

OCTOBER 2018

FOURTH QUARTER 2018 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the Fourth 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 August 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 Delaware Healthcare Reform Progressive Formulary
- C. Updates to the Pharmacy Utilization Management Programs
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 - 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/Formulary Information link from the menu on the left.



Essential Formulary - Healthcare Reform Individual Plans January 1, 2019

Effective **January 1, 2019**, there will be a new formulary for select Healthcare Reform (HCR) Individual plans. The new formulary is called the **Essential Formulary**. This formulary is being used for select Individual HCR plans in Delaware and has already been used for the last two years in Pennsylvania and West Virginia. Letters will be sent to impacted HCR members and to their prescribers who may be currently taking a medication which will be nonformulary on the Essential Formulary.

If your patient(s) who are impacted by this change remain on any of the drugs which are nonformulary on the Essential formulary after the Jan. 1, 2019, effective date, they will be responsible for the entire cost of the drug(s).

To ensure that your patients receive the maximum prescription drug coverage, please consider the available formulary drug options. A list of drugs included on the Essential Formulary, listed by therapeutic class, is available at **HighmarkEssentialFormulary.com**.

As a reminder, NaviNet® can be used for any pharmacy authorization request. It saves you time, notifies you if a duplicate request has already been received by Highmark, and confirms that the patient is a Highmark member with active pharmacy benefits.

We hope this information makes the transition easier for both you and your patients. Our goal, as always, is to work with you to help control the high cost of prescription drug coverage while maintaining high-quality patient care.

Vitamin D Coverage January 1, 2019

The United States Preventive Services Task Force (USPSTF) withdrew its prior Category B recommendation for vitamin D supplementation for adults 65 years and older, making it no longer mandatory to cover these products at a \$0 copay. These products will be removed from the Highmark Preventive Health drug lists on **January 1, 2019**. As these are OTC vitamin containing products, coverage will be based on whether the member's plan includes coverage of OTC vitamins and will be subject to the member's applicable cost share if covered.

Important Drug Safety Updates

Taytulla (norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules) by Allergan: Recall - Due to Out-of-Sequence Capsules

On May 29, 2019, Allergan announced a voluntary recall of Taytulla 1mg/20mcg, 6x28 physicians' sample pack (Lot#5620706) due to a packaging error in which four placebo capsules were placed out of order. Specifically, the first four days of therapy had four non-hormonal placebo capsules instead of active capsules. As a result of this error, oral contraceptive capsules that are taken out of sequence may place the user at risk for contraceptive failure and 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.

Fluticasone Propionate Nasal Spray by Apotex Corp: Recall - Due to Potential for Small Glass Particles

On May 31, 2018, Apotex Corp. announced a voluntary recall of Fluticasone propionate Nasal Spray 50 mcg per spray 120 Metered Sprays due to a customer complaint of the spray containing small glass particles. The potential defect could affect how the pump functions, and local trauma to the nasal mucosa might occur with use of the defective product. 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.

Naloxone Hydrochloride Injection, USP, 0.4 mg/mL, 1 mL in 2.5 mL in the Carpuject Single-use Cartridge Syringe System by Hospira: Recall - Due to the Potential Presence of Particulate Matter

On June 4, 2018, Hospira, Inc., announced a voluntary recall of Naloxone Hydrochloride Injection, USP, 0.4 mg/mL, 1 mL in 2.5 mL, Carpuject Single-use cartridge syringe system (NDC# 0409-1782-69, Lot Numbers 72680LL and 76510LL), to the hospital/institution level due to the potential presence of embedded and loose particulate matter on the syringe plunger. Use of this product may result in a low likelihood of experiencing adverse events ranging from local irritation, allergic reactions, phlebitis, end-organ granuloma, tissue ischemia, pulmonary emboli, pulmonary dysfunction, pulmonary infarction, and toxicity. Distributors or retailers with an existing inventory of the recalled products should stop use and distribution and quarantine immediately. 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.

Fluoroquinolone Antibiotics: FDA Requires Labeling Changes Due to Low Blood Sugar Levels and Mental Health Side Effects

On July 10, 2018, the FDA announced a recommendation to strengthen the current warnings in the prescribing information that fluoroquinolone antibiotics may cause significant decreases in blood sugar and certain mental health side effects. The new label changes will add that low blood sugar levels (hypoglycemia) can lead to coma and will also make the mental health side effects more prominent and more consistent across the systemic fluoroquinolone drug class. Health care professionals should be aware of the potential risk of hypoglycemia, particularly in elderly patients and patients with diabetes taking an oral hypoglycemic medicine or insulin. 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.

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

On July 13, 2018, the FDA announced an ongoing investigation into the voluntary recall of valsartan-containing products. The recalled products contain an impurity, N-nitrosodimethylamine (NDMA), in the active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals or Hetero Labs Limited, Unit-1. Not all products containing valsartan are being recalled. There are currently five voluntary recalls related to the NDMA impurity detected in the valsartan API: Teva Pharmaceuticals USA labeled as Major Pharmaceuticals, Prinston Pharmaceuticals Inc. labeled as Solco Healthcare LLC, Teva Pharmaceuticals labeled as Actavis LLC, Camber Pharmaceuticals Inc. and Torrent Pharmaceuticals Limited. 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. Additional data is being reviewed, and conclusions and recommendations will be communicated when further FDA 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.

Highmark Formulary Update -October 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 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 September 7, 2018, unless otherwise noted.)

