SPECIAL eBULLETIN

July 2017

THIRD QUARTER 2017 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the Third 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 May 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

A. Changes to the Highmark Comprehensive Formulary and the Highmark Comprehensive Healthcare Reform Formulary
B. Updates to the Pharmacy Utilization Management Programs
   1. Prior Authorization Program
   2. Managed Prescription Drug Coverage (MRxC) Program
   3. 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

Important Drug Safety Updates

Topical Products by Phillips Company: Recall Due to Concerns of Manufacturing Practices
On June 14, 2017, the FDA reported that Phillips Company has initiated a nationwide voluntary recall of all lots of Tetrastem, Diabecline, Tetracycline-ABC, VenomX, Acneen, StaphWash, StringMed, NoPain, and LidoMed. These products are being recalled after an FDA inspection found significant manufacturing practices that question the safety, identity, strength, quality, and purity of these drug products over the past three years. Although no adverse events have been reported, the possibility of decreased quality and consistency of the products poses a risk to all consumers using these products. Therefore, affected consumers should stop using the product and return it to the manufacturer. 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.

Eliquis (apixaban) 5 mg tablets: Recall – Bottle Labeled as 5 mg Was Found to Contain 2.5 mg Tablets
On June 13, 2017, the FDA reported that Bristol-Myers Squibb Company has initiated a nationwide voluntary recall of one lot (#HN0063) of Eliquis 5 mg tablets. This lot is being recalled as a precautionary measure after a customer complaint that a 5 mg bottle was found to contain 2.5 mg tablets. As a result, patients taking Eliquis 2.5 mg tablets instead of 5 mg tablets may be at increased risk of blood clots, stroke, or death. To date, there have not been any reports of injuries due to this issue, but consumers should use caution and return recalled product to receive a replacement. Adverse events or side effects related to the use of this product should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Mibelas 24 Fe by Lupin Pharmaceuticals Inc.: Recall – Out of Sequence Tablets and Missing Expiry/Lot Information
On May 29, 2017, the FDA reported that Lupin Pharmaceuticals, Inc. has initiated a nationwide voluntary recall of one lot (L600518, Exp 05/18) of Mibelas 24 Fe (Norethindrone Acetate and Ethinyl Estradiol 1 mg/0.02 mg chewable and ferrous fumarate 75 mg). This product is being recalled due to a confirmed market report that indicated a packaging error in which the four placebo tablets were improperly positioned in the sequence. Oral contraceptive tablets that are taken out of order may increase the risk for unintended pregnancy. For patients in whom a pregnancy is contraindicated or in whom using teratogenic medications, an unintended pregnancy may cause major maternal or fetal health complications, including death. To date, there have been no reports of adverse events, but consumers should return recalled product to the pharmacy and notify their health care provider. Adverse events or side effects related to the use of this product should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Brilinta (ticagrelor) 90 mg tablets, 8-count Physician Sample Bottles: Recall – Report of Another Medicine in One Bottle
On May 26, 2017, the FDA reported that AstraZeneca has initiated a nationwide voluntary recall of one lot (#JB5047) of professional sample bottles containing eight tablets of Brilinta 90 mg. This lot is being recalled as a precautionary measure after a report that a sample Brilinta 90 mg bottle also contained another medicine, Zurampic (lesinurad) 200 mg tablets. Consumption of Zurampic may

lead to adverse events such as renal complications, while missed doses of Brilinta may increase the risk of blood clots, heart attack, stroke, and death. Physicians should return recalled products, and affected consumers should use caution and follow up with their physicians. Adverse events or side effects related to the use of this product should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Canagliflozin (Invokana, Invokamet): Drug Safety Communication – Increased Risk of Leg and Foot Amputations

On May 16, 2017, the FDA issued a new Box Warning describing the risk of leg and foot amputations in patients treated with canagliflozin. This warning was added based on new data from two large clinical trials, CANVAS (Canagliflozin Cardiovascular Assessment Study) and CANVAS-R (A Study of the Effects of Canagliflozin on Renal Endpoints in Adult Participants With Type 2 Diabetes Mellitus), which demonstrated that leg and foot amputations occurred twice as often in patients treated with canagliflozin as those treated with placebo. Health care professionals should consider the benefits vs. risks regarding this medication and use caution especially in patients at increased risk, including patients with history of prior amputation, peripheral vascular disease, neuropathy, and diabetic foot ulcers. Consumers should report any development of new pain or tenderness, sores or ulcers, or infections in the legs or feet. Adverse events or side effects related to the use of this product should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Phenobarbital 15 mg Tablets, USP by C.O. Truxton: Recall – Labeling Error on Declared Strength

