SPECIAL eBULLETIN

APRIL 2019

SECOND QUARTER 2019 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the Second Quarter 2019 update to the Highmark Drug Formularies and pharmaceutical management procedures. The formularies and pharmaceutical management procedures are updated on a quarterly basis, and the following changes reflect the decisions made in February 2019 by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document. Please reference the guide below to navigate this communication:

Section I. Highmark Commercial and Healthcare Reform Formularies

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

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

Core Formulary – Select Commercial Plans
July 2019

Effective July 1, 2019, there will be a new formulary available for select Commercial plans. The new formulary, called the **Core Formulary**, will be a four-tier, closed formulary. The Core Formulary is a lean, clinically comprehensive formulary, which promotes utilization of the lowest net cost product for an indication.

If your patients who are affected by this change continue on any of the drugs not included on the Core Formulary after the effective date, they will be responsible for the entire cost of the drug(s). If you feel there is a medical reason for any of your patients to continue to take the drug(s) not on the Core Formulary, rather than the alternatives, you may also submit a request for a coverage exception.

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 Core Formulary will be available via the Provider Resource Center before July 1, 2019.

As a reminder, NaviNet® can be used for any pharmacy authorization request. It 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, as well as specific details about patients' pharmacy benefits.

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

Important Drug Safety Updates

Update Health Professional and Consumer on Recent Recalled Products Due to Detection of Probable Human Carcinogen Impurities

As part of an ongoing investigation into the voluntary recall of products due to the detection of probable human carcinogen impurities, there were eight additional voluntary recalls. Health care professionals should be aware that the recalled products pose an unnecessary risk to patients.

Pharmacists and physicians may direct patients to alternative treatment prior to returning to their medications. Physicians should evaluate the risk versus the benefit if treatment is stopped immediately, as stopping treatment immediately without alternative treatment may lead to a higher risk of harm to the patient's health.

The additional products that have been recalled due to the impurities are listed below. Not all products from all the manufacturers are recalled. Patients and physicians should check the FDA website to see if the lot number of their medication has been included in the recall.

Manufacturer	Recalled Drugs	Detected Impurity
Torrent Pharmaceuticals Limited	Losartan potassium tablets and Losartan potassium / hydrochlorothiazide (HCTZ) tablets	N-nitrosodiethylamine (NDEA)
Prinston Pharmaceutical Inc. dba Solco Healthcare LLC	Irbesartan and Irbesartan /HCTZ tablets	N-nitrosodiethylamine (NDEA)
Aurobindo Pharma USA	Valsartan tablets, Amlodipine/Valsartan tablets, and Valsartan/HCTZ tablets	N-nitrosodiethylamine (NDEA)
MacLeods Pharmaceuticals	Losartan potassium/HCTZ tablets	N-nitrosodiethylamine (NDEA)
Mylan Pharmaceuticals	Valsartan tablets, Amlodipine/Valsartan tablets, and Valsartan/HCTZ tablets	N-nitrosodiethylamine (NDEA)
Camber Pharmaceuticals, Inc.	Losartan Potassium tablets	N-Nitroso N-Methyl 4-aminobutyric acid (NMBA)
Torrent Pharmaceuticals Limited	Losartan potassium tablets and Losartan potassium/HCTZ tablets	N-Methylnitrosobutyric acid (NMBA)

Dyural-40 and Dyural-80 Convenience Kits by Enovachem Pharmaceuticals: Recall of Products Containing Sodium Chloride Injection, USP, 0.9%, Due to Latex Hazard

On December 17, 2018, Asclemed USA Inc., dba Enovachem Pharmaceuticals, announced a recall of Dyural-40 and Dyural-80. The products include recalled Sodium Chloride, USP, 0.9%, manufactured by Fresenius Kabi, which has been recalled due to product labeling incorrectly stating that the stoppers do not contain latex. For those with a severe allergy to latex, there is probability of an anaphylactic reaction, which could result in hospitalization or death.

Ceftriaxone for Injection, USP, 250mg, 500mg, 1g and 2g by Lupin Pharmaceuticals, Inc.: Recall Due to Visual Particulate Matter

On January 5, 2019, Lupin Pharmaceuticals, Inc., announced a recall of Ceftriaxone for Injection, USP, 250mg, 500mg, 1g, and 2g, due to these products having been found to contain visual particulate matter (grey rubber flecks) in reconstituted vials. Improper piercing and use of a needle greater than 21 gauge while reconstituting the vial can push these rubber flecks into the solution. If injected, this product (containing rubber flecks) could cause vein irritation/phlebitis or pulmonary embolic events that could result in permanent impairment of body function or damage to body structures, such as the lungs and vascular system. In addition, as ceftriaxone can be administered intramuscularly, the use of the product may result in local muscle inflammation and/or abscesses.

