	oxymetazoline ophthalmic solution	Provider Discretion
Eysuvis 0.25% ophthalmic suspension	loteprednol etabonate 0.25% ophthalmic suspension	fluorometholone
Gemtesa	vibegron	Myrbetriq
Klisyri	tirbanibulin	Fluorouracil cream 5 %, Fluorouracil solution 2 %, Imiquimod cream in packet 5 %
RediTrex	methotrexate	methotrexate sodium tablet
Sutab	sodium sulfate/magnesium sulfate/potassium chloride	Suprep Bowel Prep Kit, Gavilyte-C, peg 3350-electrolytes
Thyquidity 100 mcg/5 mL oral solution	levothyroxine sodium 100 mcg/5 mL oral solution	levothyroxine sodium tablet

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:

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

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

Brand Name	Generic Name	Comments
Inmazeb	atoltivimab/maftivimab/odesivimab-ebgn	Zaire Ebolavirus
Alkindi Sprinkle oral granules	hydrocortisone oral granules	Adrenal Insufficiency
Bronchitol	mannitol	Cystic Fibrosis
Xeljanz oral solution	tofacitinib oral solution	Chronic Inflammatory Diseases
Ebanga	ansuvimab-zykl	Zaire Ebolavirus Infection

Xofluza oral suspension	baloxavir marboxil oral suspension	Influenza
Danyelza	naxitamab-gqgk	Neuroblastoma
Hetlioz LQ oral solution	tasimelteon oral solution	Smith-Magenis Syndrome
Margenza	margetuximab-cmkb	Breast Cancer
Orgovyx	relugolix	Prostate Cancer
Orladeyo	berotralstat	Hereditary Angioedema Prophylaxis
Oxlumo	lumasiran	Primary hyperoxaluria type 1
Riabni	rituximab-arrx	Leukemias/Lymphomas
Zokinvy	lonafarnib	Hutchinson-Gilford Progeria Syndrome; Processing-Deficient Progeroid Laminopathies

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

Brand Name	Generic Name	Preferred Alternatives
Klisyri	tirbanibulin	Fluorouracil cream 5 %, Fluorouracil solution 2 %, Imiquimod cream in packet 5 %
RediTrex	methotrexate	methotrexate sodium tablet
Sutab	sodium sulfate/magnesium sulfate/potassium chloride	Suprep Bowel Prep Kit, Gavilyte-C, peg 3350-electrolytes

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

Brand Name	Generic Name	Preferred Alternatives
Breztri Aerosphere	budesonide/formoterol/glycopyrrolate	Trelegy Ellipta
Olinvyk	oliceridine	Hydromorphone Hcl Injection; Morphine Sulfate Intravenous; Morphine Sulfate Injection
Qdolo oral solution	tramadol oral solution	Tramadol HCL 50 mg tablet
Winlevi	clascoterone	Adapalene Gel (Gram); Tretinoin Cream (Gram); Clindamycin-Benzoyl Peroxide Gel (Gram)
Xeglyze	abametapir	Malathion
Lampit	nifurtimox	Provider Discretion
Upneeq ophthalmic solution	oxymetazoline ophthalmic solution	Provider Discretion
Eysuvis 0.25% ophthalmic suspension	loteprednol etabonate 0.25% ophthalmic suspension	fluorometholone
Gemtesa	vibegron	Myrbetriq

Thyquidity 100 mcg/5 mL oral solution	levothyroxine sodium 100 mcg/5 mL oral solution	levothyroxine sodium tablet

*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
Blenrep	belantamab mafodotin-blmf
Cystadrops	cysteamine ophthalmic solution
Enspryng	satralizumab-mwge
Gavreto	pralsetinib
Kesimpta	ofatumumab
Monjuvi	tafasitamab-cxix
Onureg	azacitidine
Sogroya	somapacitan-beco
Wynzora	calcipotriene/betamethasone dipriopionate
Xtandi film-coated tablet	enzalutamide film-coated tablet
Xywav	calcium/magnesium/potassium/sodium oxybates
Alkindi Sprinkle oral granules	hydrocortisone oral granules
Bronchitol	mannitol
Xeljanz oral solution	tofacitinib oral solution
Danyelza	naxitamab-gqgk
Hetlioz LQ oral solution	tasimelteon oral solution
Margenza	margetuximab-cmkb
Orgovyx	relugolix
Orladeyo	berotralstat
Oxlumo	lumasiran
Riabni	rituximab-arrx
Zokinvy	lonafarnib

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors – Medicare	08/25/2020	Policy revised for Nexletol (bempedoic acid) and Nexlizet (bempedoic acid/ezetimibe) to include statin intolerance criteria that is supported by skeletal muscle symptoms or increase in lab values