On May 8, 2017, the FDA reported that C.O. Truxton, Inc. has initiated a nationwide voluntary recall of one lot (70952A) of phenobarbital tablets, USP, 15 mg. This product is being recalled due to a confirmed customer complaint that a 15 mg bottle was found to contain 30 mg tablets. As a result, patients taking phenobarbital 30 mg instead of 15 mg tablets may be at increased risk of adverse events due to toxicity including cardiogenic shock, renal failure, coma, and death. Affected consumers should stop using the product and return it to the place of purchase. Adverse events or side effects related to the use of this product should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

General Anesthetic and Sedation Drugs: Drug Safety Communication - FDA Approves Label Change for Use in Young Children

On April 27, 2017, the FDA approved the use of general anesthetic and sedation drugs in children under the age of 3. If a surgery or procedure that is medically needed for which the use of these drugs is recommended, it should not be delayed and these drugs can be used. It is still recommended, however, if it is an elective surgery to consider the medical necessity before proceeding. A warning was also added to the label indicating brain development can be negatively impacted if long exposure or multiple surgeries with this drug occur in children less than 3 years of age. Health care professionals should weigh the benefits and risks involved when considering the use of general anesthetic and sedation drugs. 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.

Codeine and Tramadol medications: Restricted use in children and not to be used in breastfeeding women

On April 20, 2017, the FDA restricted the use of these products in children younger than 12 and recommended against the use of these products in breastfeeding women. Due to the risks involved with using these products in children the label for codeine and tramadol now include a contraindication, noting that codeine is not to be used to treat pain or cough and tramadol not to be sued to treat pain in children younger than 12 years of age. The new contraindication for tramadol also warns against its use in children younger than 18 for the treatment of pain after surgery to remove tonsils and/or adenoids. Additional warnings for codeine and tramadol include recommendations against use in adolescents between 12-18 years of age who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.

The warning was strengthened for using these products in breastfeeding women due to the serious adverse events that can occur in the infants being breastfed. 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.

Homeopathic Teething products: Recall – Confirmed Elevated Levels of Belladonna

On April 13, 2017, the FDA issued a voluntary recall on all lots of Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets by the manufacturer, Standard Homeopathic Company. The warning is due to inconsistent amounts of belladonna found in certain homeopathic teething tablets, which may be exceeding the amount claimed on the label. This may pose an unnecessary risk to infants and children, and use of these products is discouraged. Homeopathic teething products have not been evaluated or approved by the FDA for safety or effectiveness. The FDA recommends that consumers stop using these products marketed by Hyland's immediately, and dispose of any in their possession. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

EpiPen and EpiPen Jr Auto-Injector: Recall – Failure to Activate Device

On March 31, 2017, Mylan N.V announced a voluntary recall for additional lots of EpiPen and EpiPen Jr Auto-Injectors due to the devices failing to activate. This impacts the0.3 mg and 0.15 mg strengths of EpiPen Auto-injector. None of the recalled lots include the authorized generic for EpiPen Auto-Injector. . Patients are encouraged to keep their existing product until a replacement product is secured. Patients may receive either EpiPen Auto-Injector or the authorized generic for EpiPen Auto-Injector at the pharmacy as a replacement based on availability. 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.

Viberzi (eluxadoline): Drug Safety Communication – Increased Risk of Serious Pancreatitis in Patients Without a Gallbladder

On March 15, 2017, the FDA warned against the use of Viberzi in patients without a gallbladder due to development of pancreatitis that leads to hospitalization or death. Symptoms of pancreatitis have occurred with just one or two doses of Viberzi at the recommended dosage for patients who do not

have a gallbladder (75 mg), and who do not consume alcohol. The FDA recommends avoiding use of this drug in patients without a gallbladder and looking for alternative options. 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.

