

# SPECIAL eBULLETIN

OCTOBER 2017

## FOURTH QUARTER 2017 UPDATE

## CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the Fourth Quarter 2017 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 2017 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

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- B. Updates to the Pharmacy Utilization Management Programs
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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



**Delaware Progressive Formulary – Select Healthcare Reform Individual Plans**  
**Jan. 1, 2018**

Effective **Jan. 1, 2018**, there will be a new formulary for select Healthcare Reform (HCR) Individual plans in Delaware. The new formulary called the **Delaware Healthcare Reform Progressive formulary** will be an incentive formulary with four primary tiers. Again, this formulary is only being used for select Individual HCR plans in Delaware.

The four tiers on the formulary are outlined below:

- Tier 1 - Preferred Generics
- Tier 2 - Nonpreferred Generics
- Tier 3 - Preferred Brands
- Tier 4 - Nonpreferred Brands

Some of your patients' current medications may be covered on a different tier with this new formulary. To ensure that your patients receive the maximum prescription drug coverage, please consider the preferred formulary drug options. A list of drugs and their tier included on the Progressive Formulary, listed by therapeutic class, is available via the Provider Resource Center.

We hope this information makes the transition easier for both you and your patient. 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

### **Intraocular Injections of a Compounded Triamcinolone, Moxifloxacin, and Vancomycin (TMV) Formulation: FDA Statement – Case of Hemorrhagic Occlusive Retinal Vasculitis**

On October 3, 2017, the FDA advised against the prophylactic use of intraocular vancomycin, alone or in a compounded drug combining multiple active ingredients during cataract surgery with the intent of preventing postoperative endophthalmitis, due to the risk of hemorrhagic occlusive retinal vasculitis (HORV). HORV is a rare, potentially blinding postoperative complication that has been observed in dozens of patients who have received intraocular injections of vancomycin (anti-infective) formulations toward the end of otherwise uncomplicated cataract surgeries. The FDA is unaware of any adequately controlled studies demonstrating the safety and efficacy of intraocular vancomycin in preventing endophthalmitis. There is no FDA-approved vancomycin formulation for intraocular injection. 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.

### **Ocaliva (obeticholic acid): Drug Safety Communication – Increased Risk of Serious Liver Injury**

On September 21, 2017 the FDA warned that using incorrect dosing of Ocaliva (obeticholic acid) outside the drug label recommendations has resulted in an increased risk of serious liver injury and death. Ocaliva may also be associated with liver injury in some patients with mild disease who are receiving the correct dose. The recommended dosing and monitoring for patients on this medicine are outlined in the prescribing information. The FDA is working with the drug manufacturer, Intercept Pharmaceuticals, to address the above outlined safety concerns. 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.

### **Opioid Addiction Medications in Patients Taking Benzodiazepines or CNS Depressants: Drug Safety Communication – Careful Medication Management Can Reduce Risks**

On September 20, 2017 the FDA advised that buprenorphine and methadone for opioid addiction should not be withheld from patients concurrently on benzodiazepines or other central nervous system (CNS) depressing agents. Though the combined use of these agents increases the risk of serious adverse events, the harm of untreated opioid addiction typically outweighs these risks. The FDA will be requiring the addition of this information to the respective drug labels with recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together. 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.

### **Kayexalate (sodium polystyrene sulfonate): Drug Safety Communication – FDA Recommends Separating Dosing**

On Sept. 6, 2017 the FDA advised against concurrent use of the potassium-lowering drug sodium polystyrene sulfonate (Kayexalate) with other orally administered medicines. The binding of this agent with multiple oral medications can decrease the absorption and effectiveness of the medicines. Dosing should be separated by at least 3 hours. The drug labels will be updated to reflect this information. 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.

### **Keytruda (pembrolizumab) in Patients with Multiple Myeloma: FDA Statement – Two Clinical Trials on Hold**

On Aug. 31, 2017 the FDA issued a statement about the risks associated with the use of Keytruda (pembrolizumab) in combination with dexamethasone and an immunomodulatory agent (lenalidomide or pomalidomide) for the treatment of patients with multiple myeloma. Keytruda is not approved for this indication. Interim results from two clinical trials (KEYNOTE-183 and KEYNOTE-185) demonstrated an increased risk of death for patients receiving the study treatment regimen as compared to the control group. The FDA required all patients in the trials be discontinued from further investigation on July 3, 2017. 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.