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		(creatinine kinase, liver function tests), or hospitalization. **NOTE:**policy is already live on website due to CMS guidance, needs P&T approval as well.
ALK-Targeting Kinase Inhibitors - Medicare 2021	01/01/2021	Policy revised for Xalkori (crizotinib) for use in members 18 years of age or older, and to remove criteria for locally advanced disease; and for Zykadia (ceritinib) for use in members 18 years of age or older and with an FDA-approved test.
Androgen Receptor Inhibitors - Medicare 2021	01/01/2021	Policy revised for Xtandi (enzalutamide) for use in members 18 years of age or older.
Anti-Angiogenesis and VEGF Kinase Inhibitors - Medicare 2021	01/01/2021	Policy revised for Lenvima (lenvatinib) in combination with pembrolizumab for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation; for Stivarga (regorafenib) for use in members 18 years of age or older; Votrient (pazopanib) for use in members 18 years of age or older; and to add limitation of coverage for documentation of adipocytic soft tissue sarcoma or gastrointestinal stromal tumor; and for Zydelig (idelalisib) for use in members 18 years of age and older, and to add limitation of coverage in first line treatment, and combination use with bendamustine and/or rituximab for the treatment of follicular lymphoma (FL).
Anti-EGFR and HER2 Kinase Inhibitors - Medicare 2021	01/01/2021	Policy revised for Tykerb (lapatinib) for use in members 18 years of age or older and to add limitation of coverage for use without disease progression on trastuzumab prior to initiation of therapy.
Apomorphine products - Medicare 2021	01/01/2021	Future state policy revised to include Kynmobi (apomorphine hydrochloride). No changes to criteria that require a diagnosis of advanced Parkinson's disease, use for acute, intermittent treatment of

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		hypomobility "off" episodes, trial of either generic pramipexole IR or ER tablets and ropinirole IR or ER tablets, and use in combination with other Parkinson's disease therapy.
Aubagio (teriflunomide) - Medicare	10/21/2020	Policy revised to include expanded indication for clinically isolated syndrome.
BCR-ABL Kinase Inhibitors – Medicare 2021	01/01/2021	Policy revised for Bosulif (bosutinib) for members with Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML).
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors – Medicare 2021	01/01/2021	Policy revised for Braftovi (binimetinib) to add limitation of coverage for use in wild-type BRAF colorectal cancer (CRC); and for Zelboraf (vemurafenib) to add limitation of coverage for use in wild-type BRAF melanoma.
BTK inhibitors - Medicare 2021	01/01/2021	Policy revised for Imbruvica (ibrutinib) for use in members 18 years of age or older for all indications: mantle cell lymphoma (MCL), chronic lymphocytic leukemia/small lymphocytic leukemia (CLL/SLL), Waldenstrom's Macroglobulinemia (WM), marginal zone lymphoma (MZL), chronic graft versus host disease (cGVHD); and for Zydelig (idelalisib) for use in members 18 years of age or older.
Chronic Inflammatory Diseases - Medicare	10/21/2020	Policy revised to include expanded indication for Stelara (ustekinumab) for the treatment of patients 6 years of age or older (instead of 12 years of age or older) with moderate to severe plaque psoriasis and Tremfya (guselkumab) for the treatment of adult patients with active psoriatic arthritis.
Darzalex (daratumumab) and Darzalex Faspro (daratumumab and hyaluronidase-fihj) - Medicare	10/22/2020	Policy revised for Darzalex (daratumumab) to add criteria for use in combination with Kyprolis (carfilzomib) and dexamethasone after receipt of one to three prior lines of therapy.
EGFR Kinase Inhibitors - Medicare 2021	01/01/2021	Policy revised for Vizimpro (dacomitinib) for use in members 18 years of age and older; and to add limitation of coverage for Gilotrif (afatinib) safety and efficacy not established in tumors with resistant EGFR

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		mutations; and for Tagrisso (osmertinib) for use in members 18 years of age or older; and to add limitation of coverage for Tarceva (erlotinib) safety and efficacy not established in non-small cell lung cancer (NSCLC) tumors with mutations other than those in the FDA-approved indications, and not recommended for use in combination with platinum-based chemotherapy.
Enspryng (satralizumab-mwge) - Medicare	11/01/2020	New policy created for Enspryng (satralizumab-mwge) requiring age of 18 years or older and a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) anti-aquaporin-4 (AQP4) antibody positive. Reauthorization criteria for prescriber to attest the member has experienced a decrease from baseline in the number of NMOSD relapse(s).
Epidiolex (cannabidiol solution) - Medicare	11/01/2020	Policy revised to include expanded FDA labeled indication of Tuberous Sclerosis Complex and to revise age requirement to 1 year of age or older.
FGFR Kinase Inhibitors - Medicare 2021	01/01/2021	Policy revised for Balversa (erdafitinib) for use in members 18 years of age or older.
Gilenya (fingolimod) - Medicare	10/29/2020	Policy revised to remove requirement for baseline documentation of electrocardiogram, liver transaminases and bilirubin, ophthalmologic evaluation, and complete blood count. These criteria were moved to limitations of coverage. Additionally, language added to policy consistent with filing to state that concomitant use of Gilenya with other disease modifying MS agents will not be authorized.
Hedgehog Pathway Inhibitors - Medicare 2021	01/01/2021	Policy revised for Erivedge (vismodegib) to remove the requirement from metastatic disease that the member is not a candidate for radiation.
Hereditary Angioedema - Medicare	10/29/2020	Policy revised to add expanded indication for Haegarda [C1 Esterase Inhibitor (Human)] in patients 6 years of age or older.
Hereditary Angioedema - Medicare 2021	01/01/2021	Policy revised to ensure that the prescriber submits documentation of member's weight