HCG (Human Chorionic Gonadotropin) Freeze Dried Vials by Synergy Rx: Recall – Lack of Sterility Assurance

On February 15, 2017, Synergy RX voluntarily recalled all of their lots of Human Chorionic Gonadotropin (HCG) 5,000 units/vial and 11,000 units/vial to the retail level due to lack of sterility concerns. This involves all of the products distributed during 06/01/2016 to 12/22/2016 in Arizona, California, Wisconsin and Minnesota. Adverse events or side effects related to the use of these products should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Highmark Formulary Update – July 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 to the Formulary*

Brand name	Generic Name	Comments
Healthcare Reform Comprehensive Products Only		
Trulicity**	dulaglutide	Indicated for type II diabetes mellitus. *Effective date: 06/01/2017*
Jardiance**	empagliflozin	Indicated for type II diabetes mellitus; prophylaxis of disorder of cardiovascular system. *Effective date: 06/01/2017*
Synjardy**	empagliflozin/metformin	Indicated for type II diabetes mellitus. *Effective date: 06/01/2017*
Narcan**	naloxone injection	Indicated for opiate overdose; reversal of opiate activity, respiratory depression, with therapeutic opioid use; adjunct for septic shock. *Effective date: 03/01/2017*

Coverage may be contingent upon plan benefits.
*Applicable only to the Commercial Comprehensive Line of Business.

** Products add editions applicable only to Healthcare Reform Comprehensive products.

Table 2. Products Not Added*

Brand Name	Generic Name	Preferred Alternatives
Emflaza	deflazacort	prednisone
Siliq	brodalumab	humira (adalimumab)
Xermelo	telotristat ethyl	Provider discretion
Odactra	house dust mite allergen extract	Provider discretion
Kisqali	ribociclib	Provider discretion
Xadago	safinamide	Provider discretion
Symproic	naldemedine	movantik, amitiza
Zejula	niraparib	Provider discretion
Dupixent	dupilumab	Provider discretion
Austedo	deutetrabenazine	tetrabenazine
Ingrezza	valbenazine	tetrabenazine
Rydapt	midostaurin	Provider discretion
Alunbrig	brigatinib	Provider discretion
Qtern	dapagliflozin/saxagliptin	farxiga, januvia, tradjenta
Noctiva	desmopressin acetate	Provider discretion
RoxyBond	oxycodone hydrochloride	oxycodone immediate-release tablets
Xatmep	methotrexate	methotrexate tablet
Kisqali Femara Co-Pack	ribociclib; letrozole	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 3. Products to be Removed

Brand name	Generic Name	Preferred Alternatives
Healthcare Reform Comprehensive Products Only		
Zepatier	elbasvir and grazoprevir	Provider discretion
Sovaldi	sofosbuvir	Provider discretion
Evzio	naloxone	naloxone syringe/vial, narcan nasal spray

B. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Emflaza (deflazacort) – Commercial and	05/01/2017	New policy created to ensure appropriate utilization per labeled indication. Because the guidelines also

