SPECIAL eBULLETIN

JULY 2018

THIRD QUARTER 2018 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the Third Quarter 2018 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 May 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

Alka-Seltzer Plus Products: Recall - Ingredients on Front Sticker May Not Match Product in Carton
On March 16, 2018 Bayer announced a voluntary recall of Alka-Seltzer Plus packages due to the possibility that ingredients listed on the front sticker may not match the actual product in the carton. This may lead consumers to ingest a product to which they may have an allergy or anaphylactic reaction, an ingredient which may be contraindicated for their medical condition or they intend to otherwise avoid, resulting in potential serious health consequences. Adverse events or side effects related to the use of this product should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Lamictal (lamotrigine): Drug Safety Communication - Serious Immune System Reaction
On April 25, 2018 the FDA warned that the medicine Lamictal (lamotrigine) for seizures and bipolar disorder can cause a rare but very serious reaction called hemophagocytic lymphohistiocytosis (HLH), which results in excessive activation of the body's infection-fighting immune system. This can lead to severe inflammation throughout the body, resulting in hospitalization and death, especially if the reaction is not diagnosed and treated quickly. A new warning is being required to be added to the prescribing information in the lamotrigine drug labels. Health care professionals should be aware that prompt recognition and early treatment is important for improving HLH outcomes and decreasing mortality. Adverse events or side effects related to the use of this product should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Keytruda (pembrolizumab) or Tecentriq (atezolizumab): FDA Alerts Health Care Professionals and Investigators: FDA Statement - Decreased Survival in Some Patients in Clinical Trials Associated with Monotherapy
On May 18, 2018 the FDA issued an alert regarding decreased survival associated with the use of Keytruda (pembrolizumab) or Tecentriq (atezolizumab) as single therapy (monotherapy) compared to those who received cisplatin- or carboplatin-based chemotherapy in clinical trials to treat patients with metastatic urothelial cancer who have not received prior therapy and who have low expression of the protein programmed death ligand 1 (PD-L1). The FDA recommends providers select patients for the treatment of locally advanced or metastatic urothelial cancer using the criteria described in Section 14 of each label, which support the approvals of Keytruda and Tecentriq for initial monotherapy in cisplatin-ineligible patients. 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.

Juluca, Tivicay, Triumeq (dolutegravir): FDA to Evaluate - Potential Risk of Neural Tube Birth Defects
On May 18, 2018 the FDA communicated serious cases of neural tube defects of the brain, spine and spinal cord that have been reported in babies born to women treated with dolutegravir used to treat human immunodeficiency virus (HIV). Dolutegravir is available as a single ingredient product under the brand name Tivicay and as a fixed dose combination tablet with other HIV medicines under the brand names Juluca and Triumeq. Women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for these defects. Patients should not stop taking dolutegravir without first talking to their health care professional in order to maintain management of their HIV infection. Health care professionals should weigh the benefits and risks of dolutegravir when prescribing to women of childbearing age, inform them about the potential risk involved and perform

pregnancy testing to exclude pregnancy before initiating a dolutegravir-containing regimen. 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.

Oral Over-the-Counter Benzocaine Products: Drug Safety Communication – Risk of Serious and Potentially Fatal Blood Disorder

On May 23, 2018 the FDA warned that over-the-counter oral drug products containing benzocaine, a local anesthetic, should not be used to treat infants and children younger than 2 years. Oral benzocaine products with warnings on the drug label should only be used in adults and children 2 years of age and older. These products carry serious risks and provide little to no benefits for treating oral pain, including sore gums in infants due to teething. Parents and caregivers should follow the American Academy of Pediatrics' recommendations for treating teething. Benzocaine can cause a condition called methemoglobinemia in which the amount of oxygen carried through the blood is greatly reduced and which can be life-threatening. Health care professionals should warn patients of the possibility of methemoglobinemia and advise them of the signs and symptoms when recommending or prescribing local anesthetic products. When using local anesthetics during medical procedures, steps should be taken to minimize the risk for methemoglobinemia. 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 – July 2018

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 June 11, 2018, unless otherwise noted.)

