SPECIAL eBULLETIN

JANUARY 2019

FIRST QUARTER 2019 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the First Quarter 2019 update to the Highmark Drug Formularies and pharmaceutical management procedures. The formularies and pharmaceutical management procedures are updated on a quarterly basis, and the following changes reflect the decisions made in November 2018 by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Please reference the guide below to navigate this communication:

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

Important Drug Safety Updates

Valsartan-Containing Products: Update Health Professional and Consumer on Recent Recalled Products

As part of an ongoing investigation into the voluntary recall of valsartan-containing products announced by the FDA in July 2018, there are four additional voluntary recalls. The recalled products contain an impurity, N-nitrosodiethylamine (NDEA), in the active pharmaceutical ingredient (API) manufactured by various manufacturing companies. Not all products containing valsartan are being recalled. The additional four voluntary recalls related to the NDEA impurity detected in the valsartan API include: Sciegen Pharmaceuticals, Inc., labeled as Westminster Pharmaceuticals and Golden State Medical Supply, Inc., Sandoz Inc., Mylan Pharmaceuticals, and Teva Pharmaceuticals. Health care professionals should be aware that the recalled valsartan products pose an unnecessary risk to patients. Therefore, the FDA recommends patients use valsartan-containing medicines made by other companies or consider other available treatment options for the patient's medical condition. Adverse events or side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Zithromax, Zmax (azithromycin): FDA Warning - Increased Risk of Cancer Relapse with Long-Term Use after Donor Stem Cell Transplant

On August 3, 2018, the FDA warned that the antibiotic Zithromax, Zmax (azithromycin) should not be given long-term to prevent a certain inflammatory lung condition in patients with cancers of the blood or lymph nodes who undergo a donor stem cell transplant. Results of a clinical trial found an increased rate of relapse in cancers affecting the blood and lymph nodes, including death, in these patients. The FDA is reviewing additional data and will communicate the conclusions and recommendations when the review is complete. Health care professionals should not prescribe long-term azithromycin for prophylaxis of bronchiolitis obliterans syndrome to patients who undergo donor stem cell transplants because of the increased potential for cancer relapse and death. Adverse events or side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

SGLT2 (sodium-glucose cotransporter-2) Inhibitors for Diabetes: FDA Warning - Rare Occurrences of a Serious Infection of the Genital Area

On August 29, 2018, the FDA warned that cases of a rare but serious infection of the genitals and area around the genitals has been reported with the class of type 2 diabetes medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors. This infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. A new warning about this risk is to be added to the prescribing information of all SGLT2 inhibitors and to the patient Medication Guide. Health care professionals should assess patients for Fournier's gangrene, and if suspected, start treatment immediately with broad-spectrum antibiotics and surgical debridement if necessary. Discontinue the SGLT2 inhibitor, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control. Adverse events or side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Ortho-Novum (norethindrone/ethinyl estradiol tablets) by Janssen Pharmaceuticals: Recall - Due to Incorrect Veridate Dispenser Instructions

On November 2, 2018, Janssen Pharmaceuticals announced a voluntary recall of Ortho-Novum 1/35 and Ortho-Novum 7/7/7 (Lot numbers 18BM114, 18CM120, and 18BM110) due to incorrect Veridate dispenser instructions. As a result of this error, the pills could be taken in the incorrect order, which may place the user at risk for breakthrough bleeding or unintended pregnancy. Adverse events or side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Gilenya (fingolimod): FDA Warning - Severe Worsening of Multiple Sclerosis after Stopping the Medicine

On November 20, 2018, the FDA warned that when the multiple sclerosis (MS) medicine Gilenya (fingolimod) is stopped, the disease can become much worse than before the medicine was started or while it was being taken. This MS worsening is rare, but can result in permanent disability. Health care professionals should do the following: 1) inform their patients before starting treatment about the potential risk of severe increase in disability after stopping Gilenya; 2) carefully observe patients for evidence of an exacerbation of their MS and treat appropriately when Gilenya is stopped; 3) advise patients to seek immediate medical attention if they experience new or worsened symptoms of MS after Gilenya is stopped; 4) test for new or enhancing lesions by magnetic resonance imaging (MRI) if an increase in disability occurs and begin appropriate treatment as needed; and 5) encourage patients to read the patient Medication Guide they receive with their Gilenya prescriptions, which explains benefits and risks of the medicine. Adverse events or side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Highmark Formulary Update – January 2019

SECTION I. Highmark Commercial and Healthcare Reform Formularies

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

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

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

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

Table 1. Products Added
(All products added to the formulary effective in December 2018, unless otherwise noted.)

Brand Name	Generic Name	Comments
Galafold	migalastat	New oral alpha-galactosidase A (alpha-Gal A) pharmacological chaperone drug for treatment of adult patients with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant.
Xofluza	baloxavir marboxil	An antiviral given as a single dose for the treatment of uncomplicated flu in those 12 years and older.
Ajovy*	fremanezumab-vfrm	New calcitonin gene-related peptide antagonist (CGRP) for the preventive treatment of migraines.
Emgality*	galcanezumab-gnlm	New calcitonin gene-related peptide antagonist (CGRP) for the preventive treatment of migraines.

*Product not added to Healthcare Reform formularies.
Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Krintafel*	tafenoquine	Primaquine
Arakoda	tafenoquine	chloroquine, hydroxychloroquine
Annovera*	segesterone acetate and ethinyl estradiol	NuvaRing
Jornay PM*	methylphenidate	methylphenidate ER
Cequa*	cyclosporine	Restasis
Diacomit*	stiripentol	valproic acid, topiramate
Altreno	tretinoin	tretinoin
Pifeltro	doravirine	efavirenz
Delstrigo	doravirine/lamivudine/TDF	Symfi, Odefsey, Complera
Tiglutik	riluzole	riluzole
Xelpros	latanoprost	latanoprost
Vizimpro	dacomitinib	Tagrisso
Xyosted	testosterone enanthate	testosterone enanthate, testosterone gel, testosterone cypionate
Seysara*	sarecycline	minocycline, doxycycline
Nuzyra tablets*	omadacycline	linezolid, moxifloxacin
Qmiiz ODT*	meloxicam ODT	meloxicam tablet
Tibsovo	ivosidenib	Provider discretion
Nivestym	filgrastim-aafi	Provider discretion
Mulpleta	lusutrombopag	Provider discretion
Orkambi oral granules	lumacaftor/ivacaftor	Provider discretion
Oxervate	cenegermin-bkbj	Provider discretion
Inveltys	loteprednol	Provider discretion
Copiktra	duvelisib	Provider discretion
Arikayce	amikacin	Provider discretion
Tegsedi	inotersen	Provider discretion
Talzenna	talazoparib	Provider discretion
Takhzyro	lanadelumab-flyo	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
Tibsovo	ivosidenib
Nivestym	filgrastim-aafi
Mulpleta	lusutrombopag
Orkambi oral granules	lumacaftor/ivacaftor
Galafold	migalastat
Diacomit	stiripentol
Oxervate	cenegermin-bkbj
Takhzyro	lanadelumab-flyo
Pifeltro	doravirine
Delstrigo	doravirine/lamivudine/TDF
Tiglutik	riluzole
Copiktra	duvelisib
Vizimpro	dacomitinib
Arikayce	amikacin
Nuzyra tablets	omadacycline
Tegsedi	inotersen
Talzenna	talazoparib

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

Note: The Progressive Formulary does not apply to Highmark Delaware members; see Highmark Delaware's online Provider Resource Center and access the **Pharmacy Program/Formularies** link for details on the formularies and formulary options that apply to Highmark Delaware members. For your convenience, you may search the following formularies online:

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

Table 1. Formulary Updates (All products added to the formulary effective in December 2018, unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below are preferred products			
Xofluza	baloxavir marboxil	2 - Preferred Brand	An antiviral given as a single dose for the treatment of uncomplicated flu in those 12 years and older.
Ajovy**	fremanezumab-vfrm	2 - Preferred Brand	New calcitonin gene-related peptide antagonist (CGRP) for the preventive treatment of migraines.
Emgality**	galcanezumab-gnlm	2 - Preferred Brand	New calcitonin gene-related peptide antagonist (CGRP) for the preventive treatment of migraines.
Galafold	migalastat	3 - Preferred Specialty	New oral alpha-galactosidase A (alpha-Gal A) pharmacological chaperone drug for treatment of adult patients with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant
Items listed below are non-preferred products			
Krintafel*	tafenoquine	3 - Non-preferred Brand	Primaquine
Arakoda	tafenoquine	3 - Non-preferred Brand	chloroquine, hydroxychloroquine
Annovera*	segesterone acetate and ethinyl estradiol	3 - Non-preferred Brand	NuvaRing
Jornay PM*	methylphenidate	3 - Non-preferred Brand	dextroamphetamine-amphetamine ER
Cequa*	cyclosporine	3 - Non-preferred Brand	Restasis
Altreno	tretinoin	3 - Non-preferred Brand	tretinoin
Xelpros	latanoprost	3 - Non-preferred Brand	latanoprost
Xyosted	testosterone enanthate	3 - Non-preferred	testosterone enanthate,

