SPECIAL eBULLETIN

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:

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.

Pharmacy Benefit Exclusions – West Virginia Plans
January 1, 2019

Effective **January 1, 2019,** there will be an update to the prescription drug benefit for West Virginia Commercial and HCR plans. Certain injectable drugs and medical food products will no longer be covered under the pharmacy benefit in West Virginia, and will then align with current coverage of these products in Pennsylvania and Delaware. Targeted products may be eligible for coverage under a member's medical benefit. Letters will be sent to impacted members who may be currently taking a medication which will no longer be covered under the pharmacy benefit, as well as to their prescribers.

If your patient(s) who are impacted by this change remain on any of the drugs which will not be covered after the Jan. 1, 2019, effective date, they will be responsible for the entire cost of the drug(s).

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.

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 topical foam*	halobetasol propionate topical foam	betamethasone topical cream/ointment, clobetasol 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.
*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
Jynarque	tolvaptan
Yonsa	abiraterone acetate
Palynziq	pegvaliase-pqpz
Olumiant	baricitinib
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

Brand name	Generic Name	Preferred Alternatives
Only healthcare reform comprehensive products		
Forteo	teriparatide	Tymlos
Pradaxa	dabigatran	Eliquis, Xarelto
Only commercial comprehensive products		
Farxiga	dapagliflozin	Jardiance, Invokana
Xigduo XR	dapagliflozin/metformin	Synjardy, Invokamet
Norvir capsules	ritonavir	ritonavir
All commercial & healthcare reform comprehensive products		
Mephyton	phytonadione (vit k1)	phytonadione
Biltricide	praziquantel	praziquantel
Norvir tablets	ritonavir	ritonavir
Gabitril	tiagabine	tiagabine
Adcirca	tadalafil	tadalafil

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

Note: Highmark offers the Progressive Formulary to Highmark Delaware members in select Individual Healthcare Reform plans; see Highmark Delaware's online Provider Resource Center and access the **Pharmacy Program/Formularies** link for details on the formularies and formulary options that apply to Highmark Delaware members. For your convenience, you may search the following formularies online:

Highmark Progressive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=1176922773)
Highmark Healthcare Reform Progressive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=4909431197)
Highmark Delaware Healthcare Reform Progressive Healthcare Reform Formulary:
https://client.formularynavigator.com/Search.aspx?siteCode=3597426829

Table 1. Formulary Updates (All products added to the formulary effective September 7, 2018 unless otherwise noted.)

Brand Name	Generic Name	Tier		Comments/Preferred Alternatives
		Highmark Progressive and Healthcare Reform Progressive	Highmark Delaware Healthcare Reform Progressive**	
Items listed below are preferred products				
Jynarque	tolvaptan	3-Preferred Specialty	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 Specialty	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 Specialty	3-Preferred Brand	First complete darunavir-based, single tablet regimen for HIV-1 infection.
Items listed below are non-preferred products				
halobetasol propionate topical foam*	halobetasol propionate topical foam	3-Non-preferred Brand	4-Non-preferred Brand	betamethasone topical cream/ointment, clobetasol topical cream/ointment
Prograf oral granules*	tacrolimus	3-Non-preferred Brand	4-Non-preferred Brand	tacrolimus capsules
Consensi*	amlodipine/celecoxib	3-Non-preferred Brand	4-Non-preferred Brand	celecoxib, amlodipine
moxidectin*	moxidectin	3-Non-preferred	4-Non-preferred	ivermectin

		Brand	Brand	
Nocdurna*	desmopressin acetate	3-Non-preferred Brand	4-Non-preferred Brand	generic desmopressin
Qbrexza*	glycopyrronium	3-Non-preferred Brand	4-Non-preferred Brand	aluminum chloride solution
hydrocodone bitartrate/guaifenesin tablets*	hydrocodone bitartrate/guaifenesin tablets	3-Non-preferred Brand	2-Non-preferred Generic	Provider discretion