Ibuprofen Oral Suspension Drops, USP, 50 mg per 1.25 mL by Tris Pharma, Inc.: Recall - Due to Higher Concentration of Ibuprofen

On January 29, 2019, Tris Pharma, Inc., expanded the scope of its November 2018 recall by adding three additional lots of Ibuprofen Oral Suspension Drops, USP, 50 mg per 1.25 mL, to the retail (pharmacy) level. Some units from the batches have been found to have higher concentrations of ibuprofen. As a result, infants already susceptible to the adverse effects of ibuprofen may be more vulnerable to permanent NSAID-associated renal injury if they receive medication from any of these batches.

Silver Bullet 10x by Nature’s Rx: Recall Due to Undeclared PDE-5 Inhibitors in the Product

On January 29, 2019, Nature’s Rx announced a recall of Silver Bullet 10x. The recall was initiated because the product was found to contain undeclared PDE-5 inhibitors sildenafil and tadalafil, the active ingredients in Viagra and Cialis respectively. As a result, the product may pose serious health risks to consumers with underlying medical issues who take the products without knowing that they can cause serious harm or interact in dangerous ways with other drugs they may be taking.

Drospirenone and Ethinyl Estradiol Tablets, USP, 28X3 Blister Pack/Carton by Apotex Corp.: Recall - Due to Defective Blister Packs

On March 4, 2019, Apotex Corp. announced a recall of Drospirenone and Ethinyl Estradiol Tablets. Four recalled lots of the product may possibly contain defective blister packs with incorrect table arrangements and/or an empty blister pocket. As a result, where a patient does not take a tablet due to a missing tablet, or a patient takes a placebo instead of an active tablet, loss of efficacy is possible due to variation in the dosage consumed.

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 – April 2019

SECTION I. Highmark Commercial and Healthcare Reform Formularies

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

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

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

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

Table 1. Products Added
(All products added to the formulary effective March 27, 2019, unless otherwise noted.)

Brand Name	Generic Name	Comments
Vitrakvi	larotrectinib	First tumor-agnostic kinase inhibitor which does not target a specific cell site, but rather a genetic mutation (*NTRK)* driving cancer.
Actemra ACTPen	tocilizumab	New auto-injector formulation of tocilizumab

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Bijuva	estradiol/progesterone	Amabelz, Lopreeza, Mimvey, Femhrt 1/5, Combipatch, Norethindrone Acetate-Ethinyl Estradiol, Premphase, Prempro
Hyrimoz*	adalimumab-adaz	Humira
Udenyca	pegfilgrastim-cbqv	Neulasta, Neupogen
Lorbrena	lorlatinib	Xalkori
Yupelri	revefenacin	Spiriva
Aemcolo	rifamycin	azithromycin
Sympazan	clobazam	valproic acid, lamotrigine
Daurismo	glasdegib	Venclexta
Xospata	gilteritinib	Provider discretion
Firdapse	amifampridine phosphate	Provider discretion

Brand Name	Generic Name	Preferred Alternatives
Tolsura	itraconazole	itraconazole
Motegrity	prucalopride	Amitiza, Linzess
Ezallor*	rosuvastatin	rosuvastatin, atorvastatin
Licart*	diclofenac epolamine	diclofenac, ibuprofen, naproxen
Elepsia XR*	levetiracetam ER	levetiracetam ER, Roweepra
Inbrija	levodopa	carbidopa-levodopa extended release, entacapone, ropinirole, pramipexole, rasagiline, selegiline
ProAir Digihaler*	albuterol sulfate	ProAir, Ventolin

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
Hyrimoz	adalimumab-adaz
Udenyca	pegfilgrastim-cbqv
Lorbrena	lorlatinib
Sympazan	clobazam
Daurismo	glasdegib
Vitrakvi	larotrectinib
Xospata	gilteritinib
Actemra ACTPen	tocilizumab
Firdapse	amifampridine phosphate
Tolsura	itraconazole
Elepsia XR	levetiracetam ER
Inbrija	levodopa

Table 4. Products to Be Removed or Shifted to Higher Tier– Effective July 1, 2019

Brand name	Generic Name	Preferred Alternatives
Only commercial comprehensive products		
Differin, adapalene	adapalene	tretinoin, OTC adapalene*
budesonide nasal spray	budesonide	fluticasone, OTC budesonide*
Zyrtec Rx	cetirizine	OTC cetirizine*
Zyrtex-D Rx	cetirizine/pseudoephedrine	OTC cetirizine/pseudoephedrine*

Brand name	Generic Name	Preferred Alternatives
cimetidine	cimetidine	ranitidine, famotidine, OTC cimetidine*
diphenhydramine elixir	diphenhydramine	OTC diphenhydramine*
fexofenadine	fexofenadine	OTC fexofenadine*
fexofenadine-pseudoephedrine	fexofenadine-pseudoephedrine	OTC fexofenadine-pseudoephedrine*
levocarnitine	levocarnitine	OTC levocarnitine*
Lidocaine 5% patch, lidocaine 5% ointment, lidocaine 3% lotion, Lido-K, Lidozion, lidocaine 2% jelly, Glydo	lidocaine	OTC lidocaine*
metformin ER (generic Fortamet)	metformin ER	metformin ER (generic Glucophage XR)
niacin ER	niacin ER	OTC niacin ER*
phenazopyridine	phenazopyridine	OTC phenazopyridine*
ranitidine capsules	ranitidine	ranitidine tablets
All commercial & healthcare reform comprehensive products		
Amicar	aminocaproic acid	aminocaproic acid
Ampyra	dalfampridine	dalfampridine
Androgel	testosterone	testosterone
Dexpak	dexamethasone	dexamethasone
Fareston	toremifene	toremifene
Ganirelix [brand]	ganirelix	ganirelix (generic)
Hylavite	folic acid/vit B complex and C	Activite
Ranexa	ranolazine	ranolazine
Rapamune	sirolimus	sirolimus
Sensipar	cinacalcet	cinacalcet
Sporanox	itraconazole	itraconazole
Suboxone	buprenorphine/naloxone	buprenorphine/naloxone
Yonsa	abiraterone acetate	abiraterone acetate
Zytiga	abiraterone acetate	abiraterone acetate