### **Pravastatin Sodium Tablets by International Laboratories: Recall – Mislabeling**

On Aug. 10, 2017 the FDA advised of a voluntary recall of one lot of pravastatin sodium tablets USP 40mg packaged in bottles of 30 tablets, to the consumer level, by International Laboratories, LLC. This recall is due to mislabeling of the product, which may contain bupropion hydrochloride XL 300mg tablets. The affected product is NDC# 54458-925-16; Lot# 115698A. If a patient mistakenly takes bupropion, side effects are typically mild and reversible. However, individuals with epilepsy are at higher risk of seizure on bupropion due to it lowering the seizure threshold. Also, people on MAOIs can have a risky drug interaction with bupropion (hypertensive crisis). 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.

### **Lorazepam Oral Concentrate, USP 2 mg/mL by Amneal Pharmaceuticals: Recall – Misprinted Dosing Droppers**

On Aug. 16, 2017, Amneal Pharmaceuticals LLC issued a voluntary recall for 13 lots of Lorazepam Oral Concentrate, USP 2mg/mL, due to misprinted dosing droppers. The dosing markers on the droppers have been found to be shifted, in reverse, or missing entirely. The dropper marking errors could lead to dispensing of less or more than the intended dosage of the medication. No adverse events related to the dropper defects have been noted to date. 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.

### **Compounded Triamcinolone and Moxifloxacin Product for Intravitreal Injection by Guardian Pharmacy Services: Alert to Health Professionals – Serious Adverse Events Reported**

On July 28, 2017, the FDA warned of at least 43 patients who had adverse events after receiving intravitreal injections of a drug containing triamcinolone and moxifloxacin compounded by Guardian Pharmacy Services in Dallas, TX. Guardian's product was injected into the vitreous of the eye at the end of cataract surgery as post-operative prophylaxis for ocular inflammation and endophthalmitis in place of post-operative eye drop use. Over the course of several months, patients developed various symptoms, including vision impairment (blurred or decreased vision), poor night vision, loss of color perception, photophobia (light sensitivity), glare, halos, flashing lights, ocular discomfort, pain, loss of balance, headaches, and/or nausea. A number of the symptoms were not

exhibited until at least one month postoperatively. Compounded drugs are not reviewed by FDA for safety, effectiveness, or quality. Side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

**Cyclobenzaprine HCl and Amantadine HCl by Apace Packaging: Recall – Potential Mislabeling**

On July 28, 2017, the FDA announce a recall of one lot of Cyclobenzaprine HCl Tablet, USP 5 mg 50ct Unit Dose, NDC# 50268-190-15, Lot Number 16710 and one lot of Amantadine HCl Capsule, USP 100 mg 50ct Unit Dose NDC# 50268-069-15, Lot Number 16710 from Apace Packaging LLC to the Retail level. Cyclobenzaprine HCl tablets 5 mg, blister cards may be in cartons labeled as amantadine HCl capsules USP 100 mg. The unit dose blisters inside the carton are correctly labeled as Cyclobenzaprine HCl Tablet, USP 5 mg. Unintentional dosing with Cyclobenzaprine HCl may potentially lead to the development of serotonin syndrome, which can be life-threatening. Missed doses of Amantadine in a few patients with Parkinson's disease have experienced a parkinsonian crisis, i.e., a sudden marked clinical deterioration, when this medication was suddenly stopped. 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.

**Paliperidone Extended-Release Tablets 3mg by Teva Pharmaceuticals: Recall – Dissolution Test Failure**

On June 15, 2017, Teva Pharmaceuticals USA, Inc. (Teva) issued a voluntary recall on May 31, 2017 at the retail-level for one lot of paliperidone extended-release tablets (3mg, 90 count bottles, lot 1160682A, expiration 6/2018, NDC 0591-3693-19) that was distributed under the Actavis Pharma Inc. label. The product is being recalled due to failing test results for dissolution. Based on Teva's investigation, the likelihood of consuming two or more consecutive doses with affected product is low. 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 2017

### SECTION I. Highmark Commercial and Healthcare Reform Formularies

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

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

Highmark Comprehensive Formulary:

<https://client.formularynavigator.com/Search.aspx?siteCode=8103967260>

Highmark Comprehensive Healthcare Reform Formulary:

<https://client.formularynavigator.com/Search.aspx?siteCode=4906449921>

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

**Table 1. Products Added**

(All products added to the formulary effective date to be determined in 4Q2017, unless otherwise noted.)