Plenvu*	polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride	3-Non-preferred Brand	4-Non-preferred Brand	Provider discretion
Lucemyra	lofexidine	3-Non-preferred Brand	4-Non-preferred Brand	Provider discretion
Aimovig	erenumab	3-Non-preferred Brand	4-Non-preferred Brand	Provider discretion
Lokelma	sodium zirconium cyclosilcate	3-Non-preferred Brand	4-Non-preferred Brand	Provider discretion
Atropine Auto-injector*	atropine	3-Non-preferred Brand	4-Non-preferred Brand	Provider discretion
TPOXX*	tecovirimat	3-Non-preferred Brand	4-Non-preferred Brand	Provider discretion
Olumiant	baricitinib	4-Non-preferred Specialty	4-Non-preferred Brand	Actemra, Enbrel, Humira, Xeljanz
Retacrit	epoetin alfa-epbx	4-Non-preferred Specialty	4-Non-preferred Brand	Aranesp
Fulphila	pegfilgrastim-jmdb	4-Non-preferred Specialty	4-Non-preferred Brand	Neulasta, Neupogen
Epidiolex*	cannabidiol	4-Non-preferred Specialty	4-Non-preferred Brand	topiramate
Braftovi	encorafenib	4-Non-preferred Specialty	4-Non-preferred Brand	Tafinlar
Mektovi	binimetinib	4-Non-preferred Specialty	4-Non-preferred Brand	Mekinist
Orilissa	elagolix	4-Non-preferred Specialty	4-Non-preferred Brand	Danazol, Lupron Depot, Synarel
Renvela	sevelamer carbonate	4-Non-preferred Specialty	4-Non-preferred Brand	sevelamer carbonate
Renagel	sevelamer	4-Non-preferred Specialty	4-Non-preferred Brand	sevelamer carbonate
Phoslyra	calcium acetate	4-Non-preferred Specialty	4-Non-preferred Brand	calcium acetate
Fosrenol	lanthanum carbonate	4-Non-preferred Specialty	4-Non-preferred Brand	lanthanum carbonate
Orkambi	lumacaftor, ivacaftor	4-Non-preferred	4-Non-preferred	Provider discretion

		Specialty	Brand	
Palynziq	pegvaliase-pqpz	4-Non-preferred Specialty	4-Non-preferred Brand	Provider discretion
Doptelet	avatromobopag	4-Non-preferred Specialty	4-Non-preferred Brand	Provider discretion
Nuplazid capsule	pimavanserin	4-Non-preferred Specialty	4-Non-preferred Brand	Provider discretion

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
**Effective January 1, 2019, the Progressive Formulary will not apply to Highmark Delaware members.

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

Brand Name	Generic Name	Preferred Alternatives
Only healthcare reform 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		
Norvir tablets	ritonavir	ritonavir
Estrace	Estradiol	estradiol
Zavesca	Miglustat	miglustat
Adcirca	tadalafil	tadalafil

C. Changes to the Highmark Healthcare Reform Essential Formulary

The Essential Formulary is a closed formulary for select Healthcare Reform (HCR) Individual plans in Pennsylvania and West Virginia. 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 September 7, 2018 unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Symtuza	darunavir, cobicistat, emtricitabine, tenofovir alafenamide	3	First complete darunavir-based, single tablet regimen for HIV-1 infection.
Plenvu*	polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride	3	New low-volume (1L) PEG-based bowel preparation for cleansing of the colon in preparation for colonoscopies in adults.
Lucemyra	lofexidine	3	First non-opioid for the mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.
Jynarque	tolvaptan	4	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	4	New formulation of abiraterone acetate, for the treatment of metastatic castration-resistant prostate cancer, in combination with methylprednisolone.
Items listed below were not added to the formulary			
halobetasol propionate topical foam*	halobetasol propionate topical foam	NF	betamethasone topical cream/ointment
Olumiant	baricitinib	NF	Actemra, Enbrel, Humira, Xeljanz
Retacrit	epoetin alfa-epbx	NF	Procrit, Epogen
Prograf oral granules*	tacrolimus	NF	tacrolimus capsules
Fulphila	pegfilgrastim-jmdb	NF	Zarxio
Consensi*	amlodipine/celecoxib	NF	celecoxib, amlodipine
moxidectin*	moxidectin	NF	ivermectin
Epidiolex*	cannabidiol	NF	topiramate
Nocdurna*	desmopressin acetate	NF	desmopressin acetate
Braftovi	encorafenib	NF	Tafinlar
Mektovi	binimetinib	NF	Mekinist
Qbrexza*	glycopyrronium	NF	aluminum chloride solution
Orilissa	elagolix	NF	Danazol