Brand Name	Generic Name	Comments
Jynarque	tolvaptan	New formulation of tolvaptan, indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).
Plenvu*,**	polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride	New low-volume (1L) PEG-based bowel preparation for cleansing of the colon in preparation for colonoscopies in adults.
Lucemyra**	lofexidine	First non-opioid for the mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.
Yonsa	abiraterone acetate	New formulation of abiraterone acetate, for the treatment of metastatic castration-resistant prostate cancer, in combination with methylprednisolone.
Symtuza	darunavir, cobicistat, emtricitabine, tenofovir alafenamide	First complete darunavir-based, single tablet regimen for HIV-1 infection.

^{*}Effective date to be determined.

^{**} Product not added to Healthcare Reform Comprehensive Open/Incentive formularies Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives	
halobetasol propionate	halobetasol propionate topical	betamethasone topical cream/ointment, clobetasol	
topical foam*	foam	topical cream/ointment	
Olumiant	baricitinib	Actemra, Enbrel, Humira, Xeljanz	
Retacrit	epoetin alfa-epbx	Procrit, Epogen	
Prograf oral granules*	tacrolimus	tacrolimus capsules	
Fulphila	pegfilgrastim-jmdb	Neulasta, Neupogen	
Consensi*	amlodipine/celecoxib	celecoxib, amlodipine	
moxidectin*	moxidectin	ivermectin	
Epidiolex*	cannabidiol	topiramate	
Nocdurna*	desmopressin acetate	generic desmopressin	
Braftovi	encorafenib	Tafinlar	
Mektovi	binimetinib	Mekinist	
Qbrexza*	glycopyrronium	aluminum chloride solution, Xerac Ac	
Orilissa	elagolix	Danazol, Lupron Depot, Synarel, Zoladex	
hydrocodone bitartrate/ guaifenesin tablets*	hydrocodone bitartrate/ guaifenesin tablets	Provider discretion	
Aimovig	erenumab	Provider discretion	
Lokelma	sodium zirconium cyclosilcate	Provider discretion	
Palynziq	pegvaliase-pqpz	Provider discretion	
Doptelet	avatrombopag	Provider discretion	
Nuplazid capsule	pimavanserin	Provider discretion	
Atropine Auto-injector*	atropine	Provider discretion	
TPOXX*	tecovirimat	Provider discretion	

Coverage may be contingent upon plan benefits.

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
Jynarque	tolvaptan
Yonsa	abiraterone acetate
Palynziq	pegvaliase-pqpz
Olumiant	baricitinib

^{*}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**.

Retacrit	epoetin alfa-epbx
Fulphila	pegfilgrastim-jmdb
Epidiolex	cannabidiol
Braftovi	encorafenib
Mektovi	binimetinib
Doptelet	avatrombopag
Nuplazid capsule	pimavanserin
Symtuza	darunavir, cobicistat, emtricitabine, tenofovir alafenamide
Orilissa	elagolix
Renvela	sevelamer carbonate
Renagel	sevelamer
Phoslyra	calcium acetate
Fosrenol	lanthanum carbonate
Orkambi	lumacaftor, ivacaftor

Table 4. Products to be Removed or Shifted to Higher Tier – Effective January 1, 2019

		The Effective Junuary 17 2013			
Brand name	Generic Name	Preferred Alternatives			
	Only healthcare reform co	omprehensive products			
Forteo	teriparatide	Tymlos			
Pradaxa	dabigatran	Eliquis, Xarelto			
	Only commercial comp	orehensive products			
Farxiga	dapagliflozin	Jardiance, Invokana			
Xigduo XR	dapagliflozin/metformin	Synjardy, Invokamet			
Norvir capsules	ritonavir ritonavir				
All c	All commercial & healthcare reform comprehensive products				
Copaxone	glatiramer acetate	glatiramer acetate, Glatopa			
Mephyton	phytonadione (vit k1)	phytonadione			
Biltricide	praziquantel	praziquantel			
Norvir tablets	ritonavir	ritonavir			
Gabitril	tiagabine	tiagabine			
Adcirca	tadalafil	tadalafil			

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 September 7, 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

		·	Comments/Preferred
Brand Name	Generic Name	Tier	Alternatives
	Items liste	d below are preferred products	
Jynarque	tolvaptan	3-Preferred Brand	New formulation of tolvaptan, indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).
Yonsa	abiraterone acetate	3-Preferred Brand	New formulation of abiraterone acetate, for the treatment of metastatic castration-resistant prostate cancer, in combination with methylprednisolone.
Symtuza	darunavir, cobicistat, emtricitabine, tenofovir alafenamide	3-Preferred Brand	First complete darunavir-based, single tablet regimen for HIV-1 infection.
	Items listed l	below are non-preferred produ	cts
halobetasol propionate topical foam*	halobetasol propionate topical foam	4-Non-preferred Brand	betamethasone topical cream/ointment, clobetasol topical cream/ointment
Prograf oral granules*	tacrolimus	4-Non-preferred Brand	tacrolimus capsules
Consensi*	amlodipine/celecoxib	4-Non-preferred Brand	celecoxib, amlodipine
moxidectin*	moxidectin	4-Non-preferred Brand	ivermectin
Nocdurna*	desmopressin acetate	4-Non-preferred Brand	generic desmopressin
Qbrexza*	glycopyrronium	4-Non-preferred Brand	aluminum chloride solution
hydrocodone bitartrate/guaifene sin tablets*	hydrocodone bitartrate/guaifenesin tablets	2-Non-preferred Generic	Provider discretion
Plenvu*	polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and	4-Non-preferred Brand	Provider discretion