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		for Berinert [C1 Esterase Inhibitor (Human)], Ruconest [C1 Esterase Inhibitor (Recombinant)], and Haegarda [C1 Esterase Inhibitor (Human)], the member is not on two acute therapies simultaneously for Berinert [C1 Esterase Inhibitor (Human)], Ruconest [C1 Esterase Inhibitor (Recombinant)], and Firazyr (icatibant), and the member is not on two prophylactic therapies simultaneously for Cinryze [C1 Esterase Inhibitor (Human)], Haegarda [C1 Esterase Inhibitor (Human)], and Takhzyro (lanadelumab-flyo).
Human Growth Hormone - Medicare	09/30/2020	Policy revised to add Sogroya (somapacitan-beco), a new therapy, to the list of hormones. Policy revised to include the glucagon stimulation test in the adult growth hormone deficiency section.
Injectable Octreotide Products – Medicare	01/01/2021	New policy created for injectable octreotide products to require diagnosis of acromegaly, severe diarrhea/flushing episodes associated with metastatic carcinoid tumors, or profuse watery diarrhea associated with vasoactive intestinal peptide tumors. If diagnosis is acromegaly, member has high pretreatment insulin-like growth factor (IGF-1). For reauthorization of acromegaly the member has decreased IGF-1 from baseline or normalized IGF-1 from baseline.
Interleukin (IL)-5 Antagonists - Medicare	11/02/2020	Policy revised for Nucala (mepolizumab) to add criteria for a new indication: hypereosinophilic syndrome (HES)
JAK Inhibitors - Medicare 2021	01/01/2021	Policy revised for Inrebic (fedratinib) for use in members 18 years of age or older.
Kalydeco (ivacaftor) - Medicare	11/02/2020	Policy for Kalydeco (ivacaftor) revised to change minimum patient age requirement from 6 months of age to 4 months of age.
Kalydeco (ivacaftor) - Medicare 2021	01/01/2021	Policy for Kalydeco (ivacaftor) revised to change minimum patient age requirement from 6 months of age to 4 months of age.
Kesimpta (ofatumumab) - Medicare	11/03/2020	New policy for Kesimpta (ofatumumab) requiring diagnosis of a relapsing form of multiple sclerosis.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Lupron Depot and Lupron Depot-Ped (leuprolide acetate for depot suspension) - Medicare 2021	01/01/2021	New policy created for Lupron Depot (leuprolide acetate for depot suspension) and Lupron Depot-Ped (leuprolide acetate for depot suspension to require diagnosis of FDA-approved indication and therapeutic failure, intolerance, or contraindication to Eligard for Lupron Depot products that are indicated for prostatic cancer.
Mavenclad (cladribine) - Medicare	11/03/2020	Policy revised to remove language stating "member is an adult" and to remove documentation requirements that Mavenclad will not be used in combination with other disease modifying therapies and for baseline cancer screening, liver function tests, infection screening, and complete blood count. The latter two criteria were moved to limitations of coverage.
Mayzent (siponimod) - Medicare	11/03/2020	Policy revised to remove language stating "member is an adult" and to remove documentation requirements that Mayzent will not be used in combination with other disease modifying therapies and for baseline cardiac evaluation, liver function tests, ophthalmologic evaluation, and complete blood count. The latter two criteria were moved to limitations of coverage.
Miscellaneous Immunomodulators - Medicare 2021	01/01/2021	Policy revised for Pomalyst (pomalidomide) for use in members 18 years of age and older; and for Revlimid (lenalidomide) for use in members 18 years of age or older for all indications, and for previous marginal zone lymphoma (MZL) treatment.
Oral Hypomethylating Agents - Medicare	03/01/2021	Policy revised to add Onureg (azacitidine) criteria for use in members 18 years of age or older with acute myeloid leukemia (AML) after the member has achieved complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy; and for prescriber attestation that the member is unable to complete intensive curative therapy.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Orkambi (lumacaftor/ivacaftor) – Medicare	01/01/2021	Policy revised for Orkambi (lumacaftor/ivacaftor) reauthorization to ask for documentation of FEV_1 improvement instead of just attestation and removed "Revised respiratory domain score" requirement for CF Questionnaire.
PI3K Inhibitors - Medicare 2021	01/01/2021	Policy revised for Piqray (alpelisib) for use in members 18 years of age or older.
RET Kinase Inhibitors - Medicare	02/16/2021	Policy revised to include Gavreto (pralsetinib) with criteria of age 18 years or older and diagnosis of metastatic non-small cell lung cancer classified as RET (rearranged during transfection) fusion-positive as detected by an FDA approved test.
Soliris (eculizumab) - Medicare 2021	01/01/2021	Policy revised for Soliris (eculizumab) to remove mitoxantrone as a disqualifying agent. Criteria that the member should not use in combination with another monoclonal antibody used for treatment of NMSOD moved to limitations of coverage.
Targretin (bexarotene) - Medicare 2021	01/01/2021	Policy revised for Targretin (bexarotene) for use in members 18 years of age or older and to remove criteria for mycosis fungoides.
Tecentriq (atezolizumab) - Medicare	11/03/2020	Policy revised for Tecentriq (atezolizumab) for use in members with BRAF V600 mutation-positive unresectable or metastatic melanoma, in combination with cobimetinib and vemurafenib.
Tegsedi (inotersen) - Medicare	11/03/2020	Policy revised for Tegsedi (inotersen) that prescriber attests the product is not being used for sensorimotor or autonomic neuropathy unrelated to hereditary amyloidosis. Criteria removed as it is duplicative.
Testosterone (Androgens) - Medicare 2021	01/01/2021	Policy revised to remove criteria allowing for approval of topical ointments for the treatment of vulvar dystrophies in women per CMS direction.
Trelstar (triptorelin pamoate) – Medicare	01/01/2021	New policy created for Trelstar (triptorelin pamoate) to require diagnosis of advanced prostate cancer and using the product for palliative treatment.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Valchlor (mechlorethamine) - Medicare		Policy revised for Valchlor (mechlorethamine) for members with Stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma after receiving at least one of the following skin-directed therapies: topical corticosteroids, topical chemotherapy (e.g. carmustine), local radiation, topical retinoids (e.g. bexarotene, tazarotene), phototherapy, topical imiquimod, total skin electron beam radiation (TSEBT).
Valchlor (mechlorethamine) - Medicare 2021	01/01/2021	Policy revised for Valchlor (mechlorethamine) to be used in members 18 years of age or older.
Venclexta (venetoclax) - Medicare 2021	01/01/2021	Policy revised for Venclexta (venetoclax) for use in members 18 years of age or older.
Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates) - Medicare	11/03/2020	Policy for Xyrem (sodium oxybate) revised to include new medication Xywav (calcium, magnesium, potassium, and sodium oxybates). In order to obtain Xywav (calcium, magnesium, potassium, and sodium oxybates), member must be sensitive to sodium intake because of heart failure, hypertension, or impaired renal function. Name of policy now includes Xywav (calcium, magnesium, potassium, and sodium oxybates).
Yosprala (aspirin/omeprazole) - Medicare 2021	01/01/2021	Policy revised for Yosprala (aspirin and omeprazole) to require step therapy through generic omeprazole or pantoprazole and aspirin and omeprazole (the generic of Yosprala).
Zolinza (vorinostat) - Medicare 2021	01/01/2021	Policy revised for Zolinza (vorinostat) for use in members 18 years of age or older.
ZTLido (lidocaine 1.8% topical system) - Medicare	11/03/2020	Policy revised to require use of Lidoderm OR lidocaine prior to coverage of ZTLido; other criteria still applies
Zytiga and Yonsa (abiraterone acetate) - Medicare 2021	01/01/2021	Policy revised for Zytiga (abiraterone) for use in members 18 years of age or older; and for Yonsa (abiraterone) for use in members 18 years of age or older.
Adalimumab BIOSIMILARS - Medicare	TBD	Policy revised to include updated reauthorization criteria to ensure that the prescriber attests that the member has