hydrocodone bitartrate/guaifenesin tablets*	hydrocodone bitartrate/guaifenesin tablets	NF	Provider discretion
Aimovig	erenumab	NF	Provider discretion
Lokelma	sodium zirconium cyclosilcate	NF	Provider discretion
Palynziq	pegvaliase-pqpz	NF	Provider discretion
Doptelet	avatrombopag	NF	Provider discretion
Nuplazid capsule	pimavanserin	NF	Provider discretion
Atropine Auto-injector*	atropine	NF	Provider discretion
TPOXX*	tecovirimat	NF	Provider discretion

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

Table 2. Products to be Removed or Shifted to Higher Tier – Effective January 1, 2019

Brand Name	Generic Name	Preferred Alternatives
All Healthcare Reform Essential Products		
Welchol	colesevelam	colesevelam
Estrace	estradiol	estradiol
Zavesca	miglustat	miglustat
Mephyton	phytonadione (vit k1)	phytonidione
Biltricide	praziquantel	praziquantel
Norvir tablets	ritonavir	ritonavir
Syprine	trientine	trientine
Forteo	teriparatide	tymlos
Adcirca	tadalafil	tadalafil
Cialis	tadalafil	tadalafil

D. 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) – Commercial and Healthcare Reform	09/21/2018	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., nonsteroidal anti-inflammatory drugs [NSAIDs], combined hormonal contraceptive, progestin, gonadotropin-releasing hormone [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

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		cell pain crises within previous 12 months to align with clinical trial inclusion criteria.
Syndros (dronabinol oral solution) – Commercial and Healthcare Reform	08/20/2018	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	08/01/2018	Policy revised to remove specific prescriber requirements (e.g., cardiologist) and to remove attestation patient is undergoing

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Reform		lifestyle changes or enrolled in a lipid clinic for those with atherosclerotic cardiovascular disease (ASCVD). Coverage of the additional indication (primary hyperlipidemia) for evolocumab (Repatha) was also added.
Venclexta (venetoclax) – Commercial and Healthcare Reform	08/20/2018	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	08/20/2018	Policy revised to include expanded indication for enzalutamide (Xtandi) for treatment of non-metastatic castration-resistant prostate cancer.
Human Growth Hormone – Commercial and Healthcare Reform & Delaware Commercial and Healthcare Reform	08/20/2018	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	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
and Healthcare Reform		
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	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Topical Antifungals – Commercial NSF	07/01/2018	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	07/01/2018	Policy revised to note exclusion of plans with the Commercial NSF.
Non-Preferred Dipeptidyn Peptidase IV Inhibitors – 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
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 (luliconazole 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	01/01/2019	New policy created to promote appropriate use of plecanatide (Trulance) and use of Linzess and Amitiza prior to Trulance.
Evekeo (amphetamine sulfate) – Healthcare Reform	01/01/2019	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	01/01/2019	Policy revised to include step through Androgel 1.62% for all other topical products.
Preferred Chemotherapy Induced Nausea and Vomiting (CINV) – Healthcare Reform	TBD	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 Steglurometa).

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.

SECTION II. Highmark Medicare Part D Formularies

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

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

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

No changes at this time.

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

Brand Name	Generic Name	Preferred Alternatives

Brand Name	Generic Name	Preferred Alternatives
Prograf oral granules	tacrolimus	tacrolimus capsules
Plenvu	polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride	Provider discretion
Lucemyra	lofexidine	Provider discretion
Lokelma	sodium zirconium cyclosilcate	Provider discretion
halobetasol propionate topical foam	halobetasol propionate topical foam	Provider discretion
Consensi	amlodipine/celecoxib	Provider discretion
moxidectin	moxidectin	Provider discretion
Nocdurna	desmopressin acetate	Provider discretion
Glyrx-PF	glycopyrrolate	Provider discretion
Atropine Auto-injector	atropine	Provider discretion
TPOXX	tecovirimat	Provider discretion

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

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

Table 1. Preferred Products

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

No changes at this time.