*An alternative medication with the same active ingredient is available for members to purchase over the counter (OTC). Coverage of OTC products is contingent upon plan benefits.

B. 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 March 27, 2019, unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Vitrakvi	larotrectinib	4	First tumor-agnostic kinase inhibitor which does not target a specific cell site, but rather a genetic mutation (*NTRK)* driving cancer.
Xospata	gilteritinib	4	New kinase inhibitor treatment for adults with relapsed or refractory acute myeloid leukemia (AML) with an FLT3 mutation
Actemra ACTPen	tocilizumab	4	New autoinjector formulation of tocilizumab
Items listed below were not added to the formulary			
Bijuva	estradiol/progesterone	NF	Amabelz, Lopreeza, Mimvey, Norethindrone Acetate-Ethinyl Estradiol, Premphase, Prempro, Estradiol-Norethindrone Acet, Jevantique Lo, Jinteli
Hyrimoz*	adalimumab-adaz	NF	Humira
Udenyca	pegfilgrastim-cbqv	NF	Zarxio
Lorbrena	lorlatinib	NF	Xalkori, Zykadia, Alunbrig
Yupelri	revefenacin	NF	Spiriva
Aemcolo	rifamycin	NF	Azithromycin
Sympazan	clobazam	NF	valproic acid, lamotrigine
Daurismo	glasdegib	NF	Venclexta
Firdapse	amifampridine phosphate	NF	Provider discretion
Tolsura	itraconazole	NF	itraconazole
Motegrity	prucalopride	NF	Amitiza, Linzess
Ezallor*	rosuvastatin	NF	rosuvastatin, atorvastatin
Licart*	diclofenac epolamine	NF	diclofenac, ibuprofen, naproxen
Elepsia XR*	levetiracetam ER	NF	levetiracetam ER, Roweepra
Inbrija	levodopa	NF	carbidopa-levodopa extended release, carbidopa-levodopa-entacapone, ropinirole, pramipexole, selegiline
ProAir Digihaler*	albuterol sulfate	NF	Ventolin, Xopenex

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 July 1, 2019

Brand Name	Generic Name	Preferred Alternatives
All Healthcare Reform Essential Products		
Albenza	albendazole	albendazole
Ampyra	dalfampridine	dalfampridine
Canasa	mesalamine	mesalamine
Elidel	pimecrolimus	pimecrolimus
Fareston	toremifene	toremifene
Finacea	azelaic acid	azelaic acid
Ganirelix [brand]	ganirelix	ganirelix (generic)
Invanz	ertapenem	ertapenem
Ranexa	ranolazine	ranolazine
Rapaflo	silodosin	silodosin
Renagel	sevelamer	sevelamer
Sensipar	cinacalcet	cinacalcet
Tekturna	aliskiren	aliskiren
Yonsa	abiraterone acetate	abiraterone acetate
Zytiga	abiraterone acetate	abiraterone acetate

D. Changes to the Highmark National Select Formulary

The National Select Formulary is an incentive formulary with a non-formulary drug list to manage products in therapeutic categories for which preferred alternatives are available. The National Select Formulary is available for select Commercial self-funded (ASO) plans. A list of drugs included on the National Select Formulary, listed by therapeutic class, is available at https://client.formularynavigator.com/Search.aspx?siteCode=3442182690.

Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (preferred)			
Vitrakvi	larotrectinib	2	First tumor-agnostic kinase inhibitor which does not target a specific cell site, but rather a genetic mutation (*NTRK)* driving cancer.
Xospata	gilteritinib	2	New kinase inhibitor treatment for adults with relapsed or refractory acute myeloid leukemia (AML) with an FLT3 mutation
Actemra ACTPen	tocilizumab	2	New autoinjector formulation of tocilizumab
Lorbrena	lorlatinib	2	New kinase inhibitor treatment for patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on prior ALK-targeted therapies.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Yupelri	revefenacin	2	New anticholinergic inhalation solution for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)
Firdapse	amifampridine phosphate	2	New aminopyridine potassium channel blocker for the treatment of Lambert-Eaton myasthenic syndrome (LEMS).
Udenyca	pegfilgrastim-cbqv	2	New biosimilar to Neulasta indicated to decrease the incidence of infection in patients receiving myelosuppressive anti-cancer drugs associated with febrile neutropenia.
Items listed below were added to the formulary (non-preferred)			
Sympazan	clobazam	3	clobazam, valproic acid, lamotrigine
Daurismo	glasdegib	3	Venclexta
Aemcolo	rifamycin	3	azithromycin, Xifaxan
Motegrity*	prucalopride	3	Amitiza, Linzess
Inbrija*	levodopa	3	carbidopa-levodopa extended release, carbidopa-levodopa-entacapone, ropinirole, pramipexole, selegiline
Bijuva*	estradiol/progesterone	3	Amabelz, Lopreeza, Mimvey, Norethindrone Acetate-Ethinyl Estradiol, Premphase, Prempro, Estradiol-Norethindrone Acet, Jevantique Lo, Jinteli
Hyrimoz*	adalimumab-adaz	3	Humira
Ezallor*	rosuvastatin	3	rosuvastatin, atorvastatin
Licart*	diclofenac epolamine	3	diclofenac, ibuprofen, naproxen
Elepsia XR*	levetiracetam ER	3	levetiracetam ER, Roweepra
ProAir Digihaler*	albuterol sulfate	3	ProAir, Ventolin
Items listed below were not added to the formulary			
Tolsura	itraconazole	NF	itraconazole

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

Table 2. Additions to the Specialty Tier Copay Option

(Effective upon completion of internal review and implementation unless otherwise noted.)

Brand Name	Generic Name
Hyrimoz	adalimumab-adaz
Udenyca	pegfilgrastim-cbqv
Lorbrena	lorlatinib
Sympazan	clobazam
Daurismo	glasdegib
Vitrakvi	larotrectinib
Xospata	gilteritinib
Actemra ACTPen	tocilizumab
Firdapse	amifampridine phosphate
Tolsura	itraconazole
Elepsia XR	levetiracetam ER
Inbrija	levodopa

E. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Vitrakvi (larotrectinib) – Commercial and Healthcare Reform	02/25/2019	New policy created to ensure appropriate use of larotrectinib (Vitrakvi) in members with a neurotrophic tyrosine receptor kinase (*NTRK)* mutation-positive tumor.
Sympazan (clobazam) – Commercial and Healthcare Reform	03/11/2019	New policy created for clobazam (Sympazan) oral films requiring trial and failure of standard of care and rationale as to why the member cannot use generic clobazam tablets or suspension.
Arikayce (amikacin) – Commercial and Healthcare Reform	02/25/2019	New policy created to ensure appropriate use of amikacin (Arikayce) in adults with refractory Mycobacterium Avium complex (MAC) lung disease.
Lorbrena (lorlatinib) – Commercial and Healthcare Reform	02/25/2019	New policy created to ensure appropriate use of lorlatinib (Lorbrena) in adults with non-small-cell lung cancer (NSCLC) with disease progression on crizotinib and at least one other anaplastic lymphoma kinase (ALK) inhibitor for metastatic disease; or alectinib or ceritinib as the first ALK therapy for metastatic disease.
Daurismo (glasdegib) – Commercial and Healthcare Reform	02/25/2019	New policy created to ensure appropriate use of glasdegib (Daurismo) in newly-diagnosed acute myeloid leukemia (AML) in adult patients who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Xospata (gilteritinib) – Commercial and Healthcare Reform	02/25/2019	New policy created to ensure appropriate use of gilteritinib (Xospata) in adult patients who have relapsed or refractory AML with an FLT3 mutation as detected by an FDA-approved test.
Firdapse (amifampridine) – Commercial and Healthcare Reform	03/11/2019	New policy created to ensure appropriate use of amifampridine (Firdapse) in adults with Lambert-Eaton myasthenic syndrome.
Inbrija (levodopa) – Commercial and Healthcare Reform	03/20/2019	New policy created to ensure appropriate use of levodopa (Inbrija) in adults with Parkinson's disease experiencing intermittent off episodes while on carbidopa/levodopa. The member must have an inability to swallow tablets or has stepped through two of the following agents used for off episodes: carbidopa-levodopa extended release, carbidopa-levodopa-entacapone, entacapone, pramipexole, rasagiline, ropinirole, or selegiline. Reauthorization criteria requires attestation of positive clinical response to therapy.
Tolsura (itraconazole) – Commercial and Healthcare Reform	03/11/2019	New policy created to ensure itraconazole (Tolsura) is reserved for use in patients with an FDA-approved diagnosis who cannot tolerate generic itraconazole capsules and who demonstrate clinical need for super-bioavailable (SUBA) technology.
Halobetasol Propionate Topical Products – Commercial and Healthcare Reform	TBD	New policy created to ensure appropriate use of cost-effective halobetasol propionate topical products (ointment and/or cream) for moderate to severe plaque psoriasis in patients 18 years of age and older prior to use of branded products, Ultravate Cream, Ointment, Lotion, Lexette foam, and halobetasol foam. In addition, course of treatment will not exceed two weeks.
Erelzi – Commercial and Healthcare Reform	TBD	Policy revised to include reauthorization criteria to ensure that the member is responding to or is stable on therapy.
Thrombopoiesis Stimulating Agents – Commercial and Healthcare Reform	02/25/2019	Policy revised to include expanded FDA indications: (a) Promacta in the first-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia in combination with standard immunosuppressive therapy and (b) Nplate in pediatric patients one year of age and older with immune thrombocytopenic purpura (ITP) for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Policy approval criteria revised to include FDA-expanded indications to label.
Venclexta (venetoclax) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include expanded FDA indication for the treatment of newly-diagnosed AML in adult patients who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy. Policy revised from lifetime to two-year authorization duration. Policy revised to include reauthorization criteria to ensure that the member is tolerating therapy and has experienced a therapeutic response.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Solaraze (diclofenac sodium 3%) and Carac Cream – Commercial and Healthcare Reform	02/25/2019	Policy revised to include in limitations of coverage that diclofenac sodium 3% (Solaraze) gel is contraindicated in setting of coronary artery bypass graft surgery. Authorization duration changed from 12 months to three months for diclofenac sodium 3% (Solaraze) gel and one month for Carac cream.
Apokyn (apomorphine hydrochloride injection) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include reauthorization criteria that prescriber attests member has experienced positive clinical response.
Anabolic Steroids – Commercial and Healthcare Reform	02/25/2019	Policy revised to include myelofibrosis as an approvable condition for treatment with oxymetholone (Anadrol-50).
Sabril and Vigadrone (vigabatrin) – Commercial	02/25/2019	Policy revised to remove reauthorization criteria that member's vision has been assessed and the benefits of therapy continue to outweigh the risks of vision loss.
Idiopathic Pulmonary Fibrosis – Commercial and Healthcare Reform	02/25/2019	Policy revised to edit reauthorization criteria that the prescriber attests that the member has experienced positive clinical response to therapy defined as delayed disease progression.
Hemlibra (emicizumab) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include maintenance dosage regimens of 3 mg/kg once every two weeks or 6 mg/kg once every four weeks.
Thiola (tioponin) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include reauthorization criteria to ensure that the member is responding to or is stable on therapy.
Vimpat (lacosamide) – Healthcare Reform	02/25/2019	Policy revised to include reauthorization criteria to ensure that the member is responding to or is stable on therapy.
Procysbi (cysteamine bitartrate) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include reauthorization criteria to ensure that the member is responding to or is stable on therapy. Policy revised from lifetime authorization to 12 months.
Urea Cycle Disorder Medications – Commercial and Healthcare Reform	02/25/2019	Policy revised to include reauthorization criteria to ensure that the member is responding to or is stable on therapy.
Entresto (sacubitril/valsartan) – Healthcare Reform	02/25/2019	Policy revised to include reauthorization criteria to ensure that the member is responding to or is stable on therapy. Policy revised from lifetime authorization to 12 months.
Chenodal (chenodiol) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include reauthorization criteria to ensure that the provider provides attestation of clinical improvement or response to therapy.
Relistor (methylnaltrexone bromide) – Commercial	02/25/2019	Policy revised to include reauthorization criteria to ensure that the provider provides attestation of clinical improvement or response to therapy.
Xermelo (telotristat ethyl) – Commercial and Healthcare Reform	02/25/2019	Policy revised to update authorization duration from lifetime to 12 months and to include reauthorization criteria to ensure that the provider provides attestation of clinical improvement or response to therapy.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Xadago (safinamide) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include reauthorization criteria to ensure that the provider provides attestation of clinical improvement or response to therapy. Policy revised from lifetime to two-year authorization duration.
Symproic (naldemedine) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include reauthorization criteria to ensure that the provider provides attestation of clinical improvement or response to therapy.
Fertility – Commercial and Select Healthcare Reform Plans	02/25/2019	Policy revised to remove discontinued fertility agents: urofollitropin (Bravelle) and menotropin (Repronex). Policy revised to include use of chorionic gonadotropins (Novarel and Pregnyl) with Assisted Reproductive Technology (ART).
Horizant (gabapentin enacarbil) – Commercial and Healthcare Reform	02/25/2019	Policy revised to modify the authorization duration from lifetime to one year.
Intra-articular hyaluronan – Commercial and Healthcare Reform	02/25/2019	Policy revised to include new HCPCS code for Durolane (J7318), effective 01/01/2019.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	02/25/2019	Policy revised to include a footnote for the Stelara section as a reminder to enter a Patient Level Authorization (PLA) when patient has Crohn's disease and requires 1 syringe every 56 days (or eight weeks).
Afinitor (everolimus) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include updated NCCN guidelines for everolimus + lenvatinib as a category 1 place of therapy. Authorization duration changed from lifetime to 2 years. Policy revised to include reauthorization criteria to ensure that the provider provides attestation of clinical improvement or response to therapy.
Verzenio (abemaciclib) – Commercial and Healthcare Reform	02/25/2019	Policy revised to reflect FDA-approved indications. Authorization duration changed from lifetime to 2 years. Policy revised to include reauthorization criteria to ensure that the provider provides attestation of clinical improvement or response to therapy.
Actimmune (interferon gamma) – Commercial and Healthcare Reform	02/25/2019	Authorization duration changed from lifetime to 12 months. Policy revised to include reauthorization criteria to ensure that the provider provides attestation of clinical improvement or response to therapy.
Erleada (apalutamide) – Commercial and Healthcare Reform	02/25/2019	Authorization duration changed from lifetime to 2 years. Policy revised to include reauthorization criteria to ensure that the provider provides attestation of clinical improvement or response to therapy.
Zyban (bupropion) and Chantix (varenicline) – Commercial	02/25/2019	Policy revised to remove criteria stating that requests for combination therapy of bupropion and prescription nicotine replacement therapy will be denied.
Hetlioz (tasimelteon) – Commercial and Healthcare Reform	02/25/2019	Policy revised to change authorization duration to 12 months.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Kinase Inhibitors – Commercial and Healthcare Reform	02/25/2019	Policy revised to include expanded FDA indications: (a) Lynparza in the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy; (b) Sprycel in the treatment of pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy; (c) Cabometyx in the treatment of patients with hepatocellular carcinoma who have previously been treated with sorafenib. Policy revised to include reauthorization criteria to ensure that the provider provides attestation of clinical improvement or response to therapy.
Syprine (trientine) and Cuprimine, Depen, D-penamine (penicillamine) – Commercial and Healthcare Reform	02/25/2019	Policy revised to remove the requirement for trial and failure of penicillamine (Depen) for trientine (Syprine) to be approved. Policy revised to require trial and failure of generic trientine for approval of Syprine. Policy revised to include reauthorization criteria to ensure that the member is responding to or is stable on therapy. Policy revised to include penicillamine (D-penamine) to be approved for the same indications as penicillamine (Depen) due to shortage of penicillamine products.
Cholbam (cholic acid) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include reauthorization criteria to ensure that the provider provides attestation of disease stability or improvement.
CGRP Inhibitors – Commercial and Healthcare Reform	03/21/2019	Policy revised to condense episodic and chronic migraines into one initial authorization criteria. Removal of headache days and severity for Ajovy. Removal of selective serotonin reuptake inhibitors as an alternative to try and fail. Removal of attestation that alternative medications have been prescribed at an adequate dose and for reasonable length of time. Reauthorization criteria condensed to either experiencing 50% reduction in migraine days per month or a reduction by at least four migraine days per month if episodic or by at least five migraine days per month if chronic.
Opioid Management – Commercial and Healthcare Reform	02/01/2019	Policy revised to increase the Morphine Equivalent Daily Dose limit to 90 and increase authorization to 12 months. Short acting opioid therapy duration limits and a long-acting opioid prior authorization will be required for Healthcare Reform members who are new starts to therapy starting on 04/01/2019.
Xyrem (sodium oxybate) – Commercial and Healthcare Reform	02/25/2019	Policy revised to update the expanded indication for treatment of cataplexy or excessive daytime sleepiness (EDS) in patients seven years of age and older with narcolepsy.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Hepatitis C Oral Therapy – Commercial and Healthcare Reform	02/25/2019	Policy revised to add the following note: the manufacturer of daclatasvir (Daklinza) plans to discontinue distribution of this drug in June 2019. Due to the necessity of a 12-week treatment duration and impending changes to drug availability, it is recommended to consider an alternative agent. Policy also revised to include authorized generics for ledipasvir/sofosbuvir (Harvoni) and sofosbuvir/velpatasvir (Epclusa) as preferred products like the reference brands.
Hepatitis C Oral Agents – Commercial National Select Formulary	02/25/2019	Policy revised to add the following note: the manufacturer of daclatasvir (Daklinza) plans to discontinue distribution of this drug in June 2019. Due to the necessity of a 12-week treatment duration and impending changes to drug availability, it is recommended to consider an alternative agent. Policy also revised to include authorized generics for ledipasvir/sofosbuvir (Harvoni) and sofosbuvir/velpatasvir (Epclusa) as non-preferred agents.