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		demonstrated a disease stability or beneficial response to therapy.
Alkindi Sprinkle (hydrocortisone) - Medicare	01/01/2021	New policy created for Alkindi Sprinkle (hydrocortisone) to ensure that members have a diagnosis of adrenocortical insufficiency, are 17 years of age or younger, and have experienced therapeutic failure or intolerance to generic hydrocortisone tablets.
Anabolic Steroids – Medicare	01/01/2021	Policy revised to include target drug Androxy (fluoxymesterone) and member has a diagnosis of one (1) of the following: primary or secondary hypogonadism, is female with a diagnosis of metastatic breast cancer, or is male with a diagnosis of delayed puberty.
Chronic Inflammatory Diseases - Medicare 2021	01/01/2021	Policy revised to include expanded indication of polyarticular juvenile idiopathic arthritis (JIA) for Simponi Aria (golimumab) in members 2 years of age or older with a diagnosis of JIA. Policy revised to include newly FDA-approved Xeljanz (tofacitinib) oral solution and Xeljanz oral tablet in members 2 years of age or older with a diagnosis of juvenile idiopathic arthritis with a step through at least one non-biologic disease-modifying antirheumatic drug.
Conjupri (levamlodipine) - Medicare	TBD	Policy revised for Conjupri (levamlodipine) to require member is 6 years of age and older.
Cystic Fibrosis Inhaled Medications - Medicare	01/01/2021	Policy revised to add Bronchitol (mannitol inhalation powder). Criteria includes member's age 18 years and older, diagnosis of cystic fibrosis, passing of Bronchitol Tolerance Test and that the member will be using Bronchitol in conjunction with standard therapies.
Dymista (azelastine hydrochloride/fluticasone propionate) - Medicare	12/09/2021	New policy created for Dymista (azelastine hydrochloride/fluticasone propionate) to ensure that members have a diagnosis of seasonal allergic rhinitis and have experienced therapeutic failure or intolerance to generic azelastine hydrochloride/fluticasone propionate.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Endari (L-glutamine) - Medicare	01/01/2021	Policy revised for Endari (L-glutamine) to clarify indication to include "acute" complications.
Etanercept BIOSIMILARS - Medicare	TBD	Policy revised to include expanded indication for Erelzi (etanercept-szzs) in members 4 years of age or older for the treatment of plaque psoriasis and updated reauthorization criteria to ensure that the prescriber attests that the member has demonstrated a disease stability or beneficial response to therapy. Policy revised to include updated reauthorization criteria to ensure that the prescriber attests that the member has demonstrated a disease stability or beneficial response to therapy.
Fumarate Products - Medicare 2021	12/01/2021	Policy revised to clarify the types of relapsing multiple sclerosis (e.g. clinically isolated syndrome, relapsing-remitting, or active secondary progressive disease) and to add a step through generic dimethyl fumarate for brand Tecfidera (dimethyl fumarate).
Homozygous Familial Hypercholesterolemia - Medicare 2021	01/01/2021	Policy revised to change treated LDL-C level ≥ 300 mg/dL to member has a LDL-C > 100 mg/dL for homozygous familial hypercholesterolemia (HoFH).
Infliximab BIOSIMILARS - Medicare	TBD	Policy revised to include updated reauthorization criteria to ensure that the prescriber attests that the member has demonstrated disease stability or a beneficial response to therapy.
Lidoderm (lidocaine patch) - Medicare 2021	01/01/2021	Policy revised to include criteria for patients unable to swallow oral medications or unable to take an oral medication due to potential adverse events (e.g. sedation).
Ofev (nintedanib) and Esbriet (pirfenidone) - Medicare	01/01/2021	Moved concomitant use of Ofev and Esbriet from approval criteria to limitations of coverage.
Onfi (clobazam) and Sympazan (clobazam oral film) - Medicare 2021	01/01/2021	Policy revised to apply to new starts only for protected indications.
PCSK9 Inhibitors - Medicare 2021	01/01/2021	Policy revised to remove treated LDL-C levels ≥ 300 mg/dL in homozygous familial hypercholesterolemia (HoFH) or LDL-C