Table 2. Non-Preferred Products

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

Brand Name	Generic Name	Preferred Alternatives
Prograf oral granules	tacrolimus	tacrolimus capsules
Lucemyra	lofexidine	Provider discretion
Lokelma	sodium zirconium cyclosilcate	Provider discretion
halobetasol propionate topical foam	halobetasol propionate topical foam	Provider discretion
moxidectin	moxidectin	Provider discretion
Glyrx-PF	glycopyrrolate	Provider discretion

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

Brand Name	Generic Name	Preferred Alternatives
Consensi	amlodipine/celecoxib	celecoxib, amlodipine
Plenvu	polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride	Provider discretion
Nocdurna	desmopressin acetate	Provider discretion
Atropine Auto-injector	atropine	Provider discretion
TPOXX	tecovirimat	Provider discretion

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

C. Additions to the Specialty Tier

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

Brand Name	Generic Name
Jynarque	tolvaptan
Andexxa	coagulation factor Xa (recombinant), inactivated-zhzo
Akynzeo IV	fosnetupitant and palonosetron
Yonsa	abiraterone acetate
Palynziq	pegvaliase-pqpz
Olumiant	baricitinib
Retacrit	epoetin alfa
Fulphila	pegfilgrastim-jmdb
Zemdri	plazomicin
Epidiolex	cannabidiol
Braftovi	encorafenib
Mektovi	binimetinib
Doptelet	avatrombopag
Nuplazid capsule	pimavanserin
Aristada Initio	aripiprazole
Symtuza	darunavir, cobicistat, emtricitabine, tenofovir alafenamide
Infugem	gemcitabine
Orilissa	elagolix

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Jynarque (tolvaptan) – Medicare	TBD	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) – Medicare	TBD	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) – Medicare	TBD	New policy created for newly FDA-approved cannabidiol solution (Epidiolex). Policy requires appropriate diagnosis of Lennox-Gastaut syndrome (LGS) 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 (clonazepam, topiramate, lamotrigine, clobazam) for LGS only.
Nuedexta (dextromethorphan/quindine) – Medicare	2019	New policy created for confirmation of diagnosis of pseudobulbar affect. For reauthorization policy required attestation of improvement of symptoms.
Thiola (tiopronin) – Medicare	2019	New policy created to confirm diagnosis of severe homozygous cystinuria in members 9 years of age and older with one 24-hour urine collection measurement of urinary cysteine greater than 500mg/day and failure of conservative treatments. For reauthorization policy requires urine cysteine less than 300mg/L or decrease production of cysteine stones.
Daytrana (methylphenidate patch) – Medicare	2019	New policy created to confirm diagnosis of attention-deficit hyperactivity disorder for members between the age of 6 and 17 years.
Braftovi (encorafenib) and Mektovi (binimetinib) – Medicare	TBD	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) – Medicare	TBD	New policy created for newly FDA-approved agent indicated for treatment of adult patients with thrombocytopenia who have chronic liver disease (CLD) and are schedule to undergo a procedure. Policy requires demonstration of appropriate diagnosis, documentation of platelet count and quantity limit description per member platelet count.
Vimpat (lacosamide) – Medicare	2019	New policy created to ensure appropriate use of lacosamide (Vimpat) for monotherapy or adjunctive therapy for partial-onset seizures in members 4 years of age or older.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Epinephrine Auto-Injectors – Medicare	2019	New policy created for Auvi-q to ensure use for medically accepted indication. Policy requires failure of generic epinepherine injection and Epipen.
Neurontin (gabapentin) – Medicare	2019	New policy created to confirm gabapentin (Neurontin) is being used for medically accepted indication.
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).
Eosinophilic Severe Asthma – Medicare	TBD	Policy revised to modify the required documented number of blood eosinophil count that members must have for benralizumab (Fasenra), from 300 cells/microliter to 150 cells/microliter.
Immune Globulin – Medicare	TBD	Policy revised to match 2019 filing with CMS. Removed certain non-FDA-approved indications. Added criteria for Dermatomyositis and Polymyositis for trial/failure or intolerance to standard first line therapy.
Darzalex (daratumumab) – Medicare	08/20/2018	Policy revised to include expanded indications: Combination with pomalidomide (Pomalyst) and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide (Revlimid) and a proteasome inhibitor and combination with bortezomib (Velcade), melphalan (Alkeran) and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
Tecentriq (atezolizumab) – Medicare	08/20/2018	Policy revised to include coverage for expanded indication of metastatic urothelial carcinoma in patients not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1, or in patients not eligible for any platinum-containing chemotherapy regardless of PD-L1 expression.
Onfi (clobazam) – Medicare	2019	Revised policy to add criteria that member has experienced therapeutic failure, contraindication or intolerance to previous antiepileptic therapy.
Samsca (tolvaptan) – Medicare	2019	Policy revised to include approval criteria for members who have serum sodium levels greater than 125 MEq/L based on the prescribing information. Currently, the policy only includes approval criteria for members whose serum sodium levels are less than 125 MEq/L.
Syndros (dronabinol oral solution) – Medicare	08/20/2018	Policy revised to include criteria for part B coverage.
Chronic Inflammatory Diseases – Medicare	TBD	Policy revised to include expanded indication of polyarticular juvenile idiopathic arthritis for tocilizumab (Actemra) where