		Brand	testosterone gel, testosterone cypionate
Seysara*	sarecycline	3 - Non-preferred Brand	minocycline, doxycycline
Qmiiz ODT*	meloxicam ODT	3 - Non-preferred Brand	meloxicam tablet
Inveltys	loteprednol	3 - Non-preferred Brand	Provider discretion
Diacomit*	stiripentol	4 - Non-preferred Specialty	valproic acid, topiramate
Pifeltro	doravirine	4 - Non-preferred Specialty	efavirenz
Delstrigo	doravirine/lamivudine/TDF	4 - Non-preferred Specialty	Symfi, Odefsey, Complera
Tiglutik	riluzole	4 - Non-preferred Specialty	riluzole
Vizimpro	dacomitinib	4 - Non-preferred Specialty	Tagrisso, Tarceva
Nuzyra tablets*	omadacycline	4 - Non-preferred Specialty	linezolid, moxifloxacin
Tegsedi	inotersen	4 - Non-preferred Specialty	Provider discretion
Talzenna	talazoparib	4 - Non-preferred Specialty	Provider discretion
Tibsovo	ivosidenib	4 - Non-preferred Specialty	Provider discretion
Nivestym	filgrastim-aafi	4 - Non-preferred Specialty	Provider discretion
Mulpleta	lusutrombopag	4 - Non-preferred Specialty	Provider discretion
Orkambi oral granules	lumacaftor/ivacaftor	4 - Non-preferred Specialty	Provider discretion
Oxervate	cenegermin-bkbj	4 - Non-preferred Specialty	Provider discretion
Copiktra	duvelisib	4 - Non-preferred Specialty	Provider discretion
Arikayce	amikacin	4 - Non-preferred Specialty	Provider discretion
Takhzyro	lanadelumab-flyo	4 - Non-preferred Specialty	Provider discretion

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
**Product not added to Healthcare Reform formularies
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.

C. Changes to the Highmark Healthcare Reform Essential Formulary

The Essential Formulary is a closed formulary for select Healthcare Reform (HCR) Individual plans. A list of drugs included on the Essential Formulary, listed by therapeutic class, is available at https://client.formularynavigator.com/Search.aspx?siteCode=6571849149.

Table 1. Formulary Updates
(All formulary changes effective in December 2018, unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Xofluza	baloxavir marboxil	3	An antiviral given as a single dose for the treatment of uncomplicated flu in those 12 years and older
Tibsovo	ivosidenib	4	New isocitrate dehydrogenase-1 (IDH1) inhibitor for the treatment of adults with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation
Orkambi oral granules	lumacaftor/ivacaftor	4	New formulation of Orkambi, indicated for the treatment of cystic fibrosis in patients 2 years and older who are homozygous for the F508del mutation in the CFTR gene
Galafold	migalastat	4	New oral alpha-galactosidase A (alpha-Gal A) pharmacological chaperone drug for treatment of adult patients with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant
Items listed below were not added to the formulary			
Krintafel*	tafenoquine	NF	primaquine
Arakoda	tafenoquine	NF	chloroquine, hydroxychloroquine
Annovera*	segesterone acetate and ethinyl estradiol	NF	NuvaRing
Jornay PM*	methylphenidate	NF	methylphenidate ER
Cequa*	cyclosporine	NF	Restasis
Diacomit*	stiripentol	NF	valproic acid, topiramate
Altreno	tretinoin	NF	tretinoin
Pifeltro	doravirine	NF	efavirenz
Delstrigo	doravirine/lamivudine/TDF	NF	Symfi, Odefsey, Complera
Tiglutik	riluzole	NF	riluzole
Xelpros	latanoprost	NF	latanoprost
Vizimpro	dacomitinib	NF	Tarceva, Gilotrif
Xyosted	testosterone enanthate	NF	testosterone enanthate, generic testosterone gel, testosterone cypionate
Seysara*	sarecycline	NF	minocycline, doxycycline
Nuzyra tablet*	omadacycline	NF	linezolid, moxifloxacin
Talzenna	talazoparib	NF	Lynparza
Qmiiz ODT*	meloxicam ODT	NF	meloxicam tablet
Nivestym	filgrastim-aafi	NF	Provider discretion

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Mulpleta	lusutrombopag	NF	Provider discretion
Oxervate	cenegermin-bkbj	NF	Provider discretion
Inveltys	loteprednol	NF	Provider discretion
Ajovy	fremanezumab-vfrm	NF	Provider discretion
Copiktra	duvelisib	NF	Provider discretion
Emgality	galcanezumab-gnlm	NF	Provider discretion
Arikayce	amikacin	NF	Provider discretion
Tegsedi	inotersen	NF	Provider discretion
Takhzyro	lanadelumab-flyo	NF	Provider discretion

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

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Tibsovo (ivosidenib) – Commercial and Healthcare Reform	11/12/2018	New policy created for newly FDA-approved ivosidenib (Tibsovo) to ensure appropriate use in adult members with a diagnosis of relapsed or refractory (R/R) acute myeloid leukemia (AML). The member must be isocitrate dehydrogenase-1 (IDH-1) mutation-positive.
Cequa (cyclosporine) – Commercial and Healthcare Reform	TBD	New policy created for newly FDA-approved cyclosporine (Cequa) to ensure appropriate use in adult members with a diagnosis of dry eye disease who have experienced therapeutic failure, contraindication, or intolerance to artificial tears and cyclosporine (Restasis).
Qbrexza (glycopyrronium) Cloth 2.4% – Commercial and Healthcare Reform	01/07/2019	New policy created for newly FDA-approved glycopyrronium (Qbrexza) to ensure appropriate use in members 9 years of age or older with a diagnosis of primary axillary hyperhidrosis with a Hyperhidrosis Disease Severity Scale (HDSS) score of 3 or 4 and have experienced therapeutic failure, contraindication, or intolerance to at least one prescription-strength aluminum chloride product. Reauthorization criteria includes prescriber attestation that member is experiencing a reduction in sweat production defined as a HDSS score of 2 or lower. Initial authorization duration of 6 months. Reauthorization thereafter of 12 months.
Arakoda and Krintafel (tafenoquine) – Commercial and Healthcare Reform	01/07/2019	New policy created for newly FDA-approved tafenoquine (Arakoda and Krintafel) to ensure appropriate use in members 18 years and older for prophylaxis of malaria and for member 16 years and older for the radical cure of *Plasmodium vivax* malaria who are receiving appropriate antimalarial therapy.
Diacomit (stiripentol) – Commercial and Healthcare	TBD	New policy created for newly FDA-approved stiripentol (Diacomit) to ensure appropriate use in members 2 years of

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Reform		age and older who are also taking clobazam for the treatment of seizures associated with Dravet syndrome.
Tiglutik (riluzole) – Commercial and Healthcare Reform	01/07/2019	New policy created for newly FDA-approved riluzole (Tiglutik) to ensure appropriate use in patients with amyotrophic lateral sclerosis (ALS) with documented inability to swallow tablets.
Oxervate (cenegermin-bkbj) – Commercial and Healthcare Reform	12/24/2018	New policy created for newly FDA-approved cenegermin-bkbj (Oxervate) to ensure appropriate use in members with neurotrophic keratitis (NK) who are 2 years of age or older. There is documentation that NK is in the left, right, or both eyes. There is documentation of diagnosis with reduced corneal sensitivity testing, slit-lamp examination, and dilated funduscopic examination. The member has experienced therapeutic failure, contraindication, or intolerance to artificial tears. Reauthorization criteria is for one eye and includes that the member is 2 years of age or older, documentation that the eye affected is different from the initial authorization, documentation of diagnosis with reduced corneal sensitivity testing, slit-lamp examination, and dilated funduscopic examination, and the member has experienced therapeutic failure, contraindication, or intolerance to artificial tears. Reauthorization will not be approved for both eyes. Quantity limitations to override coding for both eyes included. Authorization duration of 8 weeks.
Galafold (migalastat) – Commercial and Healthcare Reform	11/12/2018	New policy created for newly FDA-approved migalastat (Galafold) to ensure appropriate use in adult members with a confirmed diagnosis of Fabry disease. The member must have an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.
Vizimpro (dacomitinib) – Commercial and Healthcare Reform	01/07/2019	New policy created for newly FDA-approved dacomitinib (Vizimpro) to ensure appropriate use in members with a confirmed diagnosis of metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R substitution mutations.
Copiktra (duvelisib) – Commercial and Healthcare Reform	01/07/2019	New policy created for newly FDA-approved duvelisib (Copiktra) to ensure appropriate use in members over 18 years old with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies; as well as relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies.
Talzenna (talazoparib) – Commercial and Healthcare Reform	11/12/2018	New policy created for newly FDA-approved talazoparib (Talzenna) to ensure appropriate use in members with a confirmed diagnosis of deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer and that were previously treated with chemotherapy in the neoadjuvant, adjuvant and/or metastatic setting.
Qmiiz ODT (meloxicam) – Commercial and Healthcare	TBD	New policy created for newly FDA-approved meloxicam (Qmiiz ODT) to ensure appropriate use in members with a confirmed

