Most Part D-eligible drugs and drug policies are not effective and administered until Centers for Medicare and Medicaid Services approval is obtained. Please refer to the most current approved Formulary (List of Covered Drugs) and prior authorization criteria documents at premera.com/medicare-advantage/pharmacy-services/.

You can also check the Premera MA Formulary using Epocrates.com:

- To download the formulary from epocrates.com onto your tablet or smartphone, log in to your Epocrates account, and select “Edit Formularies”
- Select “Washington” and “Medicare Part D—MA.” Add “Premera Medicare Advantage” to “Formularies on My Device” and select “Done”

Premera Medicare Advantage plans have a different covered drug list (formulary) than non–Medicare Advantage plans. There may also be differences in prior authorization criteria for Premera Medicare Advantage members and Premera members on non–Medicare Advantage plans. If you have questions on specific criteria, formulary alternatives, or prior authorization/exception processes, please contact Pharmacy Services at 877-216-3644.

**Pharmacy & Therapeutics**

**Effective Oct. 1, 2016**

(Until noted otherwise below)

Effective dates are pending CMS approval

**Class Reviews:**

**Antiparkinson Agents**

The following drugs were reviewed: amantadine hcl, Apokyn® (apomorphine hcl), Azilect® (rasagiline mesylate), benztropine mesylate, entacapone, selegiline hcl, carbidopa, pramipexole hcl, pramipexole hcl er, bromocriptine mesylate, ropinirole hcl, ropinirole hcl er, carbidopa/levodopa, carbidopa/levodopa/entacapone, tolcapone, trihexyphenidyl hcl, and rotigotine.

No formulary status changes are recommended at this time.

**Musculoskeletal Therapy Agents**

The following drugs were reviewed: baclofen, carisoprodol, carisoprodol/aspirin, chlorzoxazine, cyclobenzaprine hcl, dantrolene sodium, metaxalone, methocarbamol, orphenadrine citrate, orphenadrine citrate/aspirin/caffeine, and tizanidine hcl.

No formulary status changes are recommended for the 2016 calendar year. For the 2017 calendar year cyclobenzaprine hcl and tizanidine hcl tablets will be changed from a preferred generic status to non-preferred generic status.

**Anticonvulsants**

The following drugs were reviewed: carbamazepine, clobazam, clonazepam, diazepam, divalproex sodium,
eslicabazepine, ethosuximide, Peganone® (ethotoin), Potiga® (ezogabine), felbamate, gabapentin, Horizant® (gabapentin enacarbil), Vimpat® (lacosamide), lamotrigine, levetiracetam, Celontin® (methsuximide), oxcarbazepine, Fycompa® (perampanel), phenytoin, phenytoin er, Lyrica® (pregabalin), primidone, Banzel® (rufinamide), tiagabine hcl, topiramate, topiramate er, valproic acid, Sabril® (vigabatrin), and zonisamide.

Retire the prior authorization policy for Banze® (rufinamide). No formulary status changes for the other drugs under this class review.

### Antidepressants

The following drugs were reviewed: amitriptyline hcl, amoxapine, bupropion hbr, bupropion hcl, citalopram, hydrobromide, clomipramine hcl, desipramine hcl, desvenlafaxine, desvenlafaxine fumarate, desvenlafaxine succinate, doxepin hcl, duloxetine hcl, escitalopram oxalate, fluoxetine hcl, fluvoxamine maleate, imipramine pamoate, Marplan® (isocarboxazid), Fetzima® (levomilnacipran hcl) maprotiline hcl, mirtazapine, nefazodone hcl, nortriptyline hcl, paroxetine hcl, Pexeva® (paroxetine mesylate), phenelzine sulfate, protriptyline hcl, sertraline hcl, tranylcypromine sulfate, trazodone hcl, trimipramine maleate, venlafaxine hcl, vilazodone hcl, and vortioxetine hydrobromide.