*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
Vusion (miconazole nitrate, zinc oxide, white petrolatum) – Commercial and Healthcare Reform	03/11/2019	New policy created to ensure appropriate use of Vusion in pediatric patients with diaper dermatitis complicated by candidiasis. Note: Management of brand Vusion effective 2020 for Healthcare Reform.
Motegrity (prucalopride) – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use of prucalopride (Motegrity) in adults with chronic idiopathic constipation (CIC). Patients must experience therapeutic failure or intolerance to both of the following agents: linaclotide (Linzess) and lubiprostone (Amitiza).
Soliqua (insulin glargine and lixisenatide) – Commercial and Healthcare Reform	TBD	New policy created to ensure appropriate use of insulin glargine and lixisenatide (Soliqua) in patients with type 2 diabetes inadequately controlled on basal insulin or lixisenatide (Adlyxin). Patient must experience therapeutic failure or intolerance to insulin degludec and liraglutide (Xultophy) and a metformin-containing product.
Methotrexate Injections – Commercial and Healthcare Reform	TBD	New policy created to ensure appropriate use of brand name methotrexate injections. Patient must experience therapeutic failure or intolerance to generic methotrexate solution for injection.
Elepsia XR (levetiracetam) – Commercial and Healthcare Reform	TBD	New policy created to ensure appropriate use of Elepsia XR in patients 12 years of age and older with partial-onset seizures. The member must experience therapeutic failure,