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Reform		diagnosis of rheumatoid arthritis, osteoarthritis, or juvenile rheumatoid arthritis after trial and failure or intolerance to generic meloxicam and two additional nonsteroidal anti-inflammatory drugs (NSAIDs).
Tegsedi (inotersen) – Commercial and Healthcare Reform	01/07/2019	New policy created to ensure appropriate use of inotersen (Tegsedi) for the indication of polyneuropathy associated with hereditary amyloidosis. Initial authorization criteria ensure appropriate criteria and neurologic markers to help validate stability or improvement upon re-authorization.
Onpattro (patisiran) – Commercial and Healthcare Reform	01/07/2019	New policy created to ensure appropriate use of patisiran (Onpattro) for the indication of polyneuropathy associated with hereditary amyloidosis. Initial authorization criteria ensure appropriate criteria and neurologic markers to help validate stability or improvement upon re-authorization.
Arikayce (amikacin) – Commercial and Healthcare Reform	TBD	New policy created to ensure appropriate use of amikacin (Arikayce) in members with refractory *Mycobacterium avium complex* (MAC) lung disease.
Doptelet (avatrombopag) and Mulpleta (lusutrombopag) – Commercial and Healthcare Reform	01/07/2019	Policy revised to include newly FDA-approved lusutrombopag (Mulpleta) to ensure appropriate use in adult patients with thrombocytopenia who have chronic liver disease (CLD) and are scheduled to undergo a procedure.
Tretinoin Therapy – Commercial and Healthcare Reform	01/07/2019	Policy revised to add tretinoin lotion (Altreno) as a targeted therapy.
Opioid Management – Commercial	02/01/2019	Policy revised to include a Morphine Equivalent Daily Dose limit.
Opioid Management – Healthcare Reform	02/01/2019	Policy revised to include a Morphine Equivalent Daily Dose limit.
CGRP Inhibitors – Commercial and Healthcare Reform	11/12/2018	Policy revised to include two recently approved CGRP inhibitors: fremanezumab (Ajovy) and galcanezumab (Emgality), in addition to erenumab (Aimovig), to ensure appropriate use for prevention of episodic migraine (EM) or chronic migraine (CM) in adults. Policy criteria include initial authorization to confirm the appropriate diagnosis, document average number of monthly migraine days, attestation that the headaches are not caused by medication rebound, overutilization, or lifestyle factors, and attestation of trial and failure of two alternative prophylactic medications. Re-authorization criteria include documentation of improvement from baseline, as measured by a reduction in migraine frequency (e.g. reduction in average monthly migraine days or number of migraine episodes by 50% [EM] or 30% [CM]).
CFTR Modulators – Commercial and Healthcare Reform	01/07/2019	Policy revised to add new formulation lumacaftor-ivacaftor (Orkambi) granules along with authorization criteria that member is 2 to 5 years of age or inability to swallow tablets,

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		diagnosis of cystic fibrosis, and homozygous F508del mutation as detected by an FDA-approved test. Added ivacaftor's (Kalydeco's) expanded indication for use in patients 12 months of age or older.
Hereditary Angioedema – Commercial and Healthcare Reform	11/12/2018	Policy revised to include lanadelumab-flyo (Takhzyro) along with authorization criteria that the member displays clinical laboratory performance for hereditary angioedema (HAE), diagnosis of HAE, medications known to cause angioedema have been evaluated and discontinued and documentation of the member's body weight has been provided.
Epidiolex (cannabidiol solution) – Commercial and Healthcare Reform	11/12/2018	Policy revised to remove the requirement for "monotherapy" with standard of care drugs prior to approval of cannabidiol (Epidiolex).
Xtandi (enzalutamide) – Commercial and Healthcare Reform	11/12/2018	Policy revised to update authorization duration from lifetime to 12 months. Reauthorization criteria added to ensure member is tolerating therapy and experiencing disease improvement or delayed disease progression.
Calquence (acalabrutinib) – Commercial and Healthcare Reform	11/12/2018	Policy revised to update to 12-month approval duration. Reauthorization criteria added documenting therapeutic response (disease improvement or delayed disease progression).
Lonsurf (trifluridine-tipiracil) – Commercial and Healthcare Reform	11/12/2018	Policy revised to update to 12-month approval duration. Reauthorization criteria added documenting therapeutic response (disease improvement or delayed disease progression).
Miscellaneous Immunomodulators – Commercial and Healthcare Reform	11/12/2018	Policy revised to update to 12-month approval duration. Reauthorization criteria added documenting therapeutic response (disease improvement or delayed disease progression).
Alcortin A – Commercial and Healthcare Reform	11/12/2018	Policy revised to add reauthorization criteria to ensure members are responding to therapy and to decrease authorization duration from lifetime to 3 months.
Interleukin-1β blockers – Commercial and Healthcare Reform	11/12/2018	Policy revised to update authorization duration from lifetime to 12 months and add reauthorization criteria to ensure that the member is stable on therapy.
Nascobal (cyanocobalamin) – Commercial and Healthcare Reform	11/12/2018	Policy revised to update FDA indication to include dietary deficiency of vitamin B12 occurring in strict vegetarians, malabsorption of vitamin B12 resulting from structural or functional damage to the stomach or to the ileum, inadequate secretion of intrinsic factor resulting from lesions or gastric atrophy, competition for vitamin B12 by intestinal parasites or bacteria, or inadequate utilization of vitamin B12. Authorization criteria revised to update Schilling test and removal of requirement that member has positive intrinsic factor antibodies. Reauthorization criteria added to ensure member is experiencing positive clinical response.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Pulmonary Hypertension – Commercial and Healthcare Reform	11/12/2018	Policy revised to include step therapy requirement for tadalafil (Adcirca), including trial and failure of generic sildenafil.
Spinraza (nusinersen) – Commercial and Healthcare Reform	11/12/2018	Policy revised to expand coverage for types I, II, and III spinal muscular atrophy (SMA), documentation of the number of SMN2 genes and introduction of reauthorization criteria to demonstrate stability or improvement post-therapy.
Tecfidera (dimethyl fumarate) – Commercial and Healthcare Reform	11/12/2018	Policy revised to clarify appropriate age limits for use of dimethyl fumarate (Tecfidera). The approval duration was updated from 12 to 24 months.
Nerlynx (neratinib) – Commercial and Healthcare Reform	11/12/2018	Policy revised to introduce reauthorization criteria to demonstrate delayed disease progression or demonstrate disease improvement. Duration of Authorization decreased from a lifetime to one year.
Idhifa (enasidenib) – Commercial and Healthcare Reform	11/12/2018	Policy revised to introduce reauthorization criteria to demonstrate delayed disease progression or demonstrate disease improvement.
Valchlor (mechlorethamine) – Commercial and Healthcare Reform	11/12/2018	Policy revised to introduce reauthorization criteria to demonstrate delayed disease progression or demonstrate disease improvement.
Zolinza (vorinostat) – Commercial and Healthcare Reform	11/12/2018	Policy revised to introduce reauthorization criteria to demonstrate delayed disease progression or demonstrate disease improvement. Duration of Authorization decreased from a lifetime to one year.
Kinase Inhibitors – Commercial and Healthcare Reform	11/12/2018	Policy revised to include expanded indication for lenvatinib (Lenvima) for the treatment of unresectable hepatocellular carcinoma. Policy duration revised to 12 months. Reauthorization criteria added documenting therapeutic response (disease improvement or delayed disease progression).
Austedo (deutetrabenazine) – Commercial and Healthcare Reform	09/01/2018	Policy revised to remove requirement for trial and failure of generic tetrabenazine for all applicable indications.
Targretin (bexarotene) – Commercial and Healthcare Reform	11/12/2018	Policy revised to introduce reauthorization criteria to demonstrate delayed disease progression or demonstrate disease improvement.
Benlysta (belimumab) – Commercial and Healthcare Reform	11/12/2018	Policy revised to add reauthorization criteria to ensure patients are stable or improving on therapy.
Natpara (parathyroid hormone) – Commercial and Healthcare Reform	11/12/2018	Policy revised to ensure parathyroid hormone (Natpara) will be used in patients whose hypoparathyroidism is uncontrolled despite treatment with calcium and active vitamin D and to require documentation of serum calcium level and vitamin D stores prior to approval. Reauthorization criteria were also added.
Parathyroid Hormone Analogs – Commercial and	11/12/2018	Policy revised to clarify language requiring step through abaloparatide (Tymlos) in females only. Additionally, criteria for