No formulary changes

### Antipsychotics

The following drugs were reviewed: ithium, perphenazine, clozapine, aripiprazole, quetiapine, risperidone, Equetro (carbamazepine ER), chlorpromazine, fluphenazine, haloperidol, loxapine, thiothixene, trifluoperazine, Invega (paliperidone extended release tablets), Invega Sustenna (paliperidone palmitate depot injection), olanzapine, olanzapine/ fluoxetine, Risperdal Consta (risperidone extended release injectable), ziprasidone, Abilify Maintena (aripiprazole extended release injectable), Aristada (aripiprazole lauroxil extended release injectable), Fanapt (iloperidone tablets), Invega Trinza (paliperidone palmitate extended-release injectable), Latuda (lurasidone), Rexulti (brexpiprazole), Saphris (asenapine), Vraylar (cariprazine), thioridazine

No formulary changes

### Stimulants

The following drugs were reviewed: dextroamphetamine, amphetamine/dextro-amphetamine salts, methylphenidate, clonidine extended-release, Daytrana® (methylphenidate transdermal system), dexamfetamine, guanfacine extended-release, methamphetamine, modafinil, Nuvigil® (armodafinil), Strattera® (atomoxetine), Vyvanse® (lisdexamfetamine)

No formulary changes

### New Drugs and Combinations:

**Nuplazid® (pimavanserin tartrate) tablet**

- **Indication:** Treatment of hallucinations and delusions associated with Parkinson’s disease psychosis.
- **Formulary Alternatives:** Quetiapine, clozapine.

Formulary, Tier 6 (Specialty), Prior Authorization, Quantity Limit (2 tablets per day)

**Prior Authorization Criteria:**

- [Insert table or list of prior authorization criteria here]
1. Diagnosis of Parkinson’s disease with hallucinations and/or delusions causing clinically significant distress with delirium ruled out; and
2. Mini-mental status exam (MMSE) score ≥21 or Saint Louis University Mental Status (SLUMS) exam score ≥16 to indicate that patients can self-report symptoms; and
3. Documented reduction in frequency and/or severity of hallucinations and/or delusions.

Ocaliva® (obeticholic acid) tablet

- Indication: Treatment of primary biliary cholangitis (PBC).
- Formulary Alternatives: Ursodiol

Formulary, Tier 6 (Specialty), Prior Authorization, Quantity Limit (1 tablet per day)

Prior Authorization Criteria:
1. Confirmed diagnosis of Primary Biliary Cirrhosis with two of the three of the following criteria met:
   a. Elevated alkaline phosphatase elevation (>ULN)
   b. Presence of antimitochondrial antibody (AMA) (tier ≥1:40)
   c. Liver biopsy consistent with primary biliary cirrhosis; and
2. One of the following:
   a. Use of ursodiol for a minimum of 6 months and failure to achieve: alkaline phosphatase (ALP) ≤1.5 X ULN, aspartate aminotransferase (AST) ≤1.5 X ULN, and total bilirubin (tBili) ≤ ULN. If laboratory reference values for ALP are not available, the values used in a clinical trial may be used for this assessment (ULN = 117 U/L for women; 129 U/L for men); and documentation that ursodiol will be continued; or
   b. Intolerable adverse effect with ursodiol.; and
3. Dose is appropriate based on an assessment of hepatic function (Child-Pugh class)

Cinqair® (reslizumab) vial

- Indication: Add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype.

Part B Benefit, Prior Authorization

Prior Authorization Criteria:
1. Documentation of severe eosinophilic asthma by one of the following:
   a. A blood eosinophil count of at least 150 cells/microliter in the past 3 months, or
   b. A blood eosinophil count of at least 300 cells/microliter in the past 12 months, or
   c. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids.
2. Documentation that in the past 6 months patient is adherent to a combination of a high-dose inhaled corticosteroids and a long-acting inhaled beta2-agonist.
3. Documentation of inadequate asthma control despite above therapy, defined as one of the following:
   a. Asthma Control Test (ACT) score <20 or Asthma Control Questionnaire (ACQ) score >1.5, or
   b. At least 2 asthma exacerbations requiring oral systemic corticosteroids in the last 12 months, or
   c. At least 1 asthma exacerbation requiring hospitalization.
**Briviact® (brivarecetam) solution, tablet, vial**