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		levels ≥ 160 mg/dL in heterozygous familial hypercholesterolemia (HeFH) prior to starting a PCSK9 inhibitor. For all indications, revised previous statin criteria to member has a LDL-C > 100 mg/dL in HeFH and HoFH or LDL-C > 70 in hypercholesterolemia with atherosclerotic cardiovascular disease and primary hyperlipidemia despite use with a maximally tolerated statin or member is statin intolerant. If member is statin intolerant member must show rhabdomyolysis or skeletal-related muscle symptoms while receiving at least two (2) separate trials of different statins which resolved upon discontinuation of the statins or one (1) of the following: creatinine kinase increase to 10 times upper limit of normal, liver function tests increase to 3 times upper limit of normal, or hospitalization due to severe statin-related adverse event. Removed criteria of concurrent statin therapy.
Programmed Death Receptor Therapies – Medicare	12/10/2020	Policy revised for Keytruda (pembrolizumab) for use in adult patients with relapsed or refractory classical Hodgkin Lymphoma (cHL); for Keytruda (pembrolizumab) for use in pediatric patients aged 6 months and older with refractory cHL, or cHL that has relapsed after 2 or more lines of therapy; for Keytruda (pembrolizumab) for use in combination with chemotherapy for patients with locally recurrent unresectable or metastatic triple negative breast cancer whose tumors express PD-L1 (Combined Positive Score [CPS] ≥ 10) as determined by an FDA-approved test; for Opdivo (nivolumab) for use in unresectable malignant pleural mesothelioma as first line treatment in combination with ipilimumab.
Rytary (carbidopa-levodopa) - Medicare	01/01/2021	New policy for Rytary (carbidopa/levodopa extended release capsules) created to require a diagnosis of one of the following: Parkinson's disease, post-encephalitic parkinsonism or parkinsonism after carbon