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		patients must have an inadequate response or intolerance to at least one 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 both preferred biologic products (Enbrel, Humira).
Blincyto (blintumomab) – Medicare	TBD	Policy revised to add new indication of B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.
Cerdelga (eliglustat) – Medicare	08/20/2018	Policy revised to move approval criteria regarding appropriate dosing based on CYP2D6 genotype to the background section.
Zytiga and Yonsa (abiraterone acetate) – Medicare	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.
Administrative Prior Authorizations for Medicare Part D Plans	2019	Policy revised for the addition of prasterone (Intrarosa), ospemifene (Osphena), doxylamine succinate/VIT B6 (Bonjesta), topical lidocaine and Soriatane. Policy requires the new medications added be used for a medically accepted indication.
Gilenya (fingolimod) – Medicare	08/20/2018	Policy revised to include coverage for patients with relapsing MS who are 10 years and older.
Hepatitis C Oral Agents – Medicare	2019	Policy revised to align with the most current Infectious Diseases Society of America (IDSA)/American Association for the Study of Liver Diseases (AASLD) guidelines.
PCSK9 Inhibitors – Medicare	TBD	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 atherosclerotic cardiovascular disease (ASCVD). Coverage of the additional indication (primary hyperlipidemia) for evolocumab (Repatha) was also added.
Venclexta (venetoclax) – Medicare	08/20/2018	Policy revised to include expanded indication of small lymphocytic lymphoma (SLL) with or without 17p genetic mutation, who have received at least one prior therapy for

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		ventoclax (Venclexta).
Prolia (denosumab) – Medicare	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.
Kinase Inhibitors – Medicare	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 Kisqali (ribociclib) 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.
Programmed Death Receptor Therapies – Medicare	08/20/2018	Policy revised to include expanded indication for nivolumab (Opdivo) in combination with ipilimumab (Yervoy) for the treatment of microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer that has progressed on fluropyrimidine, oxalaplatin, and irinotecan. Policy also revised to include expanded indications for pembrolizumab (Keytruda) for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL) or who have relapsed after 2 or more prior therapies; for metastatic urothelial cancer in patients who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 or who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status; and for treatment of recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1.
Xtandi (enzalutamide) – Medicare	08/20/2018	Policy revised to include expanded indication for enzalutamide (Xtandi) for treatment of non-metastatic castration-resistant prostate cancer.
Human Growth Hormone – Medicare	08/20/2018	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.
Hereditary Angioedema – Medicare	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