- **Indication:** Adjunctive therapy in the treatment of partial-onset (focal) seizures in patients with 16 years of age and older with epilepsy.
- **Formulary Alternatives:** Carbamazepine, sodium valproate, lamotrigine, topiramate, levetiracetam

Formulary, Tier 6 (Specialty), Quantity Limit (2 tablets per day)

**Prior Authorization Criteria:**
1. Documentation of trial and failure, contraindication or intolerance to levetiracetam, and
2. Documentation of trial and failure, contraindication or intolerance to a formulary generic anticonvulsant medication (e.g. carbamazepine).

**Tecentriq® (atezolizumab) vial**

- **Indication:** Treatment of patients with locally advanced or metastatic urothelial carcinoma who:
  - Have disease progression during or following platinum-containing chemotherapy
  - Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

Part B Benefit, Prior Authorization

**Prior Authorization Criteria:**
Must be prescribed by, or in consultation with, an oncologist.

**New Strengths and Formulations:**

**Otiprio® (ciprofloxacin) vial**

- **Indication:** Treatment of pediatric patients with bilateral otitis media with effusion undergoing lympanostomy tube placement.

Part B Benefit

**New Indications:**

**Entocort EC® (budesonide) capsule**

**NEW FDA-APPROVED INDICATION:**
- Treatment of mild to moderate active Crohn’s disease involving the ileum and/or the ascending colon in patient’s 8 years and older
- Maintenance of clinical remission of mild to moderate Crohn’s disease involving the ileum and/or the ascending colon for up to 3 months in adults

**Decision:** No policy currently, therefore, no additional action necessary at this time

**Proair® Respiclick (albuterol sulfate)**

**NEW FDA-APPROVED INDICATION:**
- Treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease
- Prevention of exercise-induced bronchospasm in patients 4 years of age and older
**Decision:** No policy currently, therefore, no additional action necessary at this time

---

**Viekira® (ombitasvir/paritaprevir/ritonavir) pak**

**NEW FDA-APPROVED INDICATION:**
Treatment of adult patients with chronic hepatitis C virus (HCV):
- Genotype 1b without cirrhosis or with compensated cirrhosis
- Genotype 1z without cirrhosis or with compensated cirrhosis for use in combination with ribavirin

**Decision:** Policy has previously been reviewed and updated with June 2016 P&T.

---

**Crestor® (Rosuvastatin calcium) tablet**

**NEW FDA-APPROVED INDICATION:**
- Patients with primary hyperlipidemia and mixed dyslipidemia as an adjunct to diet to reduce elevated total-C, LDL-C, ApoB, nonHDL-C, and TG levels and to increase HDL-C
- Pediatric patients 8 to 17 years of age with heterozygous familial hypercholesterolemia (HeFH) to reduce elevated total-C, LDL-C, and ApoB after failing an adequate trial of diet therapy
- **Pediatric patients 7 to 17 years of age with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, nonHDL-C, and ApoB after failing an adequate trial of diet therapy**
- Patients with hypertriglyceridemia as an adjunct to diet
- Patients with primary dysbetaIipoproteinemia (Type III hyperlipoproteinemia) as an adjunct to diet
- Patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, and ApoB
- Slowing the progression of artherosclerosis as part of a treatment strategy to lower total-C and LDL-C as an adjunct to diet
- Risk reduction of MI, stroke, and arterial revascularization procedures in patients without clinically evident CHD, but with multiple risk factors

**Decision:** No policy currently; therefore, no additional action necessary at this time.

---

**Teflaro® (ceftaroline fosamil)**

**NEW FDA-APPROVED INDICATION:**
Indicated in adult and pediatric patients 2 months of age and older for the treatment of the following infections caused by designated susceptible bacteria:
- Acute bacterial skin and skin structure infections (ABSSSI)
- Community-acquired bacterial pneumonia (CABP)