potassium chloride		
lofexidine	4-Non-preferred Brand	Provider discretion
erenumab	4-Non-preferred Brand	Provider discretion
sodium zirconium	4-Non-preferred Brand	Provider discretion
cyclosilcate		
atropine	4-Non-preferred Brand	Provider discretion
tecovirimat	4-Non-preferred Brand	Provider discretion
baricitinib	4-Non-preferred Brand	Actemra, Enbrel, Humira, Xeljanz
epoetin alfa-epbx	4-Non-preferred Brand	Aranesp
pegfilgrastim-jmdb	4-Non-preferred Brand	Neulasta, Neupogen
cannabidiol	4-Non-preferred Brand	topiramate
encorafenib	4-Non-preferred Brand	Tafinlar
binimetinib	4-Non-preferred Brand	Mekinist
elagolix	4-Non-preferred Brand	Danazol, Lupron Depot, Synarel
sevelamer carbonate	4-Non-preferred Brand	sevelamer carbonate
sevelamer	4-Non-preferred Brand	sevelamer carbonate
calcium acetate	4-Non-preferred Brand	calcium acetate
lanthanum carbonate	4-Non-preferred Brand	lanthanum carbonate
lumacaftor, ivacaftor	4-Non-preferred Brand	Provider discretion
pegvaliase-pqpz	4-Non-preferred Brand	Provider discretion
avatromobopag	4-Non-preferred Brand	Provider discretion
pimavanserin	4-Non-preferred Brand	Provider discretion
	lofexidine erenumab sodium zirconium cyclosilcate atropine tecovirimat baricitinib epoetin alfa-epbx pegfilgrastim-jmdb cannabidiol encorafenib binimetinib elagolix sevelamer carbonate sevelamer calcium acetate lanthanum carbonate lumacaftor, ivacaftor pegvaliase-pqpz avatromobopag	lofexidine erenumab 4-Non-preferred Brand sodium zirconium cyclosilcate atropine 4-Non-preferred Brand tecovirimat 4-Non-preferred Brand baricitinib 4-Non-preferred Brand epoetin alfa-epbx pegfilgrastim-jmdb 4-Non-preferred Brand cannabidiol 4-Non-preferred Brand encorafenib 4-Non-preferred Brand binimetinib 4-Non-preferred Brand binimetinib 4-Non-preferred Brand elagolix 4-Non-preferred Brand sevelamer carbonate 4-Non-preferred Brand sevelamer 4-Non-preferred Brand lanthanum carbonate 4-Non-preferred Brand lumacaftor, ivacaftor pegvaliase-pqpz 4-Non-preferred Brand pimavanserin 4-Non-preferred Brand pimavanserin 4-Non-preferred Brand

Coverage may be contingent upon plan benefits.

Table 3. Products to be Removed or Shifted to Higher Tier – Effective January 1, 2019

		<u>, </u>			
Brand Name	Generic Name	Preferred Alternatives			
	Only healthcare reform p	progressive products			
Forteo	teriparatide	Tymlos			
Only commercial progressive products					
Farxiga	dapagliflozin	Jardiance, Invokana			
Xigduo XR	dapagliflozin/metformin	Synjardy, Invokamet			
Norvir capsules	ritonavir	ritonavir			
All commercial & healthcare reform progressive products					
Copaxone	glatiramer acetate	glatiramer acetate, Glatopa			
Norvir tablets	ritonavir	ritonavir			
Estrace	Estradiol	estradiol			
Zavesca	Miglustat	miglustat			
Adcirca	tadalafil	tadalafil			

^{*}Effective date to be determined.

^{**}Effective January 1, 2019, the Progressive Formulary will not apply to Highmark Delaware members

C. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Topical Non-Steroid Therapy for Atopic Dermatitis – Commercial	07/01/2018	Policy revised to note exclusion of plans with the Commercial National Select formulary (NSF).
Topical Non-Steroid Therapy for Atopic Dermatitis – Commercial NSF	07/01/2018	New policy created for plans with the NSF. Policy outlines approval criteria for Protopic and Elidel when used for an FDA-approved indication after failure of one topical corticosteroid.
Viberzi (eluxadoline) – Commercial	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Viberzi (eluxadoline) – Commercial NSF	07/01/2018	New policy created for plans with the NSF. Policy outlines approval criteria for eluxadoline (Viberzi) when used for IBS-D in adults after failure of at least one alternative therapy.
Cystic Fibrosis (CF) – Inhaled Antibiotics – Commercial and Healthcare Reform	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Cystic Fibrosis (CF) – Inhaled Antibiotics – Commercial NSF	07/01/2018	New policy created for plans with the NSF. Policy outlines approval criteria for inhaled antibiotics. Bethkis can be approved without trial and failure of generic tobramycin for the NSF.
Nitisinone (Nityr and Orfadin) – Commercial	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Nitisinone (Nityr and Orfadin) – Commercial National Select	07/01/2018	New policy created for plans with the NSF. Policy outlines approval criteria for Nityr and Orfadin for patients with hereditary tyrosinemia type 1 following a restricted tyrosine and phenylalanine diet.
Diclofenac Containing Products – Commercial and Healthcare Reform	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Diclofenac Containing Products – Commercial National Select	07/01/2018	New policy created for plans with the NSF. Policy outlines approval criteria for Pennsaid for members with osteoarthritis who have failed generic topical diclofenac, and Zipsor after failure of generic oral diclofenac. Zorvolex continues to require trial and failure of 3 generic NSAIDs, one of which must be oral diclofenac.
Nascobal (cyanocobalamin) – Commercial	09/01/2018	New policy created to ensure that member meets FDA-approved indication and cannot continue to use intramuscular B12 injections for maintenance therapy.
Naproxen and Fenoprofen Containing Products – Commercial	09/01/2018	New policy created to ensure safety, appropriate utilization and use of cost-effective therapeutic treatments. The policy requires documentation of use for an FDA-approved indication as well as trial and failure and/or intolerance to 3 other generic NSAIDs. In addition, the policy establishes quantity limits for the naproxen CR/ER products.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Jynarque (tolvaptan) – Commercial and Healthcare Reform	09/21/2018	New policy created for newly FDA-approved agent indicated for autosomal dominant polycystic kidney disease (ADPKD). Policy requires substantiation of rapidly progressing disease and consultation with a nephrologist.
Palynziq (pegvaliase-pqpz) – Commercial and Healthcare Reform	08/20/2018	New policy created for newly FDA-approved agent. Policy requires appropriate diagnosis of phenylketonuria (PKU) and documentation of prior disease management through use of Kuvan or phenylalanine diet restriction.
Epidiolex (cannabidiol solution) – Commercial and Healthcare Reform	TBD	New policy created for newly FDA-approved cannabidiol solution (Epidiolex). Policy requires appropriate diagnosis of Lennox-Gastaut syndrome or Dravet syndrome in members 2 years of age or older, documentation of use with other conventional agents, and documentation of trial and failure of two standard of care treatments used as monotherapy (divalproex, topiramate, lamotrigine, clobazam).
Braftovi (encorafenib) and Mektovi (binimetinib) – Commercial and Healthcare Reform	08/20/2018	New policy created to ensure appropriate use of encorafenib (Braftovi) and binimetinib (Mektovi) in combination for the treatment of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation.
Doptelet (avatrombopag) – Commercial and Healthcare Reform	09/21/2018	New policy created for newly FDA-approved agent indicated for treatment of adult patients with thrombocytopenia who have chronic liver disease (CLD) and are scheduled to undergo a procedure. Policy requires demonstration of appropriate diagnosis, documentation of platelet count and quantity limit description per member platelet count.
Orilissa (elagolix) – Medicare	TBD	New policy created for newly FDA-approved agent to ensure appropriate use of elagolix (Orilissa) for adult females who are not pregnant with diagnosis of endometriosis with documentation of moderate to severe pain. Policy requires failure of at least two standard of care treatments (e.g., NSAIDs, combined hormonal contraceptive, progestin, GnRH agonist, Danazol).
Veltassa (patiromer) and Lokelma (sodium zirconium cyclosilicate) – Commercial and Healthcare Reform	09/21/2018	Policy revised to add sodium zirconium cyclosilicate (Lokelma) to the current policy and re-authorization criteria was revised to remove the requirement for having a diagnosis of a chronic condition that is contributing to persistent hyperkalemia. Coverage criteria requirements for patiromer (Veltassa) will be applicable to the Healthcare Reform line of business effective 1/1/2019.
Viberzi (eluxadoline) – Commercial, Healthcare Reform, and Commercial NSF	08/20/2018	Policy revised to include reauthorization criteria which ask for attestation of positive clinical response to eluxadoline (Viberzi).
Endari (L-glutamine) – Commercial and Healthcare Reform	08/20/2018	Policy revised to remove approval criteria requirement of trial and failure of at least one over-the-counter L-glutamine product prior to utilizing Endari. Policy revised to greater than or equal to 2 sickle cell pain crises within previous 12 months to align with clinical trial

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Syndros (dronabinol oral solution) – Commercial and Healthcare Reform	08/20/2018	inclusion criteria. Policy revised to add reauthorization criteria for anti-emetic therapy use (currently reauthorization criteria only exist for appetite stimulant therapy use, attesting to increase in weight from initial authorization). Reauthorization criteria for anti-emetic therapy require attestation that the medication is effective, in addition to meeting the current medical necessity criteria.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	08/20/2018	Policy revised to include expanded indication of polyarticular juvenile idiopathic arthritis for tocilizumab (Actemra) where patients must have an inadequate response or intolerance to at least one disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide). Policy revised to include expanded indication of ulcerative colitis for tofacitinib (Xeljanz) where patients must have an inadequate response or intolerance to at least two immunosuppressants (e.g., corticosteroids, azathioprine, 6-mercaptopurine) and the preferred biologic product (Humira). Policy revised to include expanded indication of plaque psoriasis for certolizumab pegol (Cimzia) where patients must step through phototherapy or systemic therapy and must have an inadequate response or intolerance to at least two preferred agents (e.g., Cosentyx, Humira, Otezla, Stelara). Policy revised to include the newly FDA-approved agent baricitinib (Olumiant) indicated for rheumatoid arthritis where patients must have an inadequate response or intolerance to at least one DMARD (e.g., methotrexate, leflunomide) and two preferred agents (e.g., Actemra, Enbrel, Humira, Xeljanz) where at least one of the agents has to be a tumor necrosis factor (TNF) inhibitor (e.g., Enbrel, Humira).
Zytiga and Yonsa (abiraterone acetate) – Commercial and Healthcare Reform	08/20/2018	Policy revised to include coverage for abiraterone acetate (Yonsa) in combination with methylprednisolone for the treatment of metastatic castration-resistant prostate cancer.
Strensiq (asfotase alfa) – Commercial and Healthcare Reform	08/20/2018	Policy revised to require additional substantiation of the diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia, including treatment by or in consultation with a specialist, and documentation of history of onset of symptoms prior to 18 years of age.
Immediate Release Fentanyl Citrate – Commercial and Healthcare Reform	08/20/2018	Policy revised to remove fentanyl buccal soluble film (Onsolis) as a targeted product.
Gilenya (fingoimod) – Commercial and Healthcare Reform	08/20/2018	Policy revised to include coverage for patients with relapsing multiple sclerosis (MS) who are 10 years and older.
PCSK9 Inhibitors – Commercial and Healthcare Reform	08/01/2018	Policy revised to remove specific prescriber requirements (e.g., cardiologist) and to remove attestation patient is undergoing lifestyle changes or enrolled in a lipid clinic for those with