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		(6 years of age and older) with Hereditary Angioedema (HAE).
CGRP Inhibitors – Medicare	TBD	Policy revised to remove fremanizumab, as the anticipated FDA approval date has been postponed from June to September 2018. Additional updates include removal of quantity limitations criteria, now allowing for either 70mg or 140mg per month. The ICD diagnosis codes were also updated. Additional changes include moving the requirement for prescribing by or in consultation with a neurologist or headache specialist to the background section. For both episodic (EM) 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). There will be no need to provide documentation of prophylactic medications being prescribed at adequate doses and for a reasonable length of time, as this may be implied. Reauthorization criteria were modified to only require attestation of reduction in migraine frequency by either average monthly migraine days or number of migraine episodes by 50% for EM or 30% for CM.
Brineura (cerliponase alfa) – Medicare	01/01/2019	New policy created to ensure that Brineura is being used for its FDA-approved indication of treating late infantile neuronal ceroid lipofuscinosis type 2 in patients 3 years of age and older, who are symptomatic, have documentation of their current rating on the CLN2 Clinical Rating scale, that the intent of therapy is to slow the loss of ambulation, and that Brineura is being prescribed by or in consultation with a neurologist.
Targretin (bexarotene) – Medicare	01/01/2019	Policy revised to include additional step therapy through generic bexarotene for patients requesting the brand name Targretin. The original Medicare policy has a 1/01/2018 effective date.

*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
Viibryd (vilazodone) and Brintellix/Trintellix (vortioxetine) – Medicare	07/01/2018	Policy revised to split Medicare from Commercial and Healthcare Reform lines of business.
Consensi (amlodipine/celecoxib) – Medicare	TBD	New policy created for recently approved amlodipine/celecoxib (Consensi) to ensure proper use and step therapy with two generic calcium channel blockers and two NSAIDS.
Latuda (lurasidone) – Medicare	2019	New policy created to confirm appropriate medically accepted indication. If diagnosis is Bipolar disorder, policy requires previous failure of one formulary medication.

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria
High Risk Medications in the Elderly – Medicare	2019	Policy revised to add benztropine mesylate, cyproheptadine, imipramine pamoate and promethazine due to 2019 prior authorization additions.
Combination Prescription Drug Safety – Medicare	2019	Policy revised to add guidance criteria, based on CMS, for concomitant use of opiate agonist and opiate potentiator (e.g., gabapentinoids and benzodiazepines). Policy requires use for a medically accepted indication and attestation of ongoing monitoring plan.
Lyrica (pregabalin) – Medicare	08/20/2018	Policy revised to include expanded indication for pregabalin (Lyrica) of partial onset seizures in patients age 4 years and older.

*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
Tiering Exception – Medicare	01/01/2019	Policy revised to update background section language with newest CMS guidance. No changes required for approval criteria.

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

3. Quantity Level Limit (QLL) Program*

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

Drug Name	Retail Quantity Limit	Mail Order Quantity Limit
Aimovig autoinjector (2 pack), 70 mg/mL	2 mL per 28 days	6 mL per 84 days
Arnuity Ellipta, 50 mcg	30 tablets (blister card) with inhalation device per 30 days	90 tablets (blister card) with inhalation device per 90 days
Akynzeo (fosnetupitant and palonosetron), 235mg/0.25mg	1 vial per 28 days	3 vials per 84 days
Atropine Auto-injector, 2 mg	2.1 per 31 days	6.3 per 90 days
Auvi-Q (epinephrine), 0.1 mg/0.1 mL	2 devices per 31 days	6 devices per 90 days
Braftovi (encorafenib), 50 mg, 75 mg	186 capsules per 31 days	558 capsules per 90 days
Doptelet (avatrombopag), 60 mg	15 tablets (blister card) per 31 days	45 tablets per 90 days
Doptelet (avatrombopag), 40 mg	10 tablets (blister card) per 31 days	30 tablets per 90 days
Humira, 20 mg/0.2mL	2 syringes per 28 days	6 syringes per 84 days
Lokelma (sodium zirconium cyclosilcate), 5 mg	180 packets per 30 days	540 packets per 90 days
Lokelma (sodium zirconium cyclosilcate), 10 mg	90 packets per 30 days	270 packets per 90 days
Lucemyra (lofexidine), 0.18 mg	224 tablets per 14 days	224 tablets per 14 days
Mektovi (binimetinib), 15 mg	186 oral tablets per 31 days	558 tablets per 90 days