Brand Name	Generic Name	Comments
Biktarvy	bictegravir/emtricitabine/ tenofovir alafenamide	New three-drug combination indicated as a complete regimen for the treatment of HIV-1 infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed.
Erleada	apalutamide	An androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.
Cimduo	lamivudine/tenofovir disoproxil fumarate (TDF)	New two-drug combination indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients.
Symfi	efavirenz/lamivudine/TDF	New three-drug combination indicated as a complete regimen for the treatment HIV-1 infection in adults and pediatric patients.
Symfi Lo	efavirenz/lamivudine/TDF	New three-drug combination indicated as a complete regimen for the treatment HIV-1 infection in adults and pediatric patients.
Firvanq	vancomycin oral solution	A glycopeptide antibacterial indicated for *Clostridium difficile*-associated diarrhea or

		Enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains).

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Metoprolol succinate Extended-Release Capsules*	Metoprolol succinate	metoprolol succinate ER tablets, carvedilol
Symdeko	tezacaftor/ivacaftor	Provider discretion
Imbruvica tablet	ibrutinib	Provider discretion
Osmolex ER*	amantadine ER	amantadine IR
Apadaz*	benzhydrocodone/APAP	hydrocodone/APAP
ZTlido*	lidocaine 1.8% topical system	gabapentin
Tavalisse	fostamatinib	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 **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
Erleada	apalutamide
Symdeko	tezacaftor/ivacaftor
Imbruvica tablet	ibrutinib
Tavalisse	fostamatinib

B. Changes to the Highmark Delaware Healthcare Reform Progressive Formulary

Table 1. Formulary Updates for Highmark Delaware Select Healthcare Reform Individual Plans (All products added to the formulary effective June 11, 2018 unless otherwise noted.)

Note: Highmark offers the Progressive Formulary to Highmark Delaware members in select Individual Healthcare Reform plans in Delaware. 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 formulary online at: https://client.formularynavigator.com/Search.aspx?siteCode=3597426829

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below are preferred products			
Biktarvy	bictegravir/ emtricitabine/tenofovir alafenamide	3 - Preferred Brand	New three-drug combination indicated as a complete regimen for the treatment of HIV-1 infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed.
Cimduo	lamivudine/TDF	3 - Preferred Brand	New two-drug combination indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients.
Symfi	efavirenz/lamivudine/ TDF	3 - Preferred Brand	New three-drug combination indicated as a complete regimen for the treatment HIV-1 infection in adults and pediatric patients.
Symfi Lo	efavirenz/lamivudine/ TDF	3 - Preferred Brand	New three-drug combination indicated as a complete regimen for the treatment HIV-1 infection in adults and pediatric patients.
Firvanq	vancomycin oral solution	3 - Preferred Brand	A glycopeptide antibacterial indicated for Clostridium difficile-associated diarrhea or Enterocolitis caused by Staphylococcus aureus (including methicillin-resistant strains).
Erleada	apalutamide	3 - Preferred Brand	Provider discretion
Items listed below are non-preferred products			
Metoprolol Succinate Extended-Release Capsules*	Metoprolol succinate	4 - Non-preferred Brand	metoprolol succinate ER tablets, carvedilol
Osmolex ER*	amantadine ER	4 - Non-preferred Brand	amantadine IR
Apadaz*	benzhydrocodone/ APAP	4 - Non-preferred Brand	hydrocodone/APAP
ZTlido*	lidocaine 1.8% topical system	4 - Non-preferred Brand	gabapentin
Symdeko	tezacaftor/ivacaftor	4 - Non-preferred Brand	Provider discretion
Imbruvica tablet	ibrutinib	4 - Non-preferred Brand	Provider discretion
Tavalisse	fostamatinib	4 - Non-preferred Brand	Provider discretion

Coverage may be contingent upon plan benefits.