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		monoxide or manganese intoxication, as well as the use of one of the following: carbidopa/levodopa tablets or orally disintegrating tablets (ODT) OR carbidopa/levodopa ER OR carbidopa/levodopa/entacopone tablets in order to receive coverage for Rytary.
Testosterone (Androgens) - Medicare	01/01/2021	Policy revised to include target products Testopel (testosterone) and testosterone subcutaneous implant (already filed for 2021).
Wakix (pitolisant) - Medicare	12/10/2020	Policy revised to include expanded indication of cataplexy in adult patients with narcolepsy. Addition of requirement of documentation of baseline cataplexy episodes. Reauthorization criteria revised to require improvement of symptoms of narcolepsy or cataplexy.
ZTLido (lidocaine 1.8% topical system) - Medicare 2021	01/01/2021	Policy revised to include criteria for patients unable to swallow oral medications or unable to take an oral medication due to potential adverse events (e.g. sedation). Diagnosis of Diabetic Peripheral Neuropathy removed from policy.
Austedo (deutetrabenazine) - Medicare	02/03/2021	Policy revised for Austedo (deutetrabenazine) to move criteria to limitations of coverage stating the member should not be actively suicidal and if the member has a diagnosis of depression, the prescriber attests the member is receiving adequate treatment (e.g. cognitive behavioral therapy, pharmacotherapy).
Benlysta (belimumab) - Medicare	02/09/2021	Policy revised to include expanded indication for Benlysta (belimumab) subcutaneous for members 18 years of age or older for active lupus nephritis. The prescriber submits documentation of positive anti-nuclear antibody (ANA) titer (≥1:80) or anti-double-stranded DNA antibody (anti-dsDNA) ≥ 30 IU/mL. The member has experienced therapeutic failure, contraindication, intolerance, or insufficient response while on two (2) standard of care drug classes: corticosteroids, antimalarials, and immunosuppressives. The will continue to

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		receive concomitant standard of care which includes corticosteroids with one (1) of the following: mycophenolate for induction followed by mycophenolate for maintenance or cyclophosphamide for induction followed by azathioprine for maintenance.
Chronic Inflammatory Diseases - Medicare	02/10/2021	Policy revised to include expanded indication for Kineret (anakinra) in members with a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) and the member has experienced therapeutic failure or intolerance to at least one (1) corticosteroid, or all corticosteroids are contraindicated. The recommended starting dose is 1-2 mg/kg daily. Documentation of member weight and prescribed Kineret dose consistent with dosing below is required: The dose can be individually adjusted to a maximum of 8 mg/kg daily. Kineret may be divided into twice daily dosing.
EGFR Kinase Inhibitors - Medicare	02/24/2021	Criteria added for Tagrisso (osimertinib) for use as adjuvant therapy for non-small cell lung cancer after tumor resection with an epidermal growth factor receptor (EGFR) exon 19 deletion or EGFR exon 21 L858 mutation.
Evenity (romosozumab-aqqg) - Medicare	02/15/2021	Policy revised for Evenity (romosozumab-aqqg) to clarify that history of fracture is singular and remove age of 50 years or older when providing result of Fracture Risk Assessment (FRAX) Tool. Criteria revised that member is 40 years of age or older in those with a history of glucocorticoid use.
Flector and Licart (diclofenac epolamine) - Medicare	02/01/2021	Addition of Licart topical patch to policy. Criteria requires diagnosis of acute pain due to minor strains, sprains, and contusions and therapeutic failure, contraindication, or intolerance to two (2) oral generic NSAIDs, one of which must be diclofenac. Criteria allows for intolerance or hypersensitivity to oral NSAIDs or history/high risk for adverse gastrointestinal effects associated with oral NSAID use.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Hepatitis C Oral Therapy - Medicare	02/04/2021	Policy revised for Hepatitis C preferred products HCV Genotype 1, 4, 5, and 6 with prior liver transplant and compensated cirrhosis status to update from Harvoni (ledipasvir/sofosbuvir) + ribavirin x 12 weeks to Harvoni ledipasvir/sofosbuvir) x 12 weeks.
Hereditary Angioedema - Medicare	03/01/2021	Policy revised to include newly FDA-approved Orladeyo (berotralstat) for members 12 years of age or older for prophylactic management against angioedema attacks of HAE where the member has a past medical history of at least one (1) symptom of moderate or severe angioedema attack, the member's medications known to cause angioedema (i.e. ACE-inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate, and the member should not be on two (2) prophylactic therapies simultaneously. Policy includes requirement of C4 or C1INH laboratory values and a family history of HAE or FXII mutation.
Hetlioz and Hetlioz LQ (tasimelteon) - Medicare	02/16/2021	Policy revised to add criteria for new product and new indication: Hetlioz LQ for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in pediatric patients 3 years of age to 15 years of age. Also added new criteria for Hetlioz capsules for the treatment of nighttime sleep disturbances in SMS in patients 16 years of age and older.
Interleukin (IL)-5 Antagonists - Medicare	05/03/2021	Policy revised for Nucala (mepolizumab) and Fasenra (benralizumab) to require a diagnosis of severe asthma evidence by one (1) of the following: pretreatment forced expiratory volume in 1 second (FEV1) less than 80% predicted; or FEV1 reversibility of at least 12% and 200 milliliters (mL) after albuterol (salbutamol) administration. For Nucala (mepolizumab) removed "high dose" requirement from inadequate response with high-dose inhaled corticosteroids. Added quantity level limits outlining Fasenra