Drug Name	Retail Quantity Limit	Mail Order Quantity Limit
Nocdurna (desmopressin acetate), all strengths	31 tablets per 31 days	93 tablets per 90 days
Nuplazid (pimavanserin) capsule, 34 mg	31 capsules per 31 days	93 capsules per 90 days
Nuplazid (pimavanserin) tablet, 10 mg	31 tablets per 31 days	93 tablets per 90 days
Olumiant (baricitinib), 2 mg	31 tablets per 31 days	93 tablets per 90 days
Orilissa (elagolix), 150 mg	31 tablets per 31 days	93 tablets per 90 days
Orilissa (elagolix), 200 mg	62 tablets per 31 days	186 tablets per 90 days
Ozempic, 025 mg, .5 mg, 1 mg/0.75mL	3 mL (2 pens) per month	9 mL (6 pens) per 3 months
Symtuza tablet, 800 mg, 150 mg, 200 mg, 10 mg	31 tablets per 31 days	93 tablets per 90 days
Xeljanz (tofacitinib), 10 mg	62 tablets per 31 days	186 tablets per 90 days
Yonsa (abiraterone acetate), 125 mg	124 tablets per 31 days	372 tablets per 90 days

Med D Quantity Level Limits (QLs)

Drug Name	Strength	Dosage Form	Retail Quantity Limit (units, mL, grams)	Retail Day Supply	Mail Order Quantity Limit (units or mL)	Mail Order Day Supply	MDQ Calc
Calcipotriene	0.005%	Ointment (Gram)	60	28	180	84	2.14
Calcipotriene	0.005%	Solution, Non-Oral	60	28	180	84	2.14
Calcipotriene	0.005%	Cream (Gram)	60	28	180	84	2.14
Chantix	0.5 (11)-1	Tablet, Dose Pack	106	365	106	365	0.29
Chantix	0.5 mg	Tablet	60	30	180	90	2
Chantix	1 mg	Tablet	60	30	180	90	2
Chantix	1 mg	Tablet	60	30	180	90	2
Ciclopirox	0.77%	Gel (Gram)	45	28	135	84	1.61
Ciclopirox	0.77%	Cream (Gram)	90	28	270	84	3.21
Ciclopirox	0.77%	Suspension, Topical (mL)	60	28	180	84	2.14
Colchicine	0.6 mg	Tablet	62	31	186	90	2
Daytrana	10 mg/9 Hr	Patch, Transdermal 24 Hours	30	30	90	90	1
Daytrana	15 mg/9Hr	Patch, Transdermal 24 Hours	30	30	90	90	1
Daytrana	20 mg/9 Hr	Patch, Transdermal 24 Hours	30	30	90	90	1
Daytrana	30 mg/9 Hr	Patch, Transdermal 24 Hours	30	30	90	90	1
Dexedrine	10 mg	Capsule, Extended Release	155	31	465	90	5