*Effective date to be determined.

****Tier 1:** Preferred generic drugs; **Tier 2:** Non-preferred generic drugs; **Tier 3:** Preferred brand drugs, **Tier 4:** Non-preferred brand drugs.

C. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Erleada (apalutamide) – Commercial and Healthcare Reform	05/14/2018	New policy created to ensure apalutamide (Erleada) is used for treatment of non-metastatic castration-resistant prostate cancer, in combination with a GnRH analog or after bilateral orchiectomy.
CFTR Modulators – Commercial and Healthcare Reform	05/14/2018	New combined policy created to ensure Symdeko, Orkambi, and Kalydeco are used only for mutations of the CFTR gene that are responsive to appropriate agents.
Ilumya (tildrakizumab-asmn) – Commercial and Healthcare Reform	05/14/2018	New policy created to ensure that tildrakizumab-asmn (Ilumya) is being used in patients with moderate-to-severe psoriasis after a trial and failure of phototherapy or systemic therapy and at least two biologic products (Cosentyx, Humira, Otezla, or Stelara SC).
Opioid Management – Healthcare Reform	09/01/2018	New policy created to align with recommendations from CDC safe opioid prescribing guidelines, requiring prior authorization for first-time short acting opioid users with prescriptions for greater than a 7 day supply (>14 days/30). Approval for additional days of therapy may be granted for pain due to cancer or sickle cell anemia, patients in hospice, and in those with continued need for chronic opioid therapy. Policy also requires prior authorization on long acting opioids for opioid naive patients to ensure short-acting opioid therapies are optimized prior to transitioning to long-acting opioid therapy.
Tavalisse (fostamatinib disodium hexahydrate) – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use of fostamatinib disodium hexahydrate (Tavalisse) in the treatment of adult patients with chronic immune thrombocytopenia (ITP) who had trial/failure of corticosteroid or immunoglobulin therapy or splenectomy and documentation of platelet count with or without a bleeding risk factor.
Crysvita (burosumab-twza) – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use of burosumab-twza (Crysvita) for the treatment of X-linked hypophosphatemia in adults and children, requiring documentation of baseline serum phosphorus below the normal limit and evidence of symptomatic disease in adults.
CGRP Inhibitors – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use of Calcitonin Gene-Related Peptide (CGRP) Inhibitors as Preventive Treatments for Patients with Episodic or Chronic Migraine, requiring trial and failure of two to three prophylactic medications (respectfully) and documentation of reduced migraine frequency upon reauthorization. Policy criteria are being presented prior to FDA approval of erenumab (Amgen) and fremanizumab (Teva).
Zytiga (abiraterone acetate) – Commercial and Healthcare Reform	05/14/2018	Policy revised to split Commercial and Healthcare Reform from Medicare. Criteria added for the treatment of metastatic high-risk castration-sensitive prostate cancer, in combination with