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		(benralizumab) induction dosing: One (30 mg) prefilled syringe or auto-injector every 4 weeks for 3 doses and maintenance dosing: One (30 mg) prefilled syringe or auto-injector every 8 weeks.
Kalydeco (ivacaftor) - Medicare	02/04/2021	Policy revised to include updated examples of cystic fibrosis transmembrane conductance regulator (CFTR) gene mutations that produce CFTR protein and are responsive to Kalydeco (ivacaftor).
Klisyri (tirbanibulin) – Medicare	02/04/2021	New policy created for Klisyri (tirbanibulin) for the member to have a diagnosis of actinic keratosis of the face or scalp and experienced therapeutic failure or intolerance to two of the following agents: generic imiquimod 5% cream, fluorouracil 5% topical cream, and fluorouracil topical solution. Authorization duration for 3 months.
Orgovyx (relugolix) - Medicare	05/04/2021	Policy created for Orgovyx (relugolix) for adult patients with advanced prostate cancer who meet one of the following criteria: biochemical or clinical relapse following local primary intervention, newly diagnosed castration-sensitive metastatic disease, or advanced localized disease.
Oxlumo (lumasiran) - Medicare	03/03/2021	New policy created for Oxlumo (lumasiran) for the member to have a diagnosis of primary hyperoxaluria type 1. Reauthorization criteria included to require prescriber attestation that the member has experienced positive clinical response to therapy as defined by a decrease from baseline in the frequency of kidney stones, in the 24-hour urinary oxalate excretion, in the urinary oxalate: creatinine ratio, or in the plasma oxalate level.
Parathyroid Hormone Analogs - Medicare	02/15/2021	Policy revised for Forteo (teriparatide) and Tymlos (abaloparatide) to clarify that history of fracture is singular and remove age of 50 years or older when providing result of Fracture Risk Assessment (FRAX) Tool. Criteria revised for Forteo (teriparatide) that member is 40 years of age or older in those with a history of glucocorticoid use.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Programmed Death Receptor Therapies - Medicare	05/03/2021	Policy revised for Opdivo (nivolumab) to remove criteria for small cell lung cancer following removal of the indication per FDA.
Prolia (denosumab) - Medicare	02/15/2021	Policy revised for Prolia (denosumab) to clarify that history of fracture is singular and remove age of 50 years or older when providing result of Fracture Risk Assessment (FRAX) Tool. Criteria revised that member is 40 years of age or older in those with a history of glucocorticoid use.
Pulmonary Hypertension	02/15/2021	Policy revised for Tracleer (bosentan) that exception to right heart catheterization may be allowed in pediatric patients if risk outweighs the benefit. If right heart catheterization is not performed, submission of alternative study is to be provided. For all drugs, mean pulmonary arterial pressure (mPAP) changed to > 20 mm Hg at rest from ≥ 25 mmHg and pulmonary vascular resistance (PVR) changed to ≥ 3 Wood units from > 3 Wood units.
RET Kinase Inhibitors - Medicare	02/16/2021	Policy revised to add criteria for new indications for Gavreto (pralsetinib): treatment of adult and pediatric patients 12 years of age and older with either advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy or advanced or metastatic RET fusion positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
Rituximab Products - Medicare	02/05/2021	Policy revised to include three rituximab biosimilars: Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), and Riabni (rituximab-arrx).
Symdeko (tezacaftor/ivacaftor) - Medicare	02/05/2021	Policy revised to include updated examples of cystic fibrosis transmembrane conductance regulator (CFTR) gene mutations that produce CFTR protein and are responsive to Symdeko (tezacaftor-ivacaftor).