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		contraindication, or intolerance to one other anticonvulsant and levetiracetam ER and Roweepra XR.
Lonhala Magnair (glycopyrrolate) – Commercial and Healthcare Reform	TBD	New policy created to ensure appropriate use of glycopyrrolate (Lonhala Magnair) in adults with chronic obstructive pulmonary disease (COPD). The member must experience therapeutic failure or intolerance to both of the following agents: Seebri Neohaler and Spiriva Handihaler or Respimat. Reauthorization criteria includes prescriber attestation that the member has experienced positive clinical response to therapy.
Yupelri (revefenacin) – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use of revefenacin (Yupelri) in adults with COPD. The member must experience therapeutic failure, contraindication, or intolerance to Spiriva Handihaler or Respimat and one of the following agents: Incruse Ellipta, Seebri Neohaler, or Tudorza Pressair. Reauthorization criteria include prescriber attestation that the member has experienced positive clinical response to therapy.
Licart (diclofenac epolamine) – Commercial and Healthcare Reform	Best Date	New policy created to ensure appropriate use of diclofenac (Licart) topical systems in those who have tried and failed generic oral diclofenac and one other oral generic non-steroidal anti-inflammatory drug (NSAID).
ProAir Digihaler (albuterol sulfate) – Commercial and Healthcare Reform	Best Date	New policy created to reserve use of albuterol sulfate (ProAir Digihaler) for members who have experienced inadequate response to a non-digitized albuterol inhaler and who demonstrate clinical need for a digital inhaler.
Rhopressa (netarsudil) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include ophthalmic cholinergic agents as one of the alternative options to experience therapeutic failure, contraindication for, or intolerance to. Reauthorization criteria added that the prescriber attests that the member has experienced positive clinical response to therapy.
Rhopressa (netarsudil) – Commercial NSF	02/25/2019	Policy revised to include reauthorization criteria that the prescriber attests that the member has experienced positive clinical response to therapy.
Lidoderm (lidocaine patch) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include reauthorization criteria that the prescriber attests that the member has experienced positive clinical response to therapy.
ZTLido (lidocaine 1.8% topical system) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include reauthorization criteria that the prescriber attests that the member has experienced positive clinical response to therapy.
Vyzulta (latanoprostene bunod) – Commercial and Healthcare Reform	02/25/2019	Policy revised to include reauthorization criteria that the prescriber attests that the member has experienced positive clinical response to therapy.
Topical Psoriasis Treatments – Commercial	02/25/2019	Policy revised to include reauthorization criteria to ensure that the provider provides attestation of clinical improvement or response to therapy.
One-Time Override for Quantity Limitations	02/25/2019	Policy revised to include Healthcare Reform.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Brand Statin Edit – Select Commercial and Healthcare Reform Plans	Best date	Policy revised to include rosuvastatin (Ezallor) as a target brand HMG-CoA Reductase Inhibitor (Statin). Policy revised from lifetime authorization to 12 months.
Extended Release Opioid Management – Commercial and Healthcare Reform	02/25/2019	Policy was revised to remove Opana ER reference (oxymorphone ER remains), remove Troxyca ER and Targiniq ER, and add Arymo ER with quantity limits. In background, added age restrictions for the various products.
Immediate-Release Opioid Management – Commercial and Healthcare Reform	02/25/2019	Policy revised to add RoxyBond to drug products and quantity limits.
Insomnia Medications – Commercial	02/25/2019	Policy revised to add Zolpimist, change indication and background information for Silenor; criteria were also revised to include Silenor.
Combination Prescription Drug Safety – Commercial and Healthcare Reform	TBD	Policy was revised to mirror drugs included in Medicare policy J-335. Previously only abuse-deterrent opioids included, this revision expanded the policy to all opioid agonists.
Atypical Antipsychotics – Commercial	01/30/2019	Policy revised to add the word "antidepressant" to adjunctive treatment wording, added Vraylar where it had been omitted, removed Abilify indication for the injectable, removed all ICD-9 codes, added the term "treatment-resistant" to Symbyax depression.
Latuda (lurasidone) – Commercial	02/25/2019	Policy was revised to remove Clozaril as a preferred formulary alternative.
Non-preferred ED Medications – Commercial	02/25/2019	Policy revised to include reauthorization criteria to ensure that the member is responding to or is stable on therapy.
Non-Preferred Dipeptidyl Peptidase IV Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised to include a trial and failure of a metformin containing product for the approval criteria and the automatic approval criteria. Policy revised to decrease authorization duration from lifetime to 12 months and to include reauthorization criteria, ensuring the member requires additional therapy.
Avandia (rosiglitazone) – Healthcare Reform	TBD	Policy revised to include a trial and failure of a metformin containing product for the approval criteria and the automatic approval criteria. Policy revised to include reauthorization criteria to ensure the member requires additional therapy.
Non-Preferred-Glucagon-Like-Peptide-1 Receptor Agonists	TBD	Policy revised to include a trial and failure of a metformin containing product for the approval criteria and the automatic approval criteria. Policy revised to include reauthorization criteria to ensure the member requires additional therapy.
Non-Preferred Sodium-Glucose Co-Transporter 2 Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised to include a trial and failure of a metformin containing product for the approval criteria and the automatic approval criteria. Policy revised to include reauthorization criteria to ensure the member requires additional therapy.
Selective Serotonin-Norepinephrine Reuptake Inhibitors – Commercial	02/25/2019	Policy revised to add clarity that generic desvenlafaxine is included in the MRxC policy. Authorization duration changed from lifetime to two years. Policy revised to include reauthorization criteria to ensure that the member is tolerating therapy and has experienced a therapeutic response.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Non-Preferred Bupropion Products – Commercial	04/01/2019	New policy created to require branded extended-release bupropion products to step through a generic extended-release bupropion alternative and one other generic antidepressant prior to approval.