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Healthcare Reform		highlight prednisone as an option for treatment of DMD patients, there should be documentation that the member has tried prednisone for at least 6 months, and experienced intolerable adverse events related to weight gain and Cushingoid symptoms or has demonstrated adverse behavioral events that would warrant reduction in the dose of prednisone.
Epinephrine Auto Injectors – Commercial and Healthcare Reform§	07/01/2017	New policy to ensure appropriate utilization of cost-effective products for emergency treatment of allergic reactions including anaphylaxis. Medications addressed in this policy include: EpiPen, EpiPen Jr, Adrenaclick, Auvi-Q. The policy highlights use of preferred products: epinephrine injection USP Auto-Injector (Authorized generic for Epipen or Epipen Jr) and epinephrine injection USP Auto-Injector (authorized generic for Adrenaclick).
Sabril (vigabatrin) – Commercial	06/01/2017	New policy created to ensure appropriate use based on FDA-approved indication of refractory complex partial seizures as adjunctive therapy in patients ≥10 years of age who have responded inadequately to several alternative treatments or for infantile spasms as monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.
Sabril (vigabatrin) – Healthcare Reform	06/01/2017	New policy created to ensure appropriate use based on FDA-approved indication of refractory complex partial seizures as adjunctive therapy in patients ≥10 years of age or for infantile spasms as monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.
Targretin (bexarotene) – Commercial and Healthcare Reform	06/01/2017	New policy created to ensure appropriate use based on FDA-approved indication of cutaneous manifestations of cutaneous T-cell lymphoma (CTCL), including mycosis fungoides and require documentation of insufficient response to at least one systemic therapy.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Zavesca (miglustat) – Commercial	06/01/2017	New policy created to ensure appropriate use based on FDA-approved indication of mild-moderate type 1 Gaucher disease who have had documented treatment failure, contraindication or intolerance to at least one of the following: miglucerase (Cerezyme), taliglucerase alfa (Elelyso), and velaglucerase alfa (VPRIV).
Zavesca (miglustat) – Healthcare Reform	06/01/2017	New policy created to ensure appropriate use based on FDA-approved indication of mild-moderate type 1 Gaucher disease.
Apokyn (apomorphine) – Commercial and Healthcare Reform	06/01/2017	New policy created to ensure appropriate use based on FDA-approved indication of acute, intermittent treatment of hypomobility off-episodes in advanced Parkinson's disease while the member is receiving concurrent medication for the treatment of Parkinson's disease.
Xermelo (telotristat ethyl) – Commercial and Healthcare Reform	06/01/2017	New policy created to ensure use in the appropriate population, based on FDA-approved indication of Carcinoid syndrome – diarrhea, inadequately controlled by somatostatin analog (SSA) therapy, in combination with SSA.
Xadago (safinamide) – Commercial and Healthcare Reform	07/10/2017	New policy created to ensure use in the appropriate population, based on FDA-approved indication, as adjunctive treatment with levodopa/carbidopa in patients with Parkinson disease experiencing "off" episodes. Policy criteria also promote trial of more cost-effective alternatives, rasagiline and selegiline.
Solaraze (diclofenac sodium 3%) – Commercial	06/01/2017	New policy created to ensure Solaraze and diclofenac sodium 3% topical gel are used based on FDA-approved indication of actinic keratosis in addition to the member being 18 years of age or older and a trial and failure of either fluorouracil solution or fluorouracil cream. Keratosis in addition to the member being 18 years of age or older and a trial and failure of either fluorouracil solution or fluorouracil cream.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Solaraze (diclofenac sodium 3%) – Healthcare Reform	06/01/2017	New policy created to ensure Solaraze and diclofenac sodium 3% topical gel are used based on FDA-approved indication of actinic keratosis in addition to the member being 18 years of age or older.
Carac Cream – Commercial	TBD	New policy created to ensure Carac Cream is used based on FDA-approved indication of actinic keratosis in addition to the member being 18 years of age or older and a trial and failure of topical fluorouracil.
Austedo (deutetrabenazine) – Commercial and Healthcare Reform	07/10/2017	New policy created to ensure appropriate use based on FDA-approved indication of chorea associated with Huntington's disease (HD). Due to increased risk of depression and suicidal ideation, it is recommended that those with comorbid diagnosis of depression be optimally treated with an active antidepressant. Members should also have tried and failed or have an intolerance to generic tetrabenazine. Austedo should be prescribed by or under the supervision of a neurologist.
Ingrezza (valbenazine) – Commercial and Healthcare Reform	07/10/2017	New policy created to ensure appropriate use based on FDA-approved indication, for the treatment of adults with tardive dyskinesia (TD). Members should have tried and failed or have an intolerance to generic tetrabenazine, which is a guideline supported treatment option and cost-saving alternative for the treatment of TD. Ingrezza should be prescribed by or under the supervision of a neurologist.
Xyrem (sodium oxybate) – Commercial and Healthcare Reform	05/11/2017	Policy revised to include a baseline assessment of daytime sleepiness, as well as the trial and failure of modafinil and one CNS stimulant. In addition, the policy was limited to authorization duration of one year to check for improvement in daytime sleepiness or cataplexy episodes, if applicable.
Human Growth Hormone – Delaware Commercial and Healthcare Reform	05/11/2017	Policy revised to reflect change in growth hormone product name from Tev-Tropin to Zomacton.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Afinitor (everolimus) – Commercial and Healthcare Reform	05/11/2017	Policy revised to include the combination regimen Afinitor + Lenvima and to align with NCCN Kidney Cancer guidelines for treatment of advanced renal cell carcinoma.
Syprine (trientine) & Cuprimine, Depen (penicillamine) – Commercial and Healthcare Reform	06/01/2017	Policy revised to include Commercial line of business. Penicillamine and trientine hydrochloride are oral chelating agents that promote copper excretion responsible for effectiveness in Wilson's disease. Penicillamine (Cuprimine/Depen) is indicated for Cystinuria, severe Rheumatoid Arthritis (active disease that has failed to respond to conventional therapy) and Wilson's disease. Trientine (Syprine) is indicated for the treatment of Wilson's disease in patients who are intolerant to penicillamine.
Zolinza (vorinostat) – Commercial and Healthcare Reform	05/11/2017	Policy revised to remove bexarotene (Targretin) from the approval criteria.
Topical Non-Steroid Therapy for Atopic Dermatitis – Commercial and Healthcare Reform‡	05/11/2017	Policy revised to include documentation of response for reauthorization of at least 2 grade improvements in ISGA score. Medications addressed in this policy include crisaborole (Eucrisa), pimecrolimus (Elidel) and tacrolimus (Protopic).
Dupixent (dupilumab) – Commercial and Healthcare Reform	05/11/2017	New policy created in March 2017 to require use for an FDA-approved indication and therapeutic failure, intolerance or contraindication to corticosteroids, Protpic, Elidel and Eucrisa. Policy revised in May 2017 to include documentation of response for reauthorization of at least 2 grade improvements in ISGA score. Administrative changes to update with FDA labeling information.
Sublingual Immunotherapy – Commercial and Healthcare Reform	TBD	Policy revised to include the new sublingual immunotherapy, house dust mite allergen extract (Odactra).
Symproic (naldemedine) and Relistor	TBD	Policy revised to include naldemedine (Symproic) and to ensure its use in the appropriate population, per