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Trikafta (elexacaftor/tezacaftor/ivacaftor) - Medicare	02/05/2021	Policy revised to update Trikafta's (elexacaftor/tezacaftor/ivacaftor) expanded indication.
Vimpat (lacosamide) - Medicare	02/05/2021	Policy revised to include expanded indication of adjunctive treatment of primary generalized tonic-clonic seizures for patients 4 years of age or older.
Xenazine (tetrabenazine) - Medicare	02/05/2021	Policy revised for Xenazine (tetrabenazine) to move criteria to limitations of coverage stating the member should not be actively suicidal and if the member has a diagnosis of depression, the prescriber attests the member is receiving adequate treatment (e.g. cognitive behavioral therapy, pharmacotherapy). Quantity level limits section updated to remove CYP2D6 from genotyping requirements.
Xpovio (selinexor) - Medicare	03/01/2021	Policy revised for Xpovio (selinexor) to add criteria for use in members 18 years of age or older with multiple myeloma, for use in combination with both bortezomib and dexamethasone after the member has received at least one prior therapy for multiple myeloma.
Zokinvy (lonafarnib) - Medicare	03/03/2021	New policy created for Zokinvy (lonafarnib) to require diagnosis of HGPS with a mutation in the LMNA gene OR processing-deficient PL with heterozygous LMNA mutation and progerin-like protein accumulation OR processing-deficient PL with either homozygous ZMPSTE24 mutations or compound heterozygous ZMPSTE24 mutations. Regardless of diagnosis, patient must also be 12 months of age or older and have a BSA of 0.39m2 or above.

*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
Methotrexate Injections - Medicare	02/04/2021	Policy revised to include recently-launched RediTrex (methotrexate) to ensure use for an FDA-approved indication. The member has experienced

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		therapeutic failure or intolerance to oral generic methotrexate tablets.

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)
Breztri Aerosphere (budesonide/formoterol/glycopyrrolate)	10.7 g (1 cannister)	32.1 g (3 cannisters)
Cystadrops (cysteamine) ophthalmic solution	20 mL (4 vials) per 28 days	60 mL (12 vials) per 84 days
Cystaran (cysteamine) ophthalmic solution	60 mL (4 bottles) per 28 days	180 mL (12 bottles) per 84 days
Enspryng (satralizumab-mwge)	1 syringe per 28 days	3 syringes per 84 days
Gavreto (pralsetinib)	4 capsules per day	4 capsules per day
Jynarque (tolvaptan) 15/15MG Blister Card	4 blister cards (56 tablets)	12 blister cards (168 tablets)
Jynarque (tolvaptan) 30/15 MG Blister Card	4 blister cards (56 tablets)	12 blister cards (168 tablets)
Kesimpta (ofatumumab)	1 pen/syringe per 28 days	3 pens/syringes per 84 days
Onureg (azacitidine)	14 tablets per 28 days	42 tablets per 84 days
Sogroya (somapacitan-beco)	4 pens per 28 days	12 pens per 84 days
Trulicity (dulaglutide) 3 mg/0.5 mL	2 mL per 28 days	6 mL per 84 days
Trulicity (dulaglutide) 4.5 mg/0.5 mL	2 mL per 28 days	6 mL per 84 days
Xtandi (enzalutamide) film-coated tablet	40 mg: 3 tablets per day, 80 mg tabs: 2 tabs per day	40 mg: 3 tablets per day, 80 mg tabs: 2 tabs per day
Xywav (calcium/magnesium/potassium/sodium oxybates)	18 mL per day	18 mL per day
Bronchitol (mannitol)	20 capsules per day	20 capsules per day
Eysuvis (loteprednol etabonate) 0.25% ophthalmic suspension	1 bottle per 30 days	1 bottle per 30 days
Qdolo (tramadol) oral solution	40 mL per day	40 mL per day
Xeljanz (tofacitinib) oral solution	10 mL per day	10 mL per day
Gemtesa (vibegron)	1 tablet per day	1 tablet per day
Hetlioz LQ (tasimelteon) oral solution	158 mL (1 bottle)	474 mL (3-158 mL bottles)
Orgovyx (relugolix)	1 tablet per day	1 tablet per day
Orgovyx (relugolix)	2 packs per 365 days	2 packs per 365 days
Orladeyo (berotralstat)	1 capsule per day	1 capsule per day

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Stelara (ustekinumab) intravenous	104 mL per 56 days (1.86 mL per day)	104 mL per 56 days (1.86 mL per day)
Xofluza (baloxavir marboxil) oral suspension	360 mL (18 bottles) per 365 days	360 mL (18 bottles) per 365 days

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