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Healthcare Reform		glucocorticoid-induced osteoporosis were added to teriparatide (Forteo). Updated to note that policy does not apply to the Commercial NSF.
Ingrezza (valbenazine) – Commercial and Healthcare Reform	09/01/2018	Policy revised to remove requirement for trial and failure of generic tetrabenazine for all applicable indications.
Hemlibra (emicizumab) – Commercial and Healthcare Reform	11/12/2018	Policy revised to include updated indication of hemophilia A prophylaxis with or without factor VIII inhibitors.
Provigil (modafinil) and Nuvigil (armodafinil) – Commercial and Healthcare Reform (+ Delaware Only policy)	11/12/2018	Policy revised to include higher dosing and split dosing based on the recommendations from guidelines by the American Academy of Sleep Medicine.
Chronic Inflammatory Disease – Commercial and Healthcare Reform	11/12/2018	Policy revised to include expanded indication for tocilizumab (Actemra) for the treatment of systemic juvenile idiopathic arthritis (SJIA) and to make abatacept (Orencia SC) remain as non-preferred within the polyarticular juvenile idiopathic arthritis (PJIA) indication, but to now require a trial of two step 1 (Enbrel, Humira) or step 2 (Actemra) agents. Policy revised to require a trial of adalimumab (Humira) first within the polyarticular juvenile idiopathic arthritis (PJIA) indication only. Policy revised to include expanded indications for adalimumab (Humira) for patients 12 years of age and older for hidradenitis suppurativa and for patients 2 years of age and older for uveitis.
Chronic Inflammatory Disease – Commercial and Healthcare Reform	01/01/2019	Policy revised to make tofacitinib (Xeljanz and Xeljanz XR) preferred for psoriatic arthritis and tofacitinib (Xeljanz only) preferred for ulcerative colitis for 01/01/2019.
Hepatitis C Oral Agents – Commercial and Healthcare Reform	11/12/2018	Policy revised to include additional Limitations of Coverage, where coverage of ledipasvir/sofosbuvir (Harvoni) for an 8-week duration for patients who are African-American or HIV co-infected should be denied based on the lack of clinical data.
Testosterone (Androgens) – Healthcare Reform	11/12/2018	Policy revised to specifically include delayed puberty within the approval criteria and to decrease authorization duration from lifetime to 12 months. The new product testosterone enanthate (Xyosted) was also added.
Testosterone (Androgens) – Commercial	11/12/2018	Policy revised to specifically include delayed puberty within the approval criteria and to decrease authorization duration from lifetime to 12 months. Additionally, the new product testosterone enanthate (Xyosted) was added and the step requirement altered to require branded products (including Androgel 1.62%) to step through a generic topical testosterone prior to approval.
Dupixent (dupilumab) – Commercial and Healthcare Reform	11/12/2018	Policy revised to include updated indication for eosinophilic-phenotype asthma and oral corticosteroid dependent asthma; with confirmation of diagnosis and failure of ICS+LABA or high-

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		dose corticosteroids.
Parathyroid Hormone Analogs – Commercial NSF	01/01/2019	Policy revised to outline coverage of teriparatide (Forteo) and abaloparatide (Tymlos) for Commercial NSF. Both products require documentation of high risk of fracture and therapeutic failure to at least one bisphosphonate. A step through Tymlos prior to Forteo was removed for Commercial NSF.
Hepatitis C Oral Agents – Commercial NSF	01/01/2019	Policy revised to outline coverage of Hepatitis C drugs for Commercial NSF. Preferred regimens include sofosbuvir/velptasvir (Epclusa), ledipasvir/sofosbuvir (Harvoni), sofosbuvir/velpatasvir/voxilaprevir (Vosevi) and elbasvir/grazoprevir (Zepatier).
Fertility – Commercial and Healthcare Reform	11/12/2018	Policy revised to include coverage criteria for First-Progesterone VGS in women with corpus luteum insufficiency.

*For policies that require step therapy, an exception may be made for commercial and HCR members enrolled in a West Virginia plan. For additional details, refer to pharmacy policy bulletin J-513 (West Virginia – Step Therapy Override Exception).
**All effective dates are tentative and subject to delay pending internal review or approval.

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Xelpros (latanoprost) – Commercial and Healthcare Reform	01/01/2019	New policy created for a preservative-free latanoprost (Xelpros) which requires appropriate usage (18 years of age and diagnosis of open angle glaucoma or ocular hypertension) and in addition, member must fail, have intolerance, or a contraindication to two other ophthalmic products to decrease intraocular pressure, one of which must be generic latanoprost. However, if the member cannot tolerate eye drops with a benzalkonium chloride preservative, then Xelpros can be approved.
Carbinoxamine 6 mg – Commercial	01/01/2019	New policy created for carbinoxamine 6 mg tablets to ensure appropriate use in members with seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods, mild, uncomplicated allergic skin manifestations of urticaria and angioedema, dermatographism, anaphylactic reactions after acute manifestations have been controlled adjunctive to epinephrine and other standard measures, or hypersensitivity reactions to blood or plasma who are 2 years of age or older. The member has experienced therapeutic failure, contraindication, or intolerance to carbinoxamine 4 mg tablets and to two different antihistamines. Reauthorization criteria includes prescriber attestation that member is experiencing a positive clinical response to therapy. Authorization duration of up to 12 months.
Non-Preferred Angiotensin Receptor Blockers and	TBD	Prospective policy to be implemented when valsartan products are more readily available, for use of preferred products prior to

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Combinations		the use of non-preferred generic and brand-name products.
Seysara (sarecycline) – Commercial and Healthcare Reform	TBD	New policy created for newly FDA-approved sarecycline (Seysara) to ensure proper selection of patients for treatment according to product labeling, clinical studies, and guidelines to encourage use of first-line safe and effective therapies (for treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients ≥ 9 years of age) prior to the use of Seysara.
Topical Acne Medications – Healthcare Reform	01/01/2019	Policy revised to include newly FDA-approved tretinoin (Altreno) lotion for the treatment of acne.
Minocycline Products – Commercial and Healthcare Reform	01/01/2019	Policy revised to include the recently launched product, minocycline (Minolira).
Opioid Dependence Therapy – Commercial and Healthcare Reform	TBD	Policy revised to include the newly approved FDA product (09/07/2018). Buprenorphine/naloxone (Cassipa) is a sublingual film strip containing 16 mg of buprenorphine and 4 mg of naloxone. It is to be administered as a single daily dose. Policy includes quantity based on buprenorphine content that is covered over a rolling period of 25 days.
Rhopressa (netarsudil) – Commercial and Healthcare Reform	01/01/2019	Policy revised to note that this does not apply to plans with the Commercial National Select Formulary (NSF).
Rhopressa (netarsudil) – Commercial NSF	01/01/2019	New policy created for Commercial NSF to require trial of generic latanoprost in adults with open-angle glaucoma or ocular hypertension. Step requirements were reduced from trial of two alternatives for Commercial NSF.
Latuda (lurasidone) – Healthcare Reform	01/01/2019	New policy targeting lurasidone (Latuda) which will require new starts to try and fail preferred formulary alternatives.
Leukotriene Modifiers (Accolate, Zyflo) – Commercial	11/12/2018	Policy revised to update authorization duration from lifetime to 12 months. Reauthorization criteria added requiring prescriber attestation that member has experienced positive clinical response.
Amrix (cyclobenzaprine) – Commercial and Healthcare Reform	11/12/2018	Policy revised to remove cyclobenzaprine (Fexmid), since it is off the market. Policy revised to update authorization duration from lifetime to 12 months. Policy revised to include reauthorization criteria where provider provides attestation of improvement or response to cyclobenzaprine (Amrix).
Duexis (ibuprofen/famotidine) – Commercial and Healthcare Reform	11/12/2018	Policy revised to update authorization duration from lifetime to 12 months. Policy revised to include reauthorization criteria where provider provides attestation of improvement or response to ibuprofen/famotidine (Duexis).
Xeloda (capecitabine) – Commercial and Healthcare Reform	11/12/2018	Policy revised to introduce reauthorization criteria to demonstrate delayed disease progression or demonstrate disease improvement. Duration of authorization decreased from a lifetime to one year.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Diabetic Test Strips Quantity Limitation – Commercial and Healthcare Reform	11/12/2018	Policy revised to reflect approval criteria for more than seven diabetic test strips per day (as opposed to six per day).
Epinephrine Auto-Injectors – Commercial and Healthcare Reform	08/21/2018	Policy revised to allow for approval of epinephrine (Auvi-Q) 0.1 mg in patients less than 15 kg. Additionally, the requirement for patient education was removed and placed in the background section.
Antifungal – Commercial and Healthcare Reform	11/12/2018	Policy revised to allow additional quantities of itraconazole (Sporanox) and (Onmel) to be approved for any fungal infection other than onychomycosis.
Acute Migraine Therapies – Commercial and Healthcare Reform	11/12/2018	Policy revised to include language allowing for additional quantities of acute medication to be approved for members with cluster headaches who are on prophylactic therapy and to include zolmitriptan (Zomig) nasal spray as a targeted therapy.