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
(methylnaltrexone bromide) – Commercial		FDA-approved indication of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. The policy criteria also promote trial of more cost-effective options: laxatives, Movantik, and Amitiza.
Symproic (naldemedine) and Relistor (methylnaltrexone bromide) – Healthcare Reform	TBD	Policy revised to include naldemedine (Symproic) and to ensure its use in the appropriate population, per FDA-approved indication of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. The policy criteria also promote trial of more cost-effective options: laxatives, Movantik, and Amitiza.
Stelara (ustekinumab) – Commercial and Healthcare Reform	05/11/2017	Policy revised to update the approval criteria for the member to achieve a clinical response or clinical remission following an intravenous injection of ustekinumab (Stelara) and include the dosing (45 mg and/or 90 mg) for each disease state, including psoriasis, psoriatic arthritis, and Crohn's disease.
Siliq (brodalumab) – Commercial and Healthcare Reform	TBD	New policy created in March 2017 to limit use of this product to FDA-approved indication - moderate to severe plaque psoriasis in candidates for systemic or photo therapy after failure or intolerance of systemic therapy. Policy revised in May 2017 to limit use as second line therapy based on its FDA-approved indication - moderate to severe plaque psoriasis in candidates for systemic or photo therapy after failure or intolerance of systemic therapy.
Miscellaneous Immunomodulators – Commercial and Healthcare Reform	05/11/2017	Policy revised to include the new expanded FDA indication (multiple myeloma, as maintenance following autologous hematopoietic stem cell transplantation) for lenalidomide (Revlimid).
Provigil (modafinil) & Nuvigil (armodafinil) – Commercial and Healthcare Reform	05/11/2017	Policy revised to include step therapy, trial and failure or intolerance to modafinil - for approval of armodafinil, Provigil, and Nuvigil. Policy revised to include step therapy for armodafinil,