<b>Brand Name</b>	<b>Generic Name</b>	<b>Comments</b>
Norvir oral powder	ritonavir	New dosage form (oral powder), indicated for HIV-1 infection in pediatric patients.
Benlysta SQ	belimumab	New self-administered subcutaneous formulation, indicated for systemic lupus erythematosus (SLE). <i>Effective Date: 09/01/2017</i>
Nityr	nitisinone	Indicated for hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine. <i>Effective Date: 09/01/2017</i>
Tymlos	abaloparatide	Indicated to reduce risk of vertebral and non-vertebral fractures in postmenopausal women at high risk for fracture or who failed or were intolerant to other osteoporosis therapy. <i>Effective Date: 10/13/2017</i>

Coverage may be contingent upon plan benefits.

**Table 2. Products Not Added\***

Brand Name	Generic Name	Preferred Alternatives
Kevzara	sarilumab	methotrexate, Actemra, Humira, Enbrel, Xeljanz
Jadenu sprinkle	deferasirox	Exjade
Zerviate	cetirizine 0.24% ophthalmic solution	epinastine, olopatadine 0.2%
Baxdela oral tablets	delafloxacin	ciprofloxacin, levofloxacin
Bevyxxa	betrixaban	enoxaparin, heparin
Symjepi	epinephrine	epinephrine
Cotempla XR-ODT	methylphenidate	methylphenidate ER
Mydayis	amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextroamphetamine sulfate	dextroamphetamine-amphetamine, dextroamphetamine ER, methylphenidate ER
Endari	L-glutamine	Mydayis, Cotempla XR-ODT, Symjepi, Baxdela oral tablets, and Zerviate
Haegarda	C1 esterase Inhibitor	Provider discretion
Tremfya	guselkumab	Humira, Otezla, Stelara, Cosentyx
Vosevi	sofosbuvir/velpatasvir/voxilaprevir	Provider discretion
Idhifa	enasidenib	Provider discretion
Nerlynx	neratinib	Provider discretion
Mavyret	glecaprevir; pibrentasvir	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 **Provider Forms**, select **Miscellaneous Forms**, and select the form titled **Request for Non-Formulary Drug Coverage**.

**Table 4. Products to be Removed – Effective Jan. 1, 2018**

Brand name	Generic Name	Preferred Alternatives
<b>Only Healthcare Reform Comprehensive Products</b>		
Centrum Silver	multivitamin/fa/lycopene/lutein	Multivital Platinum
Cyclogyl	cyclopentolate HCl	cyclopentolate HCl
Farxiga	dapagliflozin	Jardiance, Invokana
Xigduo XR	dapagliflozin/metformin HCl	Synjardy XR , Invokamet XR
<b>Only Commercial Comprehensive Products</b>		
Pradaxa	dabigatran etexilate mesylate	Xarelto, Eliquis
Forteo	teriparatide	alendronate, Tymlos
<b>All Commercial &amp; Healthcare Reform Comprehensive Products</b>		
Children's Aspirin	aspirin	aspirin
Alkeran	melphalan	melphalan HCl
Antioxidant	beta-carotene(a)-c; e/selenium	super antioxidant
Bayer Chewable	aspirin	aspirin

Brand name	Generic Name	Preferred Alternatives
Carnitor	levocarnitine	levocarnitine
Cleocin HCl	clindamycin HCl	clindamycin HCl
D.H.E.45	dihydroergotamine mesylate	dihydroergotamine mesylate
Derma-Smoothe-FS	fluocinolone/shower cap	fluocinolone acetonide
E.E.S.	erythromycin ethylsuccinate	erythromycin ethylsuccinate
Ecotrin	aspirin	aspirin EC
Flintstones	multivitamin	child chew multivitamin
Flintstones Complete	multivitamin with iron; minerals	children's multivitamin w/iron
Flintstones with Extra C	multivitamin	child chew multivitamin
Loprox	ciclopirox olamine	ciclopirox
Maxidone	hydrocodone / acetaminophen	hydrocodone w/acetaminophen
Nitrostat	nitroglycerin	nitroglycerin
Orap	pimozide	pimozide
Pataday	olopatadine HCl	olopatadine HCl
Prevident	fluoride (sodium)	sodium fluoride
Scooby-Doo	multivitamin with iron; minerals	children's multivitamin w/iron
Tiazac	diltiazem HCl	diltiazem ER
Effient	prasugrel HCl	prasugrel HCl
Transderm-Scop	scopolamine	scopolamine
Bydureon	exenatide microspheres	Victoza, Trulicity
Evzio	naloxone HCl	naloxone HCl , Narcan
Mupirocin cream	mupirocin calcium	mupirocin ointment