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		prednisone.
Cerdelga (eliglustat) – Commercial and Healthcare Reform	05/14/2018	Policy revised to include documentation for presence of symptoms associated with Gaucher disease, reauthorization criteria added to ensure improvement of Gaucher symptoms after one year of therapy, and change in initial authorization duration from lifetime to one year.
Zavesca (miglustat) – Commercial and Healthcare Reform	05/14/2018	Policy revised to combine Commercial and Healthcare Reform policies, to include documentation for presence of symptoms associated with Gaucher disease, and reauthorization criteria added to ensure improvement of Gaucher symptoms after one year of therapy.
Human Growth Hormone – Commercial, Delaware Commercial and Healthcare Reform	05/14/2018	Policy revised to include expanded indication for somatropin (Zomacton) as replacement of endogenous growth hormone (GH) in adults with GH deficiency and somatropin (Norditropin) for pediatric patients with idiopathic short stature and Prader-Willi syndrome. No policy criteria changes needed.
Myalept (metreleptin) – Commercial and Healthcare Reform	05/04/2018	Policy revised to include leptin level requirements prior to initial authorization for metreleptin (Myalept) – indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.
Relistor (methylnaltrexone bromide) – Commercial and Healthcare Reform	05/14/2018	Policy revised to include the expanded indication for methylnaltrexone bromide (Relistor) subcutaneous injection, treatment of opioid-induced constipation in adults with pain caused by active cancer that require opioid dosage escalation for palliative care.
Signifor (pasireotide) – Commercial and Healthcare Reform	05/14/2018	Policy revised to include a separate reauthorization criteria for pasireotide (Signifor), indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. Reauthorization criteria include: • Clinical documentation of urinary free cortisol (UFC) levels are provided that document current UFC levels are within normal range (10-100 mcg per 24 hours) or are decreased ≥>50% from pre-treatment UFC levels.
Parathyroid Hormone Analogs – Healthcare Reform	07/01/2018	Policy revised to include a step through abaloparatide (Tymlos) to receive coverage of teriparatide (Forteo) for members at high-risk of bone fracture.
Austedo (deutetrabenazine) – Commercial and Healthcare Reform	05/14/2018	Policy revised to add coverage criteria for the expanded indication of Tardive Dyskinesia (TD).
Xenazine (tetrabenazine) – Commercial and Healthcare Reform	05/14/2018	Policy authorization duration was revised from lifetime to 12-months.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Xadago (safinamide) – Commercial and Healthcare Reform	05/14/2018	Policy authorization duration was revised from lifetime to 12-months.
Luxturna (voretigene neparvovec- rzyl) – Commercial and Healthcare Reform	05/14/2018	Policy revised to remove reference to MLMT testing, Visual Acuity and Visual Field assessments, in order to be in-line with the Medical Policy.
Korlym (mifepristone) – Commercial, Healthcare Reform	05/14/2018	Policy authorization duration was revised from lifetime to 12-months.
Sabril (vigabatrin) – Commercial	05/14/2018	Policy revised to include reauthorization criteria for the prescriber to document the member is responding to therapy, vision has been assessed, and the benefits of therapy continue to outweigh the risks of vision loss.
Sublingual Immunotherapy - Commercial and Healthcare Reform	05/14/2018	Policy revised to update limitations of coverage, and move concomitant sublingual/subcutaneous immunotherapy from the approval criteria to limitations.
Efudex, Zyclara, and Aldara – Healthcare Reform	Best Date	Policy revised to remove Carac cream indicated for the topical treatment of multiple actinic or solar keratosis of the face and anterior scalp.
Solaraze (diclofenac sodium 3%) and Carac Cream – Commercial and Healthcare Reform	Best Date	Policy revised to include Carac cream indicated for the topical treatment of multiple actinic or solar keratosis of the face and anterior scalp. Policy combined Commercial and Healthcare Reform line of business.
Gocovri and Osmolex ER (amantadine ER) – Commercial and Healthcare Reform	Best Date	Policy revised to include the newly FDA-approved agent, amantadine ER (Osmolex ER), indicated for the treatment of Parkinson's Disease and drug-induced extrapyramidal reactions in adult patients.
Thiola (tioponin) – Commercial and Healthcare Reform	TBD	Policy revised to include the Commercial line of business. Tioponin (Thiola) is indicated for severe homozygous cystinuria for prevention of cysteine (kidney) stone formation.
Dibenzyline (phenoxybenzamine) – Healthcare Reform	05/14/2018	Policy authorization duration was revised from lifetime to 12-months.
Nuplazid (pimavanserin) – Commercial and Healthcare Reform	05/14/2018	Policy authorization duration revised from lifetime to 12 months, Commercial and Healthcare Reform removed from Medicare to a separate policy.
Chronic Inflammatory Diseases - Commercial and Healthcare Reform	05/14/2018	Policy revised to include expanded indication of scalp psoriasis for secukinumab (Cosentyx). Policy revised to include approval for weekly adalimumab (Humira) dosing for Crohn's disease and ulcerative colitis when every-other-week Humira dosing was ineffective. All plaque psoriasis sections were updated to include an additional step through systemic therapy for patients that are not candidates for phototherapy.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Veltassa (patiromer) – Commercial	05/14/2018	Policy revised to make approval criteria less stringent for members with chronic kidney disease. Reauthorization criteria updated to request diagnosis of a chronic condition contributing to hyperkalemia, and reauthorization duration increased to 12 months.
Gilenya (fingolimod) – Commercial and Healthcare Reform	05/14/2018	Policy revised to streamline approval criteria. Refer to policy for additional details.
Luzu (luliconazole) – Healthcare Reform	05/14/2018	Policy revised to remove language for coverage only in adults, as the age restrictions have been removed from the indication.
Verzenio (abemaciclib) – Commercial and Healthcare Reform	05/14/2018	Policy revised to include expanded indication for the initial endocrine-based therapy for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, in combination with an aromatase inhibitor.
Kinase Inhibitors – Commercial and Healthcare Reform	05/14/2018	Policy revised to include expanded indications for nilotinib (Tasigna) in pediatric patients 1 year and older with newly diagnosed chronic phase Ph+ CML, or chronic phase Ph+ CML resistant or intolerant to prior tyrosine kinase inhibitors, rucaparib (Rubraca) as maintenance treatment for adults with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy, and osimertinib (Tagrisso) for first-line EGFR mutated NSCLC.
Afinitor (everolimus) – Commercial and Healthcare Reform	05/14/2018	Policy revised to include expanded indication for everolimus (Afinitor Disperz) for the treatment of tuberous sclerous complex (TSC)-associated partial-onset seizures.
Oral Isotretinoin Therapy – Commercial	05/04/2018	Policy revised to modify the required number of generic oral antibiotics that must be tried and failed before isotretinoin is approved, from two antibiotics to one antibiotic. Reauthorization criteria were also added to the policy to ensure that member has been off therapy for at least 8 weeks and is still experiencing persistent or recurring severe acne.