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Venclexta (venetoclax) – Commercial and Healthcare Reform	08/20/2018	atherosclerotic cardiovascular disease (ASCVD). Coverage of the additional indication (primary hyperlipidemia) for evolocumab (Repatha) was also added. Policy revised to include the expanded indication of small lymphocytic lymphoma (SLL) with or without 17p genetic mutation, who have received at least one prior therapy for venetoclax (Venclexta). Policy was split from original policy of J-479 to separate Commercial/Healthcare Reform line of business from Medicare.
Prolia (denosumab) – Commercial and Healthcare Reform	08/20/2018	Policy revised to include expanded indication for denosumab (Prolia) of treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture.
Fertility – Commercial and Select Healthcare Reform Plans	08/20/2018	Policy revised to include hypogonadotropic hypogonadism in the authorization duration section and to update coverage of cetrorelix acetate (Cetrotide) when used with assisted reproductive technology, if the member has the associated Assisted Reproductive Technology/In-Vitro Fertilization (ART/IVF) benefit.
Cystic Fibrosis (CF) Inhaled Antibiotics – Commercial, Healthcare Reform, and Commercial NSF	08/20/2018	Policy revised to add reauthorization criteria specific to dornase alfa (Pulmozyme) (e.g., improvement in forced expiratory volume (FEV1) or decrease in the number of respiratory infections).
Entresto (sacubitril/valsartan) –Healthcare Reform	09/01/2018	Policy revised to remove Commercial from policy.
Kinase Inhibitors – Commercial and Healthcare Reform	08/20/2018	Policy revised to include expanded indication for trametinib (Mekinist) and dabrafenib (Tafinlar) for the adjuvant treatment of BRAF V600E or V600K mutated melanoma with lymph node involvement, following complete resection; and for treatment of locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation. Policy also revised to include expanded indication of ribociclib (Kisqali) as initial endocrine-based treatment for pre-/peri-menopausal women with HR-positive, HER2-negative metastatic breast cancer in combination with an aromatase inhibitor, and in combination with fulvestrant in postmenopausal women as initial endocrine-based therapy or following disease progression on prior endocrine therapy.
Xtandi (enzalutamide) – Commercial and Healthcare Reform Human Growth Hormone – Commercial and Healthcare Reform & Delaware Commercial and Healthcare Reform	08/20/2018	Policy revised to include expanded indication for enzalutamide (Xtandi) for treatment of non-metastatic castration-resistant prostate cancer. Policy revised to include expanded indications for somatropin (Zomacton) for the treatment of pediatric patients with short stature associated with Turner syndrome, idiopathic short stature, short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency, and short stature born small for gestational age (SGA) with no catch-up growth by 2-4 years. No criteria changes.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Hereditary Angioedema – Commercial and Healthcare Reform	08/20/2018	Policy revised to include expanded indication for Cinryze [C1 Esterase Inhibitor (Human)] for the routine prophylaxis against angioedema attacks in adults, adolescents and pediatric patients (6 years of age and older) with Hereditary Angioedema (HAE). In addition, policy revised to include age limits from studied clinical trial experience for HAE agents.
CGRP Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised to move the requirement for prescribing by or in consultation with a neurologist or headache specialist to the background section. Additionally, for both episodic as well as chronic migraine (CM), documentation is requested to demonstrate intolerance to one agent from two prophylactic migraine medication classes (previously required three for CM). Policy applicable to erenumab (Aimovig), the only currently available CGRP inhibitor on the market.
Sabril (vigabatrin) – Healthcare Reform	TBD	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.