## **D. Updates to the Pharmacy Utilization Management Programs**

### **1. Prior Authorization Program**

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Northera (droxidopa) – Healthcare Reform	8/10/2017	New policy created for the Healthcare Reform line of business, which was split from the initially combined Commercial and Healthcare Reform policy for droxidopa (Northera). The policy criteria remains the same. Administrative changes were also made.
Northera (droxidopa) – Commercial	08/10/2017	Policy revised to split Commercial and Healthcare Reform. Commercial members will be subject to step therapy (inadequate response, intolerance or contraindication to the preferred generic alternatives, midodrine or fludrocortisone. Administrative changes were also made.
Benlysta SQ (belimumab) – Commercial and Healthcare Reform	09/29/2017	New policy created to ensure appropriate use in members who have active, autoantibody positive systemic lupus erythematosus and will be using the drug as add-on therapy to standard-of-care (e.g., corticosteroids, hydroxychloroquine, and immunosuppressants).
Endari (L-glutamine) – Commercial and Healthcare Reform	TBD	New policy created to ensure appropriate use in members who have sickle cell disease and who meet the following criteria: <ul style="list-style-type: none"> <li>• Experience greater than or equal to three complication</li> </ul>



Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		<p>episodes per year despite treatment with hydroxyurea.</p> <ul style="list-style-type: none"> <li>• Have been on hydroxyurea treatment for at least 3 months and will continue therapy while taking L-glutamine (Endari).</li> <li>• Have tried at least one over-the-counter L-glutamine product and presented an inadequate response, therapeutic failure, contraindication, or intolerance.</li> </ul>
Idhifa (enasidenib) – Commercial and Healthcare Reform	09/29/2017	New policy created to ensure appropriate use in adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test.
Ingrezza (valbenazine) – Commercial and Healthcare Reform	8/10/2017	Policy revised to include psychiatrists, in addition to neurologists as an accepted specialist who can prescribe this medication.
Fertility – Commercial and Select Healthcare Reform Plans	1/1/2018	Policy revised to encompass all Healthcare Reform plans which have the Fertility benefit prior authorized with the exception of Pennsylvania Individual Plans which are managed through policy J-472.
Anti-Obesity – Commercial and Healthcare Reform	8/10/2017	<p>Policy revised to clarify that criteria for Xenical are applicable to Commercial plans only (not Healthcare Reform). Additional criteria were added against use of Saxenda with the following products:</p> <ul style="list-style-type: none"> <li>• GLP-receptor agonist (i.e., Bydureon, Byetta, Tanzeum, Trulicity, Victoza, Adlyxin)</li> <li>• Insulin/GLP-receptor agonist combinations (i.e., Soliqua, Xultophy).</li> </ul>
Kalydeco (ivacaftor) – Commercial and Healthcare Reform	8/10/2017	Policy revised to include coverage for patients with cystic fibrosis and a mutation in the CFTR gene that is responsive to ivacaftor (23 additional mutations).
Epinephrine Auto Injectors – Commercial and Healthcare Reform	TBD	Policy revised to include Symjepi (epinephrine) as a non-preferred epinephrine product. Please refer to the policy for additional details.
Luzu (luliconazole 1% cream) – Healthcare Reform	8/10/2017	Policy revised to specify that the 2 generic antifungal alternatives (e.g., ciclopirox, terbinafine, clotrimazole, ketoconazole) that are tried and failed must be topical.
Kinase Inhibitors – Commercial and Healthcare Reform	9/1/2017	Policy revised to include new indications for pembrolizumab (Zykadia) as first-line therapy for ALK-positive NSCLC, and trametinib (Mekinist)/dabrafenib (Tafinlar) for treatment of BRAF V600E mutated metastatic NSCLC.
Kinase Inhibitors – Commercial and Healthcare Reform	TBD	<p>Policy revised to include new indications for pembrolizumab (Zykadia) as first-line therapy for ALK-positive NSCLC, trametinib (Mekinist)/dabrafenib (Tafinlar) for treatment of BRAF V600E mutated metastatic NSCLC, and Imbruvica for chronic graft vs host disease. Alecensa was updated to allow coverage as first line therapy per NCCN guidelines, and Alunbrig to allow for coverage after failure of</p>