*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
ZTLido (lidocaine 1.8% topical system) – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use for (add indication), requiring trial and failure of Lidoderm/lidocaine 5% topical patch.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Apadaz (benzhydrocodone-acetaminophen) – Commercial and Healthcare Reform	Best Date	New policy created to allow override of benzhydrocodone acetaminophen (Apadaz) quantity limit provided there is documentation of an acute injury distinct from a previous injury within the last 90 days.
Beta Blocker Management – Commercial	Best Date	Policy revised to include metoprolol succinate extended-release capsules as one of the non-preferred products as metoprolol succinate extended-release tablets are preferred products.
Non-preferred Atypical Antipsychotic Medications – Healthcare Reform	05/14/2018	Policy authorization duration was revised from lifetime to 12-months.
Vancocin (vancomycin) and Zyvox (linezolid) – Healthcare Reform	Best Date	Policy revised to include quantity limit for vancomycin (Firvanq), indicated for *C. difficile* associated diarrhea in adults and pediatric patients less than 18 years of age and entercolitis caused by *S. aureus* (including methicillin-resistant strains) in adults and pediatric patients less than 18 years of age.
Migraine Therapies – Commercial and Healthcare Reform	05/14/2018	Policy revised to exclude override for Zecuity, as safety for use of more than 4 patches per month has not been established.
Brand Statin Edit - Select Commercial and Healthcare Reform Plans	Best Date	Policy revised to include pitavastatin (Zypitamag) as a target, requiring trial and failure of a generic statin prior to use. Brand Flolipid added to description of simvastatin suspension products targeted.
Luzu (luliconazole) – Commercial	05/14/2018	Policy revised to remove language for coverage only in adults, as the age restrictions have been removed from the indication.
Migraine Therapies Step Therapy	06/01/2018	Policy revised to separate step from QLL. Step policy requires failure of two preferred generic medications before branded products.
Atypical Antipsychotics – Commercial and Healthcare Reform	Best Date	Policy revised to required trial of two oral aripiprazole formulations (generic and brand) prior to approval of Abilify Mycite for acceptable indications.
Proton Pump Inhibitors (PPIs) – Commercial	05/14/2018	Policy revised to include lansoprazole oral disintegrating tablet (generic) as non-preferred.
Proton Pump Inhibitors (PPIs) – Healthcare Reform	05/14/2018	Policy revised to include lansoprazole oral disintegrating tablet (generic) as non-preferred. Healthcare Reform split to become standalone policy.
Doxycycline Products – Commercial	06/01/2018	Policy revised to include Okebo and Targadox to the list of branded doxycycline products targeted.