For policies that require step therapy, an exception may be made for Commercial and HCR members enrolled in a West Virginia plan. For additional details, refer to pharmacy policy bulletin J-513 (West Virginia – Step Therapy Override Exception).
All effective dates are tentative and subject to delay pending internal review or approval.
Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria.

3. Formulary Program

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria
General Non-Formulary Request Criteria – Delaware – Healthcare Reform	01/01/2019	New policy created to outline the criteria for approval for a non-formulary medication for members with the Delaware Healthcare Reform Essential formulary.
General Non-Formulary Request Criteria – Healthcare Reform	11/12/2018	Policy revised to reflect that policy only applies to members in Pennsylvania and West Virginia with the Essential formulary. Duration of Authorization decreased from a lifetime to one year.
General Non-Formulary Request Criteria – Commercial	11/12/2018	Policy revised to remove targeted products no longer on the market or that no longer warrant specific non-formulary criteria. General criteria were updated to remove extended release and combination product subsections of the approval criteria. These products will be reviewed using the general non-formulary criteria section. Duration of authorization decreased from a lifetime to one year.
General Non-Formulary Request Criteria – Commercial NSF	01/01/2019	Policies updated to reflect 01/01/2019 changes to the NSF formulary exclusions and preferred alternatives outlined in the policy.

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

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
Ajovy (fremanezumab) 225 mg/1.5 mL	3 syringes per 90 days	3 syringes per 90 days
Annovera (segesterone acetate and ethinyl estradiol) 103 mg/17.4 mg*	1 vaginal ring per year	1 vaginal ring per year
Arikayce (amikacin) 590 mg/8.4 mL	1 box (28 vials) per 28 days	3 boxes (84 vials) per 84 days
Cequa (cyclosporine) all strengths*	1 box (60 vials) per 30 days	3 boxes (180 vials) per 90 days
Dupixent (dupilumab) 200 mg/1.14 mL	2 syringes per 28 days	6 syringes per 84 days
Emgality (galcanezumab) 120 mg/mL	1 syringe per 30 days	3 syringes per 90 days
Galafold (migalastat) 123 mg	14 capsules per 28 days	42 capsules per 84 days
Humira Psoriasis-uveitis starter kit all strengths	1 kit per 365 days	1 kit per 365 days
Humira Crohn-UC-HS starter kit all strengths	1 kit per 365 days	1 kit per 365 days
Krintafel (tafenoquine) 150 mg*	2 tablets per lifetime	2 tablets per lifetime
Mulpleta (lusutrombopag) 3 mg (7 tablet blister pack	7 tablets per 28 days	7 tablets per 28 days
Onpattro (patisiran) 10 mg/5 mL	3 syringes per 21 days	9 syringes per 63 days
Oxervate (cenegermin-bkbj) 0.002% (20 mcg/mL) contains 7 vials in 1 carton (1 vial per eye per day)	8 cartons (56 vials) per 8 weeks	8 cartons (56 vials) per 8 weeks
Takhzyro (lanadelumab-flyo) 300 mg/2 mL	2 single-dose vials per 28 days	6 single-dose vials per 84 days
Tegsedi (inotersen) 284 mg/1.5 mL	4 syringes per 28 days	12 syringes per 84 days
Tiglutik (riluzole) 50 mg/10 mL	2 multiple-dose bottles per 30 days	6 multiple-dose bottles per 90 days

*Effective date to be determined.

Table 2. Quantity Level Limits – Quantity per Dispensing Event – Commercial and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Xelpros (latanoprost PF) 50 mcg/mL (0.005%)	2.5 mL bottle	7.5 mL bottle
Xofluza (baloxavir marboxil) all strengths	2 tablets	2 tablets
Nuzyra (omadacycline) tablets 150 mg*	30 tablets	30 tablets

*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
carbinoxamine tablets 6 mg	4 tablets per day
Cassipa (buprenorphine/naloxone) 16 mg/4 mg*	1 sublingual film per day
Copiktra (Duvelisib) all strengths	2 capsules per day
Delstrigo (doravirine/lamivudine/TDF) 100 mg/300 mg/300 mg	1 tablet per day
Diacomit (stiripentol) 250 mg*	3 capsules or packets per day
Diacomit (stiripentol) 500 mg*	6 capsules or packets per day
Lenvima (lenvatinib) 12 mg	12 mg per day
Lenvima (lenvatinib) 4 mg	4 mg per day
Jornay PM (methylphenidate ER) all strengths*	1 capsule per day
Natpara (parathyroid hormone) all strengths*	1 syringe per day
Orkambi (lumacaftor/ivacaftor) oral granules 100 mg/125 mg and 150 mg/188 mg	2 packets of granules per day
Pifeltro (doravirine) 100 mg	2 tablets per day
Qmiiz ODT (meloxicam) all strengths*	1 oral disintegrating tablet per day
Talzenna (talazoparib) 1 mg	1 capsule per day
Talzenna (talazoparib) 0.25 mg	3 capsules per day
Tibsovo (ivosidenib) 250 mg	2 tablets per day
Vizimpro (dacomitinib) all strengths	1 tablet per day
Xarelto (rivaroxiban) 2.5 mg	2 tablets per day

*Effective date to be determined.
Members can receive up to the maximum day supply according to their benefits, but the daily limit must not be exceeded for each individual day.

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

SECTION II. Highmark Medicare Part D Formularies

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

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

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

Brand Name	Generic Name	Comments
Xofluza	baloxaavir marboxil	Provider discretion

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
Inveltys	loteprednol	Durezol
Altreno	tretinoin	tretinoin
Xelpros	latanoprost	latanoprost
Seysara	sarecycline	minocycline, doxycycline
Qmiiz ODT	meloxicam ODT	meloxicam tablet
Krintafel	tafenoquine	Provider discretion
Omegaven	fish oil triglycerides	Provider discretion
Arakoda	tafenoquine	Provider discretion
Annovera	segesterone acetate and ethinyl estradiol	Provider discretion
Jornay PM	methylphenidate	Provider discretion
Cequa	cyclosporine	Provider discretion
Ajovy	fremanezumab-vfrm	Provider discretion
Emgality	galcanezumab-gnlm	Provider discretion
Xyosted	testosterone enanthate	Provider discretion

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

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

Table 1. Preferred Products

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

Brand Name	Generic Name	Comments
Xofluza	baloxavir marboxil	Provider discretion

Table 2. Non-Preferred Products

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

Brand Name	Generic Name	Preferred Alternatives
Cequa	cyclosporine	Provider discretion