^{*}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
Minocin (minocycline HCl) – Commercial NSF	07/01/2018	New policy created for plans with the NSF. Policy outlines approval criteria for Minocin for treatment of acne after failure of two oral antibiotics, one of which must be minocycline ER, and one topical agent for the treatment of acne.
Proton Pump Inhibitors (PPIs) – Commercial	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Proton Pump Inhibitors (PPIs) – Commercial NSF	07/01/2018	New policy created for plans with the NSF. Policy outlines approval criteria for non-preferred PPIs after trial of omeprazole and pantoprazole. Nexium packets for suspension are not included as a non-preferred product for the NSF.
Beta Blocker Management – Commercial	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Beta Blocker Management – Commercial NSF	07/01/2018	New policy created for plans with the NSF. Policy outlines approval criteria for non-preferred beta blockers after failure of two generic alternatives. Bystolic and Byvalson require single generic step for the NSF.
Duexis (ibuprofen/ famotidine) – Commercial and Healthcare Reform	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Duexis (ibuprofen/ famotidine) – Commercial NSF	07/01/2018	New policy created for plans with the NSF. Policy outlines approval criteria for Duexis after trial of ibuprofen in combination with famotidine.
Selective Serotonin- Norepinephrine Reuptake Inhibitors – Commercial and Healthcare Reform	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Selective Serotonin- Norepinephrine Reuptake Inhibitors – Commercial NSF	07/01/2018	New policy created for plans with the NSF. Policy outlines approval criteria for Fetzima, Khedezla or Pristiq after failure of one prior antidepressant.
Vimovo (naproxen/ esomeprazole) – Commercial and Healthcare Reform	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Vimovo (naproxen/ esomeprazole) – Commercial NSF	07/01/2018	New policy created for plans with the NSF. Policy outlines approval criteria for Vimovo after failure of naproxen in combination with omeprazole.
Topical Antifungals – Commercial and Healthcare Reform Topical Antifungals – Commercial NSF	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF. New policy created for plans with the NSF. Policy outlines approval criteria for tavaborole (Kerydin) after failure of generic oral terbinafine and ciclopirox solution. Effinaconazole (Jublia) is not included as a targeted product for the NSF.
Viibryd (vilazodone) and Brintellix/Trintellix (vortioxetine) – Commercial and Healthcare Reform	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Viibryd (vilazodone) and Brintellix/Trintellix (vortioxetine) – Commercial NSF	07/01/2018	New policy created for plans with NSF. Policy outlines approval criteria for Viibryd and Trintellix/Brintellix after failure of one prior antidepressant.
Interferon Beta – Commercial	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Preferred Blood Glucose Testing Products – Commercial and Select Healthcare Reform Non-Preferred Dipeptidyn	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF. Policy revised to note exclusion of plans with the Commercial NSF.
Peptidase IV Inhibitors – Commercial and Healthcare Reform		

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Epinephrine Auto Injectors – Commercial and Healthcare Reform	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Non-Preferred Glucagon- Like Peptide-1 Receptor Agonists – Commercial and Healthcare Reform	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Trulance (plecanatide) – Commercial	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Topical Rosacea Treatments – Commercial	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Luzu (Iuliconazole 1% cream) – Commercial	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Solodyn and Ximino (minocycline ER) & Minocin (minocycline HCl) – Commercial	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Non-Preferred Nasal Steroids – Commercial	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Doxycycline Products – Commercial	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF. Okebo and Targadox included as targeted doxycycline products.
Acute Migraine Therapies – Commercial	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Consensi (amlodipine/ celecoxib) – Commercial and Healthcare Reform	TBD	New policy created for recently approved Consensi to ensure proper use and step therapy with two generic calcium channel blockers and two NSAIDS.
Selective Serotonin- Norepinephrine Reuptake Inhibitors – Commercial	09/01/2018	Policy revised to separate commercial and also decrease levomilnacipran (Fetzima) criteria to only require one other treatment failure.
Edarbi (azilsartan) – Healthcare Reform Essential Formulary	08/20/2018	Policy revised to update the authorization duration from lifetime to 12 months.
Xifaxan 550mg (rifaximin) – Commercial and Healthcare Reform	08/20/2018	Policy revised to include reauthorization criteria which requires a 10-week treatment-free period between courses of rifaximin (Xifaxan) therapy in members with diarrhea-predominant irritable bowel syndrome (IBS-D).
Opioid-Containing Cough and Cold Medications – Commercial and Healthcare Reform	08/20/2018	Policy revised to provide criteria for exception to the quantity limit of 21 days of therapy per 90 days for opioid-containing cough and cold medications. Additionally, codeine/pseudoephedrine/tripolidine (Triacin C) was removed from the policy, as the drug is now off-market.
Leukotriene Modifiers (Zyflo, Zyflo CR) – Healthcare Reform	08/20/2018	Policy revised to require trial of a corticosteroid (ICS) or corticosteroid/long-acting beta-agonist inhaler (ICS/LABA) agent prior to accolate approval and trial of generic zileuton ER for approval of zileuton (Zyflo/Zyflo CR).

