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:

Section I. Highmark Commercial and Healthcare Reform Formularies

A. Changes to the Highmark Comprehensive Formulary and the Highmark Comprehensive Healthcare Reform Formulary
B. Changes to the Highmark Healthcare Reform Essential Formulary
C. Updates to the Pharmacy Utilization Management Programs
    1. Prior Authorization Program
    2. Managed Prescription Drug Coverage (MRxC) Program
    3. Formulary Program
    4. Quantity Level Limit (QLL) Programs

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 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

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Nivestym	filgrastim-aafi	NF	Provider discretion
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.

C. 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.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Diacomit (stiripentol) – Commercial and Healthcare Reform	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) – 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.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Qmiiz ODT (meloxicam) – Commercial and Healthcare Reform	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 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	01/07/2019	Policy revised to add new formulation lumacaftor-ivacaftor (Orkambi) granules along with authorization criteria that

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Reform		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. 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.
Diabetic Test Strips	11/12/2018	Policy revised to reflect approval criteria for more than seven

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Quantity Limitation – Commercial and Healthcare Reform		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.

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