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		Provigil, and Nuvigil.
Hepatitis C Oral Agents – Commercial and Healthcare Reform	05/11/2017	Policy revised to include new expanded FDA indications for paritaprevir/ritonavir/ombitasvir (Technivie), sofosbuvir (Sovaldi), and ledipasvir/sofosbuvir (Harvoni). Please refer to the policy bulletin for details. Policy revised to include HCR Essential line of business. Criteria revised to include previous ledipasvir/sofosbuvir as exclusion to Harvoni treatment. The standalone HCR Essential policy (J-521) has been consolidated here and will be terminated.
C1 Esterase Inhibitors and Firazyr (icatibant) – Commercial and Healthcare Reform	05/11/2017	Policy revised to add icatibant (Firazyr) into the list of medications for hereditary angioedema (HAE), ensuring two acute medications weren't used on the same day, and that ensured members with HAE type 3 had a trial and failure of antihistamines, in addition to the removal of the age limit for C1 inhibitor, Human (Berinert). The stand-along Firazyr policy criteria will be consolidated here, and removed (policy J-423).
Kinase Inhibitors – Commercial and Healthcare Reform	07/10/2017	Policy revised to include coverage criteria for newly approved products ribociclib (Kisqali), niraparib (Zejula), brigatinib (Alunbrig) and midostaurin (Rydapt). Also revised to include coverage for expanded indications of palbociclib (Ibrance) (as initial endocrine-based therapy in combination with any aromatase inhibitor) and regorafenib (Stivarga) [hepatocellular carcinoma in patients previously treated with sorafenib tosylate (Nexavar)]).
Orencia (abatacept) – Commercial and Healthcare Reform	07/01/2017	Policy revised to include the new expanded FDA indication (treatment of moderate to severe polyarticular juvenile idiopathic arthritis (JIA) in pediatric patients 2 years of age and older by subcutaneous administration) for abatacept (Orencia).
Xenazine (tetrabenazine) – Commercial and Healthcare Reform	TBD	Policy revised to require prescribing by or under the supervision of a neurologist. Additional verbiage related to quantity limits were also added to address poor CYP2D6 metabolizers. Safety precautions were

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		also outlined in the limitation of coverage section, in addition to administrative changes. Note: HCR was added to the policy, effective 1/1/18. Xenazine is indicated for chorea associated with Huntington's Disease (Huntington's Chorea). The policy authorization duration was changed from lifetime to 12-months. A note was added to allow off-label coverage for the guideline-supported indication of TD.

*All effective dates are tentative and subject to delay pending internal review or approval.
‡ Elidel (pimecrolimus) and Protopic (tacrolimus) criteria are applicable to Healthcare Reform Only
§Step-therapy for Auvi-Q with preferred products implemented in February, 2017. Step-therapy for all other brand-products noted in the policy will be effective July 1, 2017.

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria**
Insomnia Medications – Commercial	TBD	New policy created to ensure appropriate use and promote trial of more cost-effective generic alternatives. Medications addressed in this policy include zolpidem tartrate (Ambien, Ambien CR, Edluar, Intermezzo), eszopiclone (Lunesta), doxepin (Silenor), suvorexant (Belsomra), ramelteon (Rozerem). Please refer to the policy bulletin for details.
Beta Blocker Management – Commercial and Healthcare Reform	TBD	New policy created to ensure appropriate use and promote trial of more cost-effective generic alternatives. Various Beta-blockers are addressed in the policy. Please refer to the policy bulletin for details.
Brand and Extended Release Metformin – Commercial	06/07/2017	Policy revised to promote utilization of the generic version of Glucophage XR (metformin extended-release), prior to the approval of either generic or brand Fortamet (metformin extended-release). The automatic approval criteria for both generic and brand formulations of Fortamet was updated to at least 1 paid claim for generic (metformin extended release) Gluocphage XR within the last 180 days.
DPP IV Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised to include dapagliflozin/saxagliptin (Qtern) as a non-preferred DPP-4 containing medication. Members will be required to step through two preferred linagliptin and sitagliptin containing products.

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria**
Brand Statin Edit – Select Commercial and Healthcare Reform Plans	TBD	Policy revised to include rosuvastatin (Crestor) as a targeted drug.
Immediate-Release Opioid Management – Commercial and Healthcare Reform	TBD	Policy revised to include newly FDA-approved oxycodone immediate-release formulation (RoxyBond) and its quantity limit of 180 tablets per 25 days.
Brand and Extended Release Metformin – Healthcare Reform	06/07/2017	Policy revised to remove Commercial line of business.
Preferred Diabetic Blood Glucose Testing Products – Commercial and Select Healthcare Reform	TBD	Policy revised to remove Freestyle Precision Neo test strips from the list of preferred products, as they are not currently preferred. Additional administrative changes.