Table 3. Products Not Added*

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

Brand Name	Generic Name	Preferred Alternatives
Inveltys	loteprednol	Durezol
Altreno	tretinoin	tretinoin
Xelpros	latanoprost	latanoprost
Seysara	sarecycline	minocycline, doxycycline
Qmiiz ODT	meloxicam ODT	meloxicam tablet
Xyosted	testosterone enanthate	testosterone enanthate oil, testosterone cypionate
Krintafel	tafenoquine	Provider discretion
Omegaven	fish oil triglycerides	Provider discretion
Arakoda	tafenoquine	Provider discretion
Annovera	segesterone acetate and ethinyl estradiol	Provider discretion
Jornay PM	methylphenidate	Provider discretion
Xerava	eravacycline	Provider discretion
Ajovy	fremanezumab-vfrm	Provider discretion
Emgality	galcanezumab-gnlm	Provider discretion

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

C. Additions to the Specialty Tier

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

Brand Name	Generic Name
Tibsovo	ivosidenib
Nivestym	filgrastim-aafi
Perseris	risperidone
Azedra	iobenguane I 131
Mulpleta	lusutrombopag
Orkambi oral granules	lumacaftor/ivacaftor
Poteligeo	mogamulizumab-kpkc
Onpattro	patisiran
Galafold	migalastat
Diacomit	stiripentol
Oxervate	cenegermin-bkbj
Takhzyro	lanadelumab-flyo
Xerava	eravacycline
Pifeltro	doravirine
Delstrigo	doravirine/lamivudine/TDF
Tiglutik	riluzole
Lumoxiti	moxetumomab pasudotox-tdfk
Copiktra	duvelisib
Vizimpro	dacomitinib
Libtayo	cemiplimab-rwlc
Arikayce	amikacin
Nuzyra intravenous	omadacycline
Nuzyra tablets	omadacycline
Revcovi	elapegademase-lvlr
Tegsedi	inotersen
Yutiq	fluocinolone acetonide
Talzenna	talazoparib
Khapzory	levoleucovorin

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Tibsovo (ivosidenib) – Medicare	TBD	New policy created for newly FDA-approved ivosidenib (Tibsovo) to ensure appropriate use in adult members with a diagnosis of relapsed or refractory (R/R) acute myeloid leukemia (AML). The member must be isocitrate dehydrogenase-1 (IDH-1) mutation-positive.
Cequa (cyclosporine) – Medicare	TBD	New policy created for newly FDA-approved cyclosporine (Cequa) to ensure appropriate use in adult members with a diagnosis of dry eye disease who have experienced therapeutic failure, contraindication, or intolerance to artificial tears and cyclosporine (Restasis).
Diacomit (stiripentol) – Medicare	TBD	New policy created for newly FDA-approved stiripentol (Diacomit) to ensure appropriate use in members 2 years of age and older who are also taking clobazam for the treatment of seizures associated with Dravet syndrome.
Tiglutik (riluzole) – Medicare	TBD	New policy created for newly FDA-approved riluzole (Tiglutik) to ensure appropriate use in patients with amyotrophic lateral sclerosis (ALS) with documented inability to swallow tablets.
Oxervate (cenegermin-bkbj) – Medicare	TBD	New policy created for newly FDA-approved cenegermin-bkbj (Oxervate) to ensure appropriate use in members with neurotrophic keratitis (NK) who are 2 years of age or older. There is documentation that NK is in the left, right, or both eyes. There is documentation of diagnosis with reduced corneal sensitivity testing, slit-lamp examination, and dilated funduscopic examination. Reauthorization criteria is for one eye and includes that the member is 2 years of age or older, documentation that the eye affected is different from the initial authorization, and documentation of diagnosis with reduced corneal sensitivity testing, slit-lamp examination, and dilated funduscopic examination. Reauthorization will not be approved for both eyes. Authorization duration of 8 weeks.
Galafold (migalastat) – Medicare	TBD	New policy created for newly FDA-approved migalastat (Galafold) to ensure appropriate use in adult members with a confirmed diagnosis of Fabry disease. The member must have an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.
Vizimpro (dacomitinib) – Medicare	TBD	New policy created for newly FDA-approved dacomitinib (Vizimpro) to ensure appropriate use in members with a confirmed diagnosis of metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R substitution mutations.
Copiktra (duvelisib) – Medicare	TBD	New policy created for newly FDA-approved duvelisib (Copiktra) to ensure appropriate use in members over 18 years old with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		least two prior therapies; as well as relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies.
Talzenna (talazoparib) – Medicare	11/12/2018	New policy created for newly FDA-approved talazoparib (Talzenna) to ensure appropriate use in members with a confirmed diagnosis of deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer and that were previously treated with chemotherapy in the neoadjuvant, adjuvant and/or metastatic setting.
Qmiiz ODT (meloxicam) – Medicare	TBD	New policy created for newly FDA-approved meloxicam (Qmiiz ODT) to ensure appropriate use in members with a confirmed diagnosis of rheumatoid arthritis, osteoarthritis, or juvenile rheumatoid arthritis after trial and failure or intolerance to generic meloxicam and one additional NSAID.
Tegsedi (inotersen) – Medicare	TBD	New policy created to ensure appropriate use of patisiran (Onpattro) for the indication of polyneuropathy associated with hereditary amyloidosis. Initial authorization criteria ensure appropriate criteria and neurologic markers to help validate stability or improvement upon re-authorization.
Onpattro (patisiran) – Medicare	TBD	New policy created to ensure appropriate use of patisiran (Onpattro) for the indication of polyneuropathy associated with hereditary amyloidosis. Initial authorization criteria ensure appropriate criteria and neurologic markers to help validate stability or improvement upon re-authorization.
Arikayce (amikacin) - Medicare	TBD	New policy created to ensure appropriate use of amikacin (Arikayce) in members with refractory *Mycobacterium avium complex* (MAC) lung disease.
Doptelet (avatrombopag) and Mulpleta (lusutrombopag) – Medicare	TBD	Policy revised to include newly FDA-approved lusutrombopag (Mulpleta) to ensure appropriate use in adult patients with thrombocytopenia who have chronic liver disease (CLD) and are scheduled to undergo a procedure.
Hetlioz (tasimelteon) – Medicare	01/01/2019	Policy revised to add reauthorization criteria requiring attestation of increased total nighttime sleep or decreased daytime nap duration. Authorization duration updated to 3 months for initial and 12 months for reauthorization.
Atypical antipsychotics – Medicare	01/01/2019	Policy revised for cariprazine (Vraylar) to require adding trial and failure of one other formulary generic antipsychotic (e.g., quetiapine).
Idiopathic Pulmonary Fibrosis – Medicare	01/01/2019	Policy revised to remove prescriber restriction from the criteria.
Northera (droxidopa) – Medicare	01/01/2019	Policy revised for the addition of failure of preferred alternative midodrine.
Pulmonary Hypertension – Medicare	01/01/2019	Policy revised to remove prescriber restriction and add reference to nebulizer BvD criteria for trepostinil (Tyvaso) and iloprost (Ventavis).

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Xyrem (sodium oxybate) – Medicare	01/01/2019	Policy revised to require mean sleep latency on Multiple Sleep Latency Test (MSLT) to be <8 minutes, documentation of baseline excessive daytime sleepiness and if diagnosis of narcolepsy with cataplexy must provide baseline number of cataplexy episodes. Members without cataplexy must have failure, intolerance or contraindication to generic modafinil and generic CNS stimulant (e.g., methylphenidate, amphetamine salts). For reauthorization criteria requires attestation of improvement of narcolepsy symptoms and cataplexy symptoms (if applicable).
Topical Retinoid Therapy – Medicare	TBD	Policy revised to include newly FDA-approved tretinoin (Altreno) lotion for the treatment of acne.
2019 Orkambi (lumacaftor-ivacaftore) – Medicare	01/01/2019	Policy revised to add new formulation lumacaftor-ivacaftor (Orkambi) granules along with authorization criteria that member is 2 to 5 years of age or inability to swallow tablets, diagnosis of cystic fibrosis, and homozygous F508del mutation as detected by an FDA-approved test. Additional reauthorization criteria of increased Body Mass Index, decreased pulmonary exacerbations, or improved quality of life as demonstrated by Cystic Fibrosis Questionnaire.
Valchlor (mechlorethamine) – Medicare	TBD	Policy revised to introduce reauthorization criteria to demonstrate delayed disease progression or demonstrate stability post therapy.
Austedo (deutetrabenazine) – Medicare	09/01/2018	Policy revised to remove requirement for trial and failure of generic tetrabenazine for all applicable indications.
Ingrezza (valbenazine) – Medicare	09/01/2018	Policy revised to remove requirement for trial and failure of generic tetrabenazine for all applicable indications.
Gilenya (fingolimod) – Medicare	01/01/2019	Policy revised to update approval duration to 24 months.
Increlex (mecasermin) – Medicare	11/12/2018	Policy revised to add patient age requirement of 17 years or younger.
Sublingual Immunotherapies – Medicare	01/01/2019	Policy revised to remove reauthorization criteria and update approval durations to 12 months.
Tecfidera (dimethyl fumarate) – Medicare	01/01/2019	Policy revised to update approval duration from 12 months to 24 months.
Programmed Death Receptor Therapies – Medicare	11/12/2018	Policy revised to include expanded indications for pembrolizumab (Keytruda) as first-line treatment of metastatic non-small cell lung cancer in combination with pemetrexed and platinum chemotherapy, and for nivolumab (Opdivo) for treatment of patients with metastatic small cell lung cancer with progression after platinum-based chemotherapy and at least one other line of therapy.
Kinase Inhibitors – Medicare	11/12/2018	Policy revised to include expanded indication for lenvatinib (Lenvima) for the treatment of unresectable hepatocellular