**Decision:** No policy currently, therefore no additional action necessary at this time.

---

**Drug Safety Monitoring**

**Diabetes Medications Containing Saxagliptin and Alogliptin: Drug Safety Communication - Risk of Heart Failure**

**BACKGROUND:**
FDA evaluated two large clinical trials conducted in patients with heart disease. Each trial showed that more patients who had received saxagliptin, or alogliptin-containing medicines were hospitalized for heart failure compared to patients who received an inactive treatment called a placebo. In the saxagliptin trial, 3.5% of patients who received the drug were hospitalized for heart failure versus 2.8% of patients who received a placebo. This is the same as 35 out of every 1,000 patients compared to 28 out of every 1,000 patients. Risk
factors included a history of heart failure or kidney impairment. In the alogliptin trial, 3.9% of alogliptin-treated patients were hospitalized for heart failure versus 3.3% in the placebo group. This is the same as 39 out of every 1,000 patients compared to 33 out of every 1,000 patients.

RECOMMENDATION:
Healthcare professionals should consider discontinuing medications containing saxagliptin and alogliptin in patients who develop heart failure and monitor their diabetes control. If a patient’s blood sugar level is not well-controlled with their current treatment, other diabetes medicines may be required. Patients taking these medicines should contact their healthcare professionals right away if they develop signs and symptoms of heart failure such as:

- Unusual shortness of breath during daily activities
- Trouble breathing when lying down
- Tiredness, weakness, or fatigue
- Weight gain with swelling in the ankles, feet, legs, or stomach.

RECOMMENDATION: Notify prescribers via MD alert

Decision: All recommendation approved by the committee

---

### Metformin-containing Drugs: Drug Safety Communication - Revised Warnings for Certain Patients With Reduced Kidney Function

#### ISSUE:
FDA concluded, from the review of studies published in the medical literature, that metformin can be used safely in patients with mild impairment in kidney function and in some patients with moderate impairment in kidney function. FDA is requiring changes to the metformin labeling to reflect this new information and provide specific recommendations on the drug’s use in patients with mild to moderate kidney impairment. FDA is also requiring manufacturers to revise the labeling to recommend that the measure of kidney function used to determine whether a patient can receive metformin be changed from one based on a single laboratory parameter (blood creatinine concentration) to one that provides a better estimate of renal function (i.e., glomerular filtration rate estimating equation (eGFR)). This is because in addition to blood creatinine concentration, the glomerular filtration rate takes into account additional parameters that are important, such as the patient’s age, gender, race and/or weight.

#### RECOMMENDATION:
Healthcare professionals should follow the latest recommendations when prescribing metformin-containing medicines to patients with impaired kidney function. Patients should talk to their healthcare professionals if they have any questions or concerns about taking metformin.

The labeling recommendations on how and when kidney function is measured in patients receiving metformin will include the following information:

- Before starting metformin, obtain the patient’s eGFR.
- Metformin is contraindicated in patients with an eGFR below 30 mL/minute/1.73 m2.
- Starting metformin in patients with an eGFR between 30-45 mL/minute/1.73 m2 is not recommended.
- Obtain an eGFR at least annually in all patients taking metformin. In patients at increased risk for the development of renal impairment such as the elderly, renal function should be assessed more frequently.
- In patients taking metformin whose eGFR later falls below 45 mL/minute/1.73 m², assess the benefits and risks of continuing treatment. Discontinue metformin if the patient’s eGFR later falls below 30 mL/minute/1.73 m².
- Discontinue metformin at the time of or before an iodinated contrast imaging procedure in patients with an eGFR between 30 and 60 mL/minute/1.73 m²; in patients with a history of liver disease, alcoholism, or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Re-evaluate eGFR 48 hours after the imaging procedure; restart metformin if renal function is stable.

**RECOMMENDATION:** Notify prescribers via MD Alert.

**Decision:** All recommendation approved by the committee

### Fluconazole (Diflucan): Drug Safety Communication - FDA Evaluating Study Examining Use of Oral Fluconazole (Diflucan) in Pregnancy

**ISSUE:**
FDA is evaluating the results of a Danish study that concluded there is a possible increased risk of miscarriage with the use of oral fluconazole (Diflucan) for yeast infections. FDA is also reviewing additional data and will communicate final conclusions and recommendations when the review is complete.