Drug Name	Strength	Dosage Form	Retail Quantity Limit (units, mL, grams)	Retail Day Supply	Mail Order Quantity Limit (units or mL)	Mail Order Day Supply	MDQ Calc
Dexedrine	15 mg	Capsule, Extended Release	124	31	372	90	4
Dexedrine	5 mg	Capsule, Extended Release	186	31	558	90	6
Dexilant	30 mg	Capsule, Delayed Release, Biphasic	31	31	93	90	1
Dexilant	60 mg	Capsule, Delayed Release, Biphasic	31	31	93	90	1
Dextroamphetamine Sulfate ER	10 mg	Tablet	186	31	558	90	6
Dextroamphetamine Sulfate ER	5 mg	Tablet	341	31	1023	90	11
Dextroamphetamine Sulfate ER	10 mg	Capsule, Extended Release	155	31	465	90	5
Dextroamphetamine Sulfate ER	15 mg	Capsule, Extended Release	124	31	372	90	4
Dextroamphetamine Sulfate ER	5 mg	Capsule, Extended Release	186	31	558	90	6
Diclofenac Sodium	1%	Gel (Gram)	300	28	900	84	10.71
Diclofenac Sodium	1.5%	Drops	450	30	1350	90	15
Diclofenac Sodium	3%	Gel (Gram)	100	28	300	84	3.57
Dovonex	0.005%	Cream (Gram)	60	28	180	84	2.14
Doxepin HCL	5%	Cream (Gram)	45	28	135	84	1.61
Enstilar	0.005-.064	Foam (Gram)	60	28	180	84	2.14
Fluocinonide	0.05%	Ointment (Gram)	60	28	180	84	2.14
Fluocinonide	0.05%	Solution, Non-Oral	60	28	180	84	2.14
Fluocinonide	0.05%	Gel (Gram)	60	28	180	84	2.14
Fluocinonide	0.1%	Cream (Gram)	120	28	360	84	4.29
Fluocinonide-E	0.05%	Cream (Gram)	60	28	180	84	2.14
Intrarosa	6.5 mg	Insert	28	28	84	84	1
Lidocaine	5%	Ointment (Gram)	50	28	150	84	1.79
Lidocaine HCL	2%	Jelly (mL)	60	28	180	84	2.14
Lidocaine HCL	40 mg/mL	Solution, Non-Oral	50	28	150	84	1.79
Lidocaine Prilocaine	2.5%-2.5%	Cream (Gram)	30	28	90	84	1.07
Loprox	0.77%	Cream (Gram)	90	28	270	84	3.21
Osphena	60 mg	Tablet	31	31	93	90	1
Pennsaid	20 mg/g (2%)	Solution in Metered Dose Pump (Gram)	224	28	672	84	8

Drug Name	Strength	Dosage Form	Retail Quantity Limit (units, mL, grams)	Retail Day Supply	Mail Order Quantity Limit (units or mL)	Mail Order Day Supply	MDQ Calc
Prudoxin	5%	Cream (Gram)	45	28	135	84	1.61
Quinine Sulfate	324 mg	Capsule	42	28	126	84	1.5
Restasis	0.05%	Dropperette, Single-Use Drop Dispenser	60	30	180	90	2
Synjardy	12.5 mg - 1000 mg	Tablet	62	31	186	90	2
Synjardy	12.5 mg - 500 mg	Tablet	62	31	186	90	2
Synjardy	5 mg - 500 mg	Tablet	62	31	186	90	2
Synjardy	5 mg - 1000 mg	Tablet	62	31	186	90	2
Synjardy XR	10 mg - 1000 mg	Tablet, Immediate and Extended Release Biphase 24 Hr	62	31	186	90	2
Synjardy XR	12.5 mg - 1000 mg	Tablet, Immediate and Extended Release Biphase 24 Hr	62	31	186	90	2
Synjardy XR	25 mg - 1000 mg	Tablet, Immediate and Extended Release Biphase 24 Hr	31	31	93	90	1
Synjardy XR	5 mg -1000 mg	Tablet, Immediate and Extended Release Biphase 24 Hr	62	31	186	90	2
Voltaren	1%	Gel (Gram)	300	28	900	84	10.71
Xiidra	5%	Dropperette, Single-Use Drop Dispenser	60	30	180	90	2
Zenzedi	10 mg	Tablet	62	31	186	90	2
Zenzedi	15 mg	Tablet	62	31	186	90	2
Zenzedi	2.5 mg	Tablet	62	31	186	90	2
Zenzedi	20 mg	Tablet	62	31	186	90	2
Zenzedi	30 mg	Tablet	62	31	186	90	2
Zenzedi	5 mg	Tablet	62	31	186	90	2
Zenzedi	7.5 mg	Tablet	62	31	186	90	2

Drug Name	Strength	Dosage Form	Retail Quantity Limit (units, mL, grams)	Retail Day Supply	Mail Order Quantity Limit (units or mL)	Mail Order Day Supply	MDQ Calc
Zonalon	5%	Cream (Gram)	30	28	90	84	1.07

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