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		carcinoma.
Eosinophilic Severe Asthma – Medicare	01/01/2019	Policy revised for mepolizumab (Nucala) to history of two or more exacerbations in previous 12 months or inadequately controlled symptoms with inhaled corticosteroids in combination with controller medication with or without glucocorticoids or intolerance/contraindications to all of these agents. Policy revised for benralizumab (Fasenra) to reduce criteria from two asthma exacerbations to one exacerbation requiring systemic corticosteroids in past 12 months.
Thiola (tiopronin) – Medicare	01/01/2019	Policy revised based on CMS feedback. Removal of requirement to fail on increased fluid intake and diet restriction.
Administrative Prior Authorizations for Medicare Part D Plans	11/01/2018	Policy revised to add criteria for Auryxia to confirm use is for medically accepted indication and not being used for excluded indication of iron deficiency anemia. Bonjesta authorization duration revised to 9 months. Per CMS feedback, denosumab (Prolia) BvD criteria revised to remove the criteria that member is female.
Chronic Inflammatory Disease – Medicare	01/01/2019	Policy revised to have indication-based preferred agents. Policy revised to include expanded indication for tocilizumab (Actemra) for the treatment of systemic juvenile idiopathic arthritis (SJIA). Policy revised to make tofacitinib (Xeljanz and Xeljanz XR) preferred for psoriatic arthritis and tofacitinib (Xeljanz only) preferred for ulcerative colitis for 01/01/2019. Policy revised to include expanded indications for adalimumab (Humira) for patients 12 years of age and older for hidradenitis suppurativa and for patients 2 years of age and older for uveitis.
CGRP Inhibitors – Medicare	TBD	Policy revised to include two recently approved CGRP inhibitors: fremanezumab (Ajovy) and galcanezumab (Emgality), in addition to erenumab (Aimovig), to ensure appropriate use for prevention of episodic migraine (EM) or chronic migraine (CM) in adults. Policy criteria include initial authorization to confirm the appropriate diagnosis, document average number of monthly migraine days, attestation that the headaches are not caused by medication rebound, overutilization, or lifestyle factors, and attestation of trial and failure of two alternative prophylactic medications. Re-authorization criteria include documentation of improvement from baseline, as measured by a reduction in migraine frequency (e.g., reduction in average monthly migraine days or number of migraine episodes by 50% (EM) or 30% (CM]).
Dupixent (dupilumab) – Medicare	11/12/2018	Policy revised to include updated indication for eosinophilic-phenotype asthma and oral corticosteroid-dependent asthma; with confirmation of diagnosis and failure of ICS+LABA or high dose corticosteroids.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Kalydeco (ivacaftor) – Medicare	01/01/2019	Policy revised to include expanded indication for use in patients 12 months of age or older. Added reauthorization criteria requiring attestation of improvement. Authorization duration updated to 6 months for initial and 12 months for reauthorization.
Aubagio (teriflunomide) – Medicare	01/01/2019	Policy revised to update approval duration to 24 months.
Hereditary Angioedema – Medicare	TBD	Policy revised to include lanadelumab-flyo (Takhzyro) along with authorization criteria that the member displays clinical laboratory performance for hereditary angioedema (HAE), diagnosis of HAE, medications known to cause angioedema have been evaluated and discontinued and documentation of the member's body weight has been provided.

*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
Non-stimulant Treatment of ADHD-ADD – Medicare	01/01/2019	Policy revised to remove atomoxetine (Strattera) as a targeted agent for prior authorization.
Combination Prescription Drug Safety – Medicare	01/01/2019	Policy revised to remove requirement of documentation of no history of alcohol and drug abuse. Per CMS guidance, criteria added for use of opioids with opioid potentiators (e.g., benzodiazepines and gabapentinoids) and requires documentation of medically accepted indication and attestation of ongoing monitoring plan. Criteria added for long-acting opioids requiring pain severe enough to require daily, around-the-clock, long-term opioid treatment, members are not opioid naïve, non-opiate therapies have been explored, patient's history has been checked on the state prescription drug monitoring program, and counseling on opioid side effects and misuse has been provided. Addition of criteria for 7-day opioid limit that requires documentation of pain related to cancer, hospice, or sickle cell anemia or member has been using opioids consistently for chronic pain or has severe pain and has failed non-opioid therapy, state prescription drug monitoring program has been checked and counseling on opioid adverse effects has been provided.
Brand and Extended Release Metformin – Medicare	01/01/2019	Policy revised to remove brand Glucophage and brand Glucophage XR as targeted agents for prior authorization.
Selective Serotonin-Norepinephrine Reuptake Inhibitors – Medicare	01/01/2019	Policy revised to update authorization duration from 12 months to 3 years.
Viibryd (vilazodone) and	01/01/2019	Policy revised to update authorization duration from 12 months

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria
Trintellix (vortioxetine) - Medicare		to 3 years.

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

3. Quantity Level Limit (QLL) Program*

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

Drug Name	Retail Quantity Limit	Mail Order Quantity Limit
Ajovy (fremanezumab) 225 mg/1.5 mL	3 syringes per 90 days	3 syringes per 90 days
Arikayce (amikacin) 590 mg/8.4 mL	1 box (28 vials) per 28 days	3 boxes (84 vials) per 84 days
Cassipa (buprenorphine/naloxone) 16 mg/4 mg	31 sublingual film per 31 days	93 sublingual films per 90 days
Cequa (cyclosporine) all strengths	62 single-use vials per 31 days	186 single-use vials per 90 days
Copiktra (Duvelisib) all strengths	62 capsules per 31 days	186 capsules per 90 days
Delstrigo (doravirine/lamivudine/TDF) 100 mg/300 mg/300 mg	31 tablets per 31 days	93 tablets per 90 days
Diacomit (stiripentol) 250 mg	93 capsules or packets per 31 days	279 capsules or packets per 90 days
Diacomit (stiripentol) 500 mg	186 capsules or packets per 31 days	558 capsules or packets per 90 days
Dupixent (dupilumab) 200 mg/1.14 mL	2 syringes per 28 days	6 syringes per 84 days
Emgality (galcanezumab) 120 mg/mL	1 syringe per 31 days	3 syringes per 90 days
Galafold (migalastat) 123 mg	14 capsules per 28 days	42 capsules per 84 days
Jornay PM (methylphenidate ER) all strengths	31 capsules per 31 days	93 capsules per 90 days
Krintafel (tafenoquine) 150 mg	2 tablets per 2 days	2 tablets per 2 days
lamivudine/nevirapine/zidovudine 15 mg/200 mg/300 mg	62 tablets per 31 days	186 tablets per 90 days
Mulpleta (lusutrombopag) 3 mg (7 tablet blister pack	7 tablets per 31 days	21 tablets per 90 days
Nuzyra (omadacycline) tablets 150 mg	31 tablets per 31 days	--
Onpattro (patisiran) 10 mg/5 mL	3 single-dose vials per 21 days	9 single-dose vials per 63 days
Orkambi (lumacaftor/ivacaftor) oral granules 100 mg/125 mg and 150 mg/188 mg	62 oral packets of granules per 31 days	186 oral packets of granules per 90 days
Oxervate (cenegermin-bkbj) 0.002% (20 mcg/mL) contains 7 vials in 1 carton (1 vial per eye per day)	8 cartons (56 vials) per 28 days	16 cartons (112 vials) per 90 days
Pifeltro (doravirine) 100 mg	62 tablets per 31 days	186 tablets per 90 days
Qmiiz ODT (meloxicam) all strengths	31 tablets per 31 days	93 tablets per 90 days