The current FDA drug label states that data available from studies in people do not suggest an increased risk of problems during pregnancy or abnormalities in developing babies when women are exposed to a single 150 mg dose of oral fluconazole to treat vaginal yeast infections. However, high doses of oral fluconazole (400-800 mg/day) taken by pregnant women for much longer than a single dose have resulted in reports of abnormalities at birth. In the Danish study, most of the oral fluconazole use appeared to be one or two doses of 150 mg.

**RECOMMENDATION:**
Until FDA’s review is complete and more is understood about this study and other available data, FDA advises cautious prescribing of oral fluconazole in pregnancy.

Healthcare professionals should be aware that the Centers for Disease Control and Prevention guidelines recommend only using topical antifungal products to treat pregnant women with vulvovaginal yeast infections, including for longer periods than usual if these infections persist or recur.

Patients who are pregnant or actively trying to get pregnant should talk to their healthcare professionals about alternative treatment options for yeast infections.

**RECOMMENDATION:** Notify prescribers via MD Alert.

**Decision:** All recommendation approved by the committee

### Brintellix (vortioxetine): Drug Safety Communication - Brand Name Change to Trintellix, to Avoid Confusion With Antiplatelet Drug Brilinta (ticagrelor)

**ISSUE:**
FDA has approved a brand name change for the antidepressant Brintellix (vortioxetine) to decrease the risk of prescribing and dispensing errors resulting from name confusion with the blood-thinning medicine Brilinta (ticagrelor). The new brand name of the drug will be Trintellix, and it is expected to be available starting in
June 2016. No other changes will be made to the label or packaging, and the medicine is exactly the same.

Because of the lag time associated with manufacturing bottles with the new brand name, healthcare professionals and patients may continue to see bottles labeled with the brand name Brintellix during the transition period.

In a July 2015 MedWatch Alert, FDA warned that name confusion between Brintellix and Brilinta had resulted in prescribing and dispensing errors since Brintellix was approved in September 2013. Due to continued reports of name confusion between the two medicines used for very different purposes, FDA worked with Brintellix manufacturer Takeda Pharmaceuticals to change the drug’s brand name.

RECOMMENDATION:
Healthcare professionals should check carefully to make sure they have prescribed or dispensed the correct medicine. During the transition to the new name change from Brintellix to Trintellix, prescribers can reduce the risk of name confusion by including the generic name of the medication they are ordering, in addition to the brand name and indication for use. Patients should make sure they have received the correct medicine. Trintellix tablets will look the same as the Brintellix tablets. Those having any questions or concerns should talk to their prescriber or pharmacist.

Individuals responsible for ordering and stocking the medicine should be aware that Trintellix will have a new National Drug Code (NDC) number. It is important for drug information content publishers and medication-related electronic system administrators to use the new brand name Trintellix and NDC number once Takeda makes vortioxetine available under the new name Trintellix.

RECOMMENDATION: Notify prescribers via MD Alert.

Decision: All recommendation approved by the committee


ISSUE:
FDA is warning that compulsive or uncontrollable urges to gamble, binge-eat, shop, and have sex have been reported with the use of the antipsychotic drug aripiprazole (Abilify, Abilify Maintena, Aristada, and generics). These uncontrollable urges were reported to have stopped when the medicine was discontinued or the dose was reduced. These impulse-control problems are rare, but they may result in harm to the patient and others if not recognized.

Although pathological gambling is listed as a reported side effect in the current aripiprazole drug labels, this description does not entirely reflect the nature of the impulse-control risk FDA identified. In addition, FDA has become aware of other compulsive behaviors associated with aripiprazole, such as compulsive eating, shopping, and sexual actions. These compulsive behaviors can affect anyone who is taking the medicine. As a result, FDA is adding new warnings about all of these compulsive behaviors to the drug labels and the patient Medication Guides for all aripiprazole products.