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Opioid Dependence Step Therapy – Healthcare Reform Essential Formulary	08/20/2018	Policy revised to limit authorization duration to 12 months.
Fosamax Plus D (alendronate sodium/cholecalciferol) – Healthcare Reform Essential Formulary	08/20/2018	Policy revised to limit authorization duration to 12 months.
Bystolic (nebivolol) – Healthcare Reform Essential	08/20/2018	Policy revised to limit authorization duration to 12 months.
Rayos (prednisone) – Commercial and Healthcare Reform WVS	08/20/2018	Policy revised to limit authorization duration to 12 months.
Vimovo (naproxen; esomeprazole) – Commercial, Healthcare Reform, and Commercial NSF	08/20/2018	Policy revised to limit authorization duration to 12 months.
Non-preferred Generic NSAIDs – Healthcare Reform Essential Formulary	08/20/2018	Policy revised to limit authorization duration to 12 months.
Avandia (rosiglitazone) – Healthcare Reform Essential Formulary	08/20/2018	Policy revised to limit authorization duration to 12 months.
Non-preferred Hypnotic Medications – Healthcare Reform Essential Formulary	08/20/2018	Policy revised to remove sleep maintenance from the ramelteon (Rozerem) criteria as this is not an FDA-approved indication.
Non-preferred Statins – Healthcare Reform Essential	09/21/2018	Policy revised to include pitavastatin (Zypitamag) as a targeted product, requiring trial and failure of at least 2 preferred generic statins prior to use.
Lyrica/Lyrica CR (pregabalin/pregabalin ER) – Commercial and Healthcare Reform	08/20/2018	Policy revised to include expanded indication for pregabalin (Lyrica) of partial onset seizures in patients age 4 years and older.
Non-preferred Migraine Medications – Healthcare Reform Essential	09/21/2018	Policy revised to include criteria for pediatric patients. Almotriptan malate may be approved for members 12-17 years of age for a diagnosis of acute migraine following therapeutic failure, intolerance or contraindication to rizatriptan benzoate. Additionally, naratriptan was removed as a preferred agent and authorization duration was decreased from lifetime to 12 months.
Acute Migraine Therapies – Commercial	TBD	Policy revised to add zolmitriptan (Zomig) nasal spray as a targeted agent and to clarify cluster headache criteria by creating a distinct review section.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Migraine Step Therapy – Healthcare Reform	01/01/2019	New step therapy policy created requiring trial and failure of two preferred generic medications before branded products.
Non-Stimulant Treatment of ADHD/ADD – Commercial and Healthcare Reform	09/01/2018	Policy revised to remove generic atomoxetine for Commercial members.
Viibryd and Brintellix/ Trintellix (vilazodone and vortioxetine) – Commercial	09/01/2018	Policy revised to include all Commercial formularies.
Viibryd and Brintellix/ Trintellix (vilazodone and vortioxetine) – Healthcare Reform	09/01/2018	Policy revised to remove Commercial formularies.
Selective Serotonin- Norepinephrine Reuptake Inhibitors – Healthcare Reform	09/01/2018	Policy revised to remove Commercial formularies.
Doxycycline Products – Healthcare Reform	01/01/2019	New policy created to promote appropriate use of branded doxycycline products requiring use of generic doxycycline, one other tetracycline or erythromycin, and a topical antibiotic for acne.
Oral Isotretinoin Therapy – Healthcare Reform	01/01/2019	New policy created targeting Absorica (isotretinoin) which promotes the use of other oral and topical acne treatments, including failure of another oral isotretinoin medication.
Nonpreferred Nasal Steroids – Healthcare Reform	01/01/2019	New policy created to require step through two preferred generic nasal steroids, fluticasone propionate nasal spray and triamcinolone nasal spray, before Beconase AQ, Dymista, Flonase, Nasacort, Nasonex (mometasone furoate nasal spray), Omnaris, Qnasl, Rhinocort, Veramyst, or Zetonna are covered.
Non-Preferred Naproxen and Fenoprofen Containing Therapy – Healthcare Reform	01/01/2019	New policy promoting the use of generic, low cost NSAIDs prior to coverage of Naprelan CR, naproxen CR, naproxen ER, Nalfon, Fenortho, Profeno and fenoprofen calcium.
Topical Lidocaine Products – Commercial and Healthcare Reform	01/01/2019	Policy revised to include lidocaine/tetracaine (Pliaglis) and include Healthcare Reform line of business.
Non-Preferred Bupropion Therapy – Healthcare Reform	01/01/2019	New policy created to promote use of generic bupropion and one additional generic antidepressant prior to branded bupropion products.
Preferred Insomnia Medications – Healthcare Reform	01/01/2019	New policy created to promote appropriate use of insomnia medications and use of generic products prior to branded products.
Topical Rosacea Treatments – Healthcare Reform	01/01/2019	New policy created to ensure appropriate use and trial/failure of generic topical metronidazole agents for coverage of branded topical rosacea products and trial/failure of generic topical metronidazole agents for coverage of Mirvaso.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Non-Preferred Benign Prostatic Hyperplasia (BPH) Therapy – Healthcare Reform	01/01/2019	New policy created to promote use of generic BPH agents prior to branded products.
Non-Preferred Erectile Dysfunction Therapy – Healthcare Reform	01/01/2019	New policy created to promote use of preferred generic product sildenafil citrate for the treatment of erectile dysfunction (ED) prior to utilizing Levitra, Staxyn, Viagra, or Stendra.
Doxepin 5% Cream – Healthcare Reform	01/01/2019	New policy created to limit use of doxepin cream to FDA-approved indications and to limit quantity as well. Policy needed for safety considerations.
Xerese (acyclovir, hydrocortisone) – Healthcare Reform	01/01/2019	New policy created to ensure appropriate use for FDA-approved indication (herpes labialis [cold sores]) and step through formulary antiviral agents such as acyclovir, valacyclovir, or acyclovir, or use of acyclovir 5% ointment and hydrocortisone 1% cream simultaneously.
Beta Blocker Management – Healthcare Reform	01/01/2019	New policy created to promote use of generic beta blockers agents prior to branded products.
Minocycline Products – Healthcare Reform	01/01/2019	Policy revised to include Minocin (minocycline) as a targeted product.
Daraprim – Healthcare Reform	01/01/2019	New policy created to promote appropriate use and failure of trimethoprim/sulfamethoxazole.
Trulance (plecanatide) – Healthcare Reform Evekeo (amphetamine sulfate) – Healthcare Reform	01/01/2019	New policy created to promote appropriate use of plecanatide (Trulance) and use of Linzess and Amitiza prior to Trulance. New policy created to promote appropriate use and failure of generic stimulants for narcolepsy and attention deficit hyperactivity disorder (ADHD).
Northera (droxidopa) – Healthcare Reform	01/01/2019	Policy revised to include step through midodrine and fludricortisone.
Nityr & Orfadin (nitisinone) – Healthcare Reform	01/01/2019	Policy revised to include step through nitisinone (Nityr) for Orfadin.
Testosterone (Androgens) – Healthcare Reform Preferred Chemotherapy Induced Nausea and Vomiting (CINV) – Healthcare Reform	01/01/2019 TBD	Policy revised to include step through Androgel 1.62% for all other topical products. New policy created to require step through generic aprepitant for aprepitant (Emend) capsule, Emend oral suspension, and rolapitant (Varubi), step through generic granisetron or generic ondansetron with generic aprepitant for netupitant/palonosetron (Akynzeo); step through generic ondansetron for ondansetron (Zuplenz), and step through generic granisetron or generic ondansetron for granisetron (Sancuso).
Hemangeol (propranolol) oral solution – Healthcare Reform	01/01/2019	New policy created to promote use of propranolol (Hemangeol) in patients two years of age or younger with proliferating infantile hemangioma.
Non-preferred Sodium- Glucose Co-Transporter 2 Inhibitors – Commercial	09/01/2018	New policy created to verify diagnosis and trial and failure of preferred canagliflozin (Invokana, Invokamet) and empagliflozin (Jardiance, Synjardy) products before receiving a non-preferred product (Farxiga, Xigduo XR, Steglatro, or Stegluromet).