Drug Name	Retail Quantity Limit	Mail Order Quantity Limit
Seysara (sarecycline) 60 mg, 100 mg, 150 mg	31 tablets per 31 days	93 tablets per 90 days
Takhzyro (lanadelumab-flyo) 300 mg/2 mL	2 single-dose vials per 1 days	6 single-dose vials per 90 days
Talzenna (talazoparib) 1 mg	31 capsules per 31 days	93 capsules per 90 days
Talzenna (talazoparib) 0.25 mg	93 capsules per 31 days	279 capsules per 90 days
Tegsedi (inotersen) 284 mg/1.5 mL	4 syringes per 31 days	12 syringes per 90 days
Tibsovo (ivosidenib) 250 mg	62 tablets per 31 days	186 tablets per 90 days
Tiglutik (riluzole) 50 mg/10 mL	2 multiple-dose bottles per 31 days	6 multiple-dose bottles per 90 days
Vizimpro (dacomitinib) all strengths	31 tablets per 31 days	93 tablets per 90 days
Xelpros (latanoprost PF) 50 mcg/mL (0.005%)	2.5 mL bottle per 31 days	7.5 mL bottle per 90 days
Xofluza (baloxavir marboxil) all strengths	2 tablets per 365 days	2 tablets per 365 days
Cimduo 300 mg	31 tablets per 31 days	93 tablets per 90 days
Stiolto Respimat 2.5 mcg	4 grams per 14 days	12 grams per 42 days
Spiriva Respimat 2.5 mcg	4 grams per 14 days	12 grams per 42 days
Humira Psoriasis-uveitis starter kit all strengths	3 kits per 28 days	9 kits per 84 days
Humira Crohn-UC-HS starter kit all strengths	3 kits per 28 days	9 kits per 84 days

Med D Quantity Level Limits (QLs)

Drug Name	Strength	Dosage Form	Retail Quantity Limit (units, mL, grams)	Retail Day Supply	Mail Order Quantity Limit (units or mL)	Mail Order Day Supply	MDQ Calc
Calcipotriene	0.005%	Ointment (Gram)	60	28	180	84	2.14
Calcipotriene	0.005%	Solution, Non-Oral	60	28	180	84	2.14
Calcipotriene	0.005%	Cream (Gram)	60	28	180	84	2.14
Chantix	0.5 (11)-1	Tablet, Dose Pack	106	365	106	365	0.29
Chantix	0.5 mg	Tablet	60	30	180	90	2
Chantix	1 mg	Tablet	60	30	180	90	2
Chantix	1 mg	Tablet	60	30	180	90	2
Ciclopirox	0.77%	Gel (Gram)	45	28	135	84	1.61
Ciclopirox	0.77%	Cream (Gram)	90	28	270	84	3.21
Ciclopirox	0.77%	Suspension, Topical (mL)	60	28	180	84	2.14
Colchicine	0.6 mg	Tablet	62	31	186	90	2

Drug Name	Strength	Dosage Form	Retail Quantity Limit (units, mL, grams)	Retail Day Supply	Mail Order Quantity Limit (units or mL)	Mail Order Day Supply	MDQ Calc
Daytrana	10 mg/9 Hr	Patch, Transdermal 24 Hours	30	30	90	90	1
Daytrana	15 mg/9Hr	Patch, Transdermal 24 Hours	30	30	90	90	1
Daytrana	20 mg/9 Hr	Patch, Transdermal 24 Hours	30	30	90	90	1
Daytrana	30 mg/9 Hr	Patch, Transdermal 24 Hours	30	30	90	90	1
Dexedrine	10 mg	Capsule, Extended Release	155	31	465	90	5
Dexedrine	15 mg	Capsule, Extended Release	124	31	372	90	4
Dexedrine	5 mg	Capsule, Extended Release	186	31	558	90	6
Dexilant	30 mg	Capsule, Delayed Release, Biphasic	31	31	93	90	1
Dexilant	60 mg	Capsule, Delayed Release, Biphasic	31	31	93	90	1
Dextroamphetamine Sulfate ER	10 mg	Tablet	186	31	558	90	6
Dextroamphetamine Sulfate ER	5 mg	Tablet	341	31	1023	90	11
Dextroamphetamine Sulfate ER	10 mg	Capsule, Extended Release	155	31	465	90	5
Dextroamphetamine Sulfate ER	15 mg	Capsule, Extended Release	124	31	372	90	4
Dextroamphetamine Sulfate ER	5 mg	Capsule, Extended Release	186	31	558	90	6
Diclofenac Sodium	1%	Gel (Gram)	300	28	900	84	10.71
Diclofenac Sodium	1.5%	Drops	450	30	1350	90	15
Diclofenac Sodium	3%	Gel (Gram)	100	28	300	84	3.57
Dovonex	0.005%	Cream (Gram)	60	28	180	84	2.14

Drug Name	Strength	Dosage Form	Retail Quantity Limit (units, mL, grams)	Retail Day Supply	Mail Order Quantity Limit (units or mL)	Mail Order Day Supply	MDQ Calc
Doxepin HCL	5%	Cream (Gram)	45	28	135	84	1.61
Enstilar	0.005-.064	Foam (Gram)	60	28	180	84	2.14
Fluocinonide	0.05%	Ointment (Gram)	60	28	180	84	2.14
Fluocinonide	0.05%	Solution, Non-Oral	60	28	180	84	2.14
Fluocinonide	0.05%	Gel (Gram)	60	28	180	84	2.14
Fluocinonide	0.1%	Cream (Gram)	120	28	360	84	4.29
Fluocinonide-E	0.05%	Cream (Gram)	60	28	180	84	2.14
Intrarosa	6.5 mg	Insert	28	28	84	84	1
Lidocaine	5%	Ointment (Gram)	50	28	150	84	1.79
Lidocaine HCL	2%	Jelly (mL)	60	28	180	84	2.14
Lidocaine HCL	40 mg/mL	Solution, Non-Oral	50	28	150	84	1.79
Lidocaine Prilocaine	2.5%-2.5%	Cream (Gram)	30	28	90	84	1.07
Loprox	0.77%	Cream (Gram)	90	28	270	84	3.21
Osphena	60 mg	Tablet	31	31	93	90	1
Pennsaid	20 mg/g (2%)	Solution in Metered Dose Pump (Gram)	224	28	672	84	8
Prudoxin	5%	Cream (Gram)	45	28	135	84	1.61
Quinine Sulfate	324 mg	Capsule	42	28	126	84	1.5
Restasis	0.05%	Dropperette, Single-Use Drop Dispenser	60	30	180	90	2
Synjardy	12.5 mg - 1000 mg	Tablet	62	31	186	90	2
Synjardy	12.5 mg - 500 mg	Tablet	62	31	186	90	2
Synjardy	5 mg - 500 mg	Tablet	62	31	186	90	2
Synjardy	5 mg - 1000 mg	Tablet	62	31	186	90	2
Synjardy XR	10 mg - 1000 mg	Tablet, Immediate and Extended Release Biphase 24 Hr	62	31	186	90	2
Synjardy XR	12.5 mg - 1000 mg	Tablet, Immediate and Extended Release Biphase	62	31	186	90	2

Drug Name	Strength	Dosage Form	Retail Quantity Limit (units, mL, grams)	Retail Day Supply	Mail Order Quantity Limit (units or mL)	Mail Order Day Supply	MDQ Calc
		24 Hr					
Synjardy XR	25 mg - 1000 mg	Tablet, Immediate and Extended Release Biphase 24 Hr	31	31	93	90	1
Synjardy XR	5 mg - 1000 mg	Tablet, Immediate and Extended Release Biphase 24 Hr	62	31	186	90	2
Voltaren	1%	Gel (Gram)	300	28	900	84	10.71
Xiidra	5%	Dropperette, Single-Use Drop Dispenser	60	30	180	90	2
Zenzedi	10 mg	Tablet	62	31	186	90	2
Zenzedi	15 mg	Tablet	62	31	186	90	2
Zenzedi	2.5 mg	Tablet	62	31	186	90	2
Zenzedi	20 mg	Tablet	62	31	186	90	2
Zenzedi	30 mg	Tablet	62	31	186	90	2
Zenzedi	5 mg	Tablet	62	31	186	90	2
Zenzedi	7.5 mg	Tablet	62	31	186	90	2
Zonalon	5%	Cream (Gram)	30	28	90	84	1.07

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