RECOMMENDATION:
Healthcare professionals should make patients and caregivers aware of the risk of these uncontrollable urges when prescribing aripiprazole, and specifically ask patients about any new or increasing urges while they are being treated with aripiprazole. Closely monitor for new or worsening uncontrollable urges in patients at higher risk for impulse-control problems. These include those with a personal or family history of obsessive-
compulsive disorder, impulse-control disorder, bipolar disorder, impulsive personality, alcoholism, drug abuse, or other addictive behaviors. Consider reducing the dose or stopping the medicine if such urges develop.

Patients and caregivers should be alert for uncontrollable and excessive urges and behaviors while taking aripiprazole. It is important to talk with a healthcare professional as soon as possible if you or a family member experiences any of these uncontrollable urges, in order to prevent or limit possible harm. Patients should not suddenly stop taking their aripiprazole medicine without first talking to their healthcare professional.

**RECOMMENDATION:** Notify prescribers via MD Alert.

**Decision:** All recommendation approved by the committee

---

**Olanzapine: Drug Safety Communication - FDA Warns About Rare But Serious Skin Reactions**

**ISSUE:**
FDA is warning that the antipsychotic medicine olanzapine can cause a rare but serious skin reaction that can progress to affect other parts of the body. FDA is adding a new warning to the drug labels for all olanzapine-containing products that describes this severe condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

A search of the FDA Adverse Event Reporting System (FAERS) database identified 23 cases of DRESS reported with olanzapine worldwide since 1996, when the first olanzapine-containing product was approved. FAERS includes only reports submitted to FDA, so there are likely to be additional cases about which FDA is unaware. One patient taking olanzapine experienced DRESS and died; however, this patient was taking multiple medicines that could also have contributed to death.

DRESS may start as a rash that can spread to all parts of the body. It can include fever and swollen lymph nodes and a swollen face. It causes a higher-than-normal number of infection-fighting white blood cells called eosinophils that can cause inflammation, or swelling. DRESS can result in injury to organs including the liver, kidneys, lungs, heart, or pancreas, and can lead to death. DRESS is a potentially fatal drug reaction with a mortality rate of up to 10%.

**RECOMMENDATION:**
Patients taking olanzapine-containing products who develop a fever with a rash and swollen lymph glands, or swelling in the face, should seek medical care right away. The combined symptoms together are commonly seen in DRESS. Talk with your healthcare professional about any questions or concerns. Do not stop taking olanzapine or change your dose without first talking with your healthcare professional. Sudden stopping of the medicine can be harmful without your healthcare professional’s direct supervision.

Healthcare professionals should immediately stop treatment with olanzapine if DRESS is suspected. There is currently no specific treatment for DRESS. The important ways to manage DRESS are early recognition of the syndrome, discontinuation of the offending agent as soon as possible, and supportive care. Treatment with systemic corticosteroids should be considered in cases with extensive organ involvement. When prescribing the medicine, explain the signs and symptoms of severe skin reactions to your patients and tell them when to seek immediate medical care.

**RECOMMENDATION:** Notify prescribers via MD Alert.

**Decision:** All recommendation approved by the committee
Fluoroquinolone Antibacterial Drugs: Drug Safety Communication - FDA Advises Restricting Use for Certain Uncomplicated Infections

**ISSUE:**
FDA is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.

An FDA safety review has shown that fluoroquinolones when used systemically (i.e. tablets, capsules, and injectable) are associated with disabling and potentially permanent serious side effects that can occur together. These side effects can involve the tendons, muscles, joints, nerves, and central nervous system.

As a result, FDA is requiring the drug labels and Medication Guides for all fluoroquinolone antibacterial drugs to be updated to reflect this new safety information. FDA is continuing to investigate safety issues with fluoroquinolones and will update the public with additional information if it becomes available.

**RECOMMENDATION:**
Patients should contact your healthcare professional immediately if you experience any serious side effects while taking your fluoroquinolone medicine. Some signs and symptoms of serious side effects include tendon, joint and muscle pain, a “pins and needles” tingling or pricking sensation, confusion, and hallucinations. Patients should talk with your healthcare professional if you have any questions or concerns.

Healthcare professionals should stop systemic fluoroquinolone