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Latuda (lurasidone) – Commercial	09/01/2018	New policy created to promote use of formulary alternatives prior to utilization of lurasidone (Latuda) for bipolar depression or schizophrenia
Topical Psoriasis Treatments – Commercial	09/01/2018	Policy revised to remove Enstilar and Taclonex from the policy
Topical Acne Medications – Commercial	09/01/2018	Policy revised to only require single step for Aczone, Acanya, and Onexton.
Topical Rosacea Treatments – Commercial	09/01/2018	Policy revised to combine current policy for Rhofade with other treatments for rosacea (Finacea, MetroCream, MetroGel, Mirvaso, and Noritate)
Non-Preferred Benign Prostatic Hyperplasia (BPH) Therapy –Commercial	09/01/2018	New policy created to promote use of generic BPH agents prior to branded products.
Non-Preferred Erectile Dysfunction Therapy – Commercial	09/01/2018	New policy created to promote use of preferred generic product sildenafil citrate for the treatment of erectile dysfunction (ED) prior to utilizing Levitra, Staxyn, Viagra, or Stendra.
Doxepin 5% Cream– Commercial	09/01/2018	New policy created to ensure doxepin 5% cream is used appropriately in patients 18 and older with moderate pruritis due to atopic dermatitis or lichen simplex chronicus, and have tried and failed two topical corticosteroids. Course of therapy is not to exceed 8 days.
Topical Lidocaine Products – Commercial	09/01/2018	New policy created to ensure appropriate use of lidocaine 5% ointment and Pliaglis (lidocaine/tetracaine) for an FDA-approved indication.

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 – NSF	07/01/2018	New policy created to outline the criteria for a targeted NSF medication which would require authorization.
General Non-Formulary Request Criteria – PA and WV- NSF	07/01/2018	New policy created to outline the criteria for a targeted NSF medication which would require authorization.
Market Watch Programs – Delaware	07/01/2018	New policy created to outline the criteria for a targeted medication by either the New to Market, Rx with OTC Equivalent, or High Cost Low Value programs.
Market Watch Programs – PA and WV	07/01/2018	New policy created to outline the criteria for a targeted medication by either the New to Market, Rx with OTC Equivalent, or High Cost Low Value programs.

^{*}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
Doptelet (avatrombopag), 20 mg	15 tablets per 28 days	15 tablets per 28 days
hydrocodone bitatrate/guaifenesin tablets, all strengths*	21 days per 90 days	21 days per 90 days
Lucemyra (lofexidine), 0.18 mg	14 days per 90 days	14 days per 90 days
Qbrexza, 2.5% topical cloth*	1 carton per 30 days	3 cartons 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
Atropine Auto-injector, 2 mg*	3 injectors	3 injectors
Auvi-Q (epinephrine), 0.1 mg/0.1 mL	2 devices	2 devices

^{*}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
Braftovi (encorafenib), 50 mg, 75 mg	6 capsules per day
Gocovri (amantadine), 68.5 mg*	1 capsule per day
Lokelma (sodium zirconium cyclosilcate), 5 mg	6 packets per day
Lokelma (sodium zirconium cyclosilcate), 10 mg	3 packets per day
Mektovi (binimetinib), 15 mg tablet	6 tablets per day
Nocdurna (desmopressin acetate), all strengths*	1 tablet per day
Nuplazid (pimavanserin) capsule, 34 mg	1 capsule per day
Nuplazid (pimavanserin) tablet, 10 mg	1 tablet per day
Olumiant (baricitinib), 2 mg	1 tablet per day
Orilissa (elagolix), 150 mg	1 tablet per day
Orilissa (elagolix), 200 mg	2 tablets per day
Symtuza tablet, 800-150 mg	1 tablet per day
Xeljanz (tofacitinib), 10 mg	2 tablets per day
Yonsa (abiraterone acetate), 125 mg	4 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.