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

3. Formulary Program

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria
Cost Share Exception: Statins	Best Date	Policy revised to include rosuvastatin (Ezallor) as a target brand HMG-CoA Reductase Inhibitor (Statin).

*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
Actemra ACTPen (tocilizumab) 162 mg/0.9 mL	4 prefilled autoinjectors per 28 days	12 prefilled autoinjectors per 84 days
Aemcolo (rifamycin) 194 mg	12 tablets per 90 days	12 tablets per 90 days
Apokyn (apomorphine) 10 mg/1 mL*	20 cartridges per 30 days	60 cartridges per 90 days
Arcalyst (rilonacept) 220 mg/2.3 mL	4 vials per 28 days	12 vials per 84 days
halobetasol foam 0.05%*	100 gm per 30 days	100 gm per 30 days
Hyrimoz (adalimumab-adaz) 40 mg/0.8 ml	80 mg (2 syringes/pens) per 28 days	6 syringes/pens per 84 days
Ilaris (canukinumab) 150 mg/mL	2 vials (300 mg) per 28 days	6 vials (300 mg) per 84 days
Inbrija (levodopa) 42 mg	5 cartons (60 capsules per carton) per month or 3 cartons (92 capsules per carton) per 30 days	15 cartons (60 capsules per carton) or 9 cartons (92 capsules per carton) per 90 days
Lexette Foam 0.05%*	100 gm per 30 days	100 gm per 30 days
Licart (diclofenac) 1.30%	30 topical systems (1 box) per 180 days	30 topical systems (1 box) per 180 days
Otrexup (methotrexate) 7.5 mg/0.4 mL, 10 mg/ 0.4 mL, 12.5 mg/0.4 mL 15 mg/0.4	4 syringes per 28 days	12 syringes per 84 days

Drug Name	Retail Edit Limit	Mail Edit Limit
mL, 17 mg/0.4 mL, 20 mg/0.4 mL, 22.5 mg/0.4 mL, 25 mg/0.4 mL*		
ProAir Digihaler (albuterol) 90 mcg	2 inhalers per lifetime	2 inhalers per lifetime
Rasuvo (methotrexate) 7.5 mg/0.15 mL, 10 mg/0.2 mL, 12.5 mg/0.25 mL, 15 mg/0.3 mL, 17.5/0.35 mL, 20 mg/0.4 mL, 22.5 mg/0.45 mL, 25 mg/0.5 mL, 27.5 mg/0.55 mL, 30 mg/0.6 mL*	4 syringes per 28 days	12 syringes per 84 days
Tolsura (itraconazole) 65 mg	120 capsules per 30 days	360 capsules per 90 days
Ultravate Lotion, Cream and Ointment 0.05%*	100 gm per 30 days	100 gm per 30 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
Yupelri (revefenacin) 175 mcg/3 mL	1 carton (30 individually pouched unit-dose vials)	3 cartons (90 individually pouched unit-dose vials)

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
Daurismo (glasdegib) 25 mg	2 tablets per day
Daurismo (glasdegib) 100 mg	1 tablet per day
Elepsia XR (levetiracetam) 1,000 mg, 1,500 mg	2 tablets per day
Ezallor (rosuvastatin) 5 mg, 10 mg, 20 mg, 40 mg	1 capsule per day
Firdapse (amifampridine) 10 mg	8 tablets per day
Lorbrena (lorlatinib) 25 mg	3 tablets per day
Lorbrena (lorlatinib) 100 mg	1 tablet per day
Motegrity (prucalopride) 1 mg, 2 mg	1 tablet per day
Sympazan (clobazam) 5 mg, 10 mg	1 film per day
Sympazan (clobazam) 20 mg	2 films per day
Vitrakvi (larotrectinib) 25 mg	6 capsules per day
Vitrakvi (larotrectinib) 100 mg	2 capsules per day
Vitrakvi (larotrectinib) 20 mg/mL	10 mL solution per day
Xospata (gilteritinib) 40 mg	3 tablets per day

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

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

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