<b>Policy Name</b>	<b>Policy Effective Date*</b>	<b>Updates and/or Approval Criteria</b>
		any first-line therapy (Xalkori, Zykadia or Alecensa). New drug neratinib (Nerlynx) approval criteria was added for patients with HR+, HER2+ early stage breast cancer following trastuzumab therapy.
Strensiq (asfotase alfa) – Commercial and Healthcare Reform	9/8/2017	Policy revised to remove Medicare line of business, limit authorization duration to 1 year, and include criteria for reauthorization in patients responding to therapy.
Human Growth Hormone – Delaware Commercial and Healthcare Reform	TBD	Policy revised to include somatropin (Genotropin) as a third preferred growth hormone product.
Nitisonone (Orfadin and Nityr) – Commercial and Healthcare Reform	09/29/2017	Policy revised to include a new nitisonone product, Nityr tablets. The same approval criteria for Orfadin will apply to Nityr, requiring diagnosis of hereditary tyrosinemia type I (HT-1), confirmed by biochemical and/or genetic testing. Patients must also be following a diet restricted in tyrosine and phenylalanine.
Hepatitis C Oral Agents – Commercial and Healthcare Reform	8/10/2017	Policy revised to include sofosbuvir/velpatasvir/voxilaprevir (Vosevi) and glecaprevir/pibrentasvir (Mavyret) based on FDA-approved indications. Please refer to the policy for additional details and coverage criteria.
Dupixent (dupilumab) – Commercial and Healthcare Reform	8/10/2017	Policy revised to remove reference to pediatric patients, as product is only indicated for patients 18 years of age or older.
Hereditary Angioedema – Commercial and Healthcare Reform [Policy Name Change]‡	09/29/2017	Policy revised to include newly FDA-approved Haegarda subcutaneous C1 esterase inhibitor. Member weight documentation will be required for all agents. In addition, quantity management of 20 vials for subcutaneous injection per 30 days will be applied to Haegarda. Policy title will be changed to Hereditary Angioedema to reflect appropriate scope of policy.
Chronic Inflammatory Diseases – Commercial and Healthcare Reform	8/10/2017	Policy revised to include the expanded indication for abatacept (Orencia) - treatment of adult patients with active psoriatic arthritis and the corrected quantity limits for ustekinumab (Stelara). Policy revised to include guselkumab (Tremfya) as a non-preferred agent for plaque psoriasis.
Rayaldee and Vitamin D Analogs – Commercial and Healthcare Reform	8/10/2017	Policy revised to modify the noted quantity limits, from 30 mcg (1 capsule) per day to 60 mcg (2 capsules) per day.

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

‡Hereditary Angioedema - implementation of quantity limits (20 vials for subcutaneous injection per 30 days) is pending internal approval, coding and communication process.

## 2. Managed Prescription Drug Coverage (MRx) Program

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria**
Topical Rosacea Treatments (Rhofade Only) – Healthcare Reform	09/22/2017	New policy created for oxymetazoline (Rhofade), with the following approval criteria: <ul style="list-style-type: none"> <li>• 18 years of age or older</li> <li>• diagnosis of persistent facial erythema associated with rosacea in adults</li> <li>• experienced therapeutic failure or intolerance to generic metronidazole for the approval of Rhofade</li> </ul>
Luzu (luliconazole 1% cream)– Commercial	8/10/2017	New Step Therapy policy created for luliconazole 1% cream (Luzu), requiring step through two generic antifungal alternatives (e.g., ciclopirox, terbinafine, clotrimazole, ketoconazole).
Antiviral Therapy (Sitavig, Denavir and Xerese) – Commercial	TBD	Policy revised to split the Healthcare Reform line of business, with the addition of acyclovir 5%/hydrocortisone 1% cream (Xerese) to the policy, indicated for the treatment of recurrent herpes labialis (cold sores). Additional criteria include trial and failure of two formulary antiviral agents such as acyclovir, valacyclovir or famciclovir, one of which must be acyclovir. Additional documentation of trial and failure of acyclovir 5% ointment and hydrocortisone 1% cream simultaneously must be provided.
Antiviral Therapy (Sitavig and Denavir) – Healthcare Reform	TBD	Policy revised to split the Commercial line of business (see above). Policy criteria remains the same for the Healthcare Reform line of business, and is applicable to acyclovir buccal tablets (Sitavig) and penciclovir 1% (Denavir).
Vimovo (naproxen; esomeprazole) – Commercial and Healthcare Reform	08/10/2017	Policy revised to include coverage of new indication for juvenile idiopathic arthritis (JIA) in adolescents 12 years of age and older.
Migraine Therapies – Commercial and Healthcare Reform	TBD	Policy revised to require therapeutic failure or contraindication to generic triptans before receiving brand triptans. Revisions were also made to the quantity limit language, from quantity per number of days to quantity per copayment limit. Quantity limitations were adjusted to align with marketed product packaging.
Azilect (rasagiline) – Healthcare Reform	1/1/2018	New policy created to ensure appropriate use and promote trial of more cost-effective generic alternatives.