*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. 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
Arcalyst (rilonacept) 220 mg	4 vials per 30 days	12 vials per 90 days
Siliq (brodalumab) 210 mg	2 prefilled syringes per 30 days	6 prefilled syringes per 90 days
Noctiva (desmopressin acetate) 0.83 mcg/0.1 mL	1 nasal spray bottle (3.8 g) per 30 days	3 nasal spray bottle (3.8 g) per 90 days
Noctiva (desmopressin acetate) 1.66 mcg/0.1 mL	1 nasal spray bottle (3.8 g) per 30 days	3 nasal spray bottle (3.8 g) per 90 days
Dupixent (dupilumab) all strengths	2 syringes per 28 days	6 syringes per 84 days
Stelara (ustekinumab) 45 mg vial	1 vial per 63 days	3 vial per 189 days
RoxyBond (oxycodone hydrochloride) all strengths	180 tablets per 25 days	540 tablets per 75 days
Acetaminophen/caffeine/dihydrocodeine 325-30-16 mg	300 tablets per 25 days	927 tablets per 75 days
Tyvaso (treprostinil) 1.74 mg/2.9mL Starter Kit	1 Starter Kit per 365 days	1 Starter Kit per 365 days
Uptravi (selexipag) 200-800 dose pack	1 titration dose-pack per 365	1 titration dose-pack per 365

Drug Name	Retail Edit Limit	Mail Edit Limit
	days	days

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

Drug Name	Retail Edit Limit	Mail Edit Limit
Kisqali (ribociclib) 200 mg	21 tablets	63 tablets
Kisqali (ribociclib) 400 mg	42 tablets	126 tablets
Kisqali (ribociclib) 600 mg	63 tablets	189 tablets
Qsymia (phentermine/topiramate ER) 11.25 mg-69 mg and 15 mg-92 mg	34 capsules	90 capsules
Gelnique (oxybutynin) 100 mg/g	30 g (1 pump)	90 g (3 pumps)
Eucrisa (crisaborole) 2%	60 g	180 g
AirDuo Respiclick (fluticasone; salmeterol) 232/14 mcg	1 inhaler	3 inhaler
Kisqali Femara Co-pack (ribociclib; letrozole) all strengths	1 pack	3 pack

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

Drug Name	Daily Limit
Qtern (dapagliflozin/saxagliptin) 10 mg/5 mg	1 tablet per day
Odactra 12 SQ-HDM	1 tablet per day
Xermelo (telotristat ethyl) 250 mg	3 tablets per day
Xadago (safinamide) all strengths	1 tablet per day
Zavesca (miglustat) 100 mg	3 capsules per day
Symproic (naldemedine) 0.2 mg	1 tablet per day
Zejula (niraparib) 100 mg	3 capsules per day
Rydapt (midostaurin) 25 mg	8 capsules per day
Alunbrig (brigatinib) 30 mg	6 tablets per day
Alunbrig (brigatinib) 90 mg	2 tablets per day
Adcirca (tadalafil) 20 mg	2 tablets per day
Adempas (riociguat) all strengths	3 tablets per day
Letairis (ambrisentan) all strengths	1 tablet per day
Opsumit (macitentan) 10 mg	1 tablet per day
Orenitram (treprostinil) 0.125 mg	3 tablets per day
Orenitram (treprostinil) 0.25 mg, 1mg	6 tablets per day
Orenitram (treprostinil) 2.5 mg	17 tablets per day
Revatio (sildenafil) 10 mg/mL powder for suspension	6 mL per day
Revatio (sildenafil) 20 mg	3 tablets per day
sildenafil 20 mg	3 tablets per day

Drug Name	Daily Limit
Tracleer (bosentan) all strengths	2 tablets per day
Uptravi (selexipag) all strengths (except 200-800 dose pack)	2 tablets per day
Tyvaso (treprostinil) 1.74 mg/2.9mL ampule	1 ampule per day
Ventavis (iloprost) all strengths	9 ampules per day
Austedo (deutetrabenazine) 6 mg, 12 mg	4 tablets per day
Austedo (deutetrabenazine) 9 mg	5 tablets per day
Ingrezza (valbenazine) 40 mg	2 tablets per day
Xenazine (tetrabenazine) 12.5mg	3 tablets per day
Xenazine (tetrabenazine) 25mg	2 tablets per day
tetrabenazine 12.5mg	3 tablets per day
tetrabenazine 25mg	2 tablets per day

*Quantity per Duration (QD) rule also applies to this medication (refer to Table 1).
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.