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**
Cost Share Exception: Statins	Best Date	Policy revised to include the newly FDA-approved agent, Zypitamag.

*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
Abilify Mycite (aripiprazole) all strengths*	1 pack per 30 days	3 packs per 90 days
Macrilen (macimorelin) all strengths*	2 packets per lifetime	2 packets per lifetime
Apadaz(benzhydrocodone, acetaminophen) all strengths*	14 days per 90 days	14 days per 90 days
Firvanq (vancomycin) 25 mg/mL**	1200 mL per 180 days	1200 mL per 180 days
Firvanq (vancomycin) 50 mg/mL**	600 mL per 180 days	600 mL per 180 days
Ilumya (tiltrakizumab-asmn) 100 mg/mL*	1 syringe per 84 days	1 syringe per 84 days
lidocaine jelly 2%	60 gm per 30 days	180 gm per 90 days
lidocaine ointment 5%	50 gm per 30 days	150 gm per 90 days
doxepin cream 5%	45 gm per 90 days	45 gm per 90 days
Crysvita (burosumab-twza) (ages 1-15 years) all strengths	180 mg per 28 days	540 mg per 84 days
Crysvita (burosumab-twza) (ages 16+ years) all strengths	90 mg per 28 days	270 mg per 84 days
erenumab 70 mg, 140 mg	1 injection per 30 days	3 injections per 90 days
fremanizumab 225 mg*	1 injection per 30 days	3 injections per 90 days
fremanizumab 675 mg*	1 injection per 90 days	1 injection per 90 days
Eliquis (apixaban) dose pack all strengths	1 dose pack per 365 days	1 dose pack per 365 days

*Effective date to be determined.

**Applicable to Healthcare Reform plans only.

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

Drug Name	Retail Edit Limit	Mail Edit Limit
None		

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

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

Drug Name	Daily Limit
Biktarvy (bictegravir, emtricitabine, tenofovir alafenamide) all strengths	1 tablet per day
Erleada (apalutamide) 60 mg	4 tablets per day
Symdeko (tezacaftor/ivacaftor) all strengths	2 tablets per day (1 tab of tezacaftor/ivacaftor and 1 tab of ivacaftor)
Imbruvica (ibrutinib) tablet all strengths	1 tablet per day
Imbruvica (ibrutinib) capsule all strengths	1 capsule per day
Cimduo (lamivudine, tenofovir fumarate) all strengths	1 tablet per day
Symfi Lo (efavirenz, lamivudine, tenofovir disproxil) all strengths	1 tablet per day
Symfi (efavirenz, lamivudine, tenofovir disproxil) all strengths	1 tablet per day
ZTLido (lidocaine) 1.8% topical system	3 patches per day
Osmolex ER (amantadine) 129 mg, 193 mg and 258 mg	1 tablet per day
Tavalisse (fostamatinib) 100 mg, 150 mg	2 tablets per day
Tasigna (nilotinib) 50 mg	4 capsules per day

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.