\*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 – Commercial and Healthcare Reform	12/1/17	New policy which outlines when low to moderate dose brand and select generic statins will be covered for \$0 based on the new United States Preventative Service Task Force recommendation.

\*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
Kevzara (sarilumab) all strengths	2 syringes per 21 days	6 syringes per 63 days
Xerese (acyclovir and hydrocortisone cream) 5%/1%, 5 gm tube	5gm tube per 30 days	5gm tube per 30 days
Tremfya (guselkumab) 100 mg/mL	1 syringe per 42 days	1 syringe per 42 days
Benlysta (belimumab) 200 mg/mL	4 syringes per 21days	12 syringes per 63 days
Haegarda (C1 esterase INH) 2000IU, 3000IU	20 vials per 30 days	60 vials per 90 days
Bevyxxa (betrixaban) all strengths	42 tablets per 60 days	42 tablets per 60 days
Tyvaso (treprostinil) starter kit	1 kit per 274 days	1 kit per 274 days
Tymlos (abaloparatide) 3120 mcg / 1.56 mL	1 pen per 30 days	3 pens per 90 days

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

Drug Name	Retail Edit Limit	Mail Edit Limit
Baxdela tablets (delafloxacin) all strengths	28 tablets	28 tablets
Symjepi (epinephrine) all strengths	2 devices	2 devices
Vosevi (sofosbuvir/velpatasvir/voxilaprevir) all strengths	28 tablet	84 tablets
Mavyret all strengths	84 tablets	252 tablets

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

Drug Name	Daily Limit
Zytiga (abiraterone) 500 mg	2 tablets per day
Rubraca (rucaparib) 250 mg	4 tablets per day
Norvir oral powder 100 mg/packet	12 packets per day
Rayaldee (calcifediol) 30 mcg capsules	2 capsules per day
Endari (L-glutamine) 5 gm/packet	6 packets per day
Orenitram (treprostinil) 5 mg	9 tablets per day
Mevacor (lovastatin) 10 mg, 20 mg	1 tablet per day
Mevacor (lovastatin) 40 mg	2 tablets per day
Pravachol (pravastatin) 10 mg, 20 mg, 40 mg, 80 mg	1 tablet per day
Zocor (simvastatin) 5mg, 10mg, 20 mg, 40 mg, 80 mg	1 tablet per day
Crestor (rosuvastatin) 5 mg, 10 mg, 20 mg, 40 mg	1 tablet per day
Lipitor (atorvastatin) 10mg, 20 mg, 40 mg, 80 mg	1 tablet per day
Altoprev (lovastatin) 20 mg, 40 mg, 60 mg	1 tablet per day

<b>Drug Name</b>	<b>Daily Limit</b>
Lescol (fluvastatin) 20 mg	1 tablet per day
Lescol (fluvastatin) 40 mg	2 capsules per day
Lescol XL (fluvastatin ER) 80 mg	1 tablet per day
Livalo (pitavastatin) 1mg, 2 mg, 4mg	1 tablet per day
Vytorin (exetimibe/simvastatin) 10 mg-10 mg, 10 mg-20 mg, 10 mg-40 mg, 10 mg-80 mg	1 tablet per day
Caduet (amlodipine/atorvastatin) 2.5 mg-10 mg, 2.5 mg-20 mg, 2.5 mg-40 mg, 5 mg-10 mg, 5 mg-20 mg, 5 mg-40 mg, 5 mg-80 mg, 10 mg-10 mg, 10 mg-20 mg, 10 mg-40 mg, 10 mg-80 mg	1 tablet per day
Ingrezza (valbenazine) 80 mg	1 tablet per day
Idhifa (enasidenib) 50 mg	2 tablets per day
Idhifa (enasidenib) 100 mg	1 tablet per day
Nerlynx (neratinib) 40 mg	6 tablets per day
Mydayis all strengths	1 capsule per day
Cotempla XR-ODT all strengths	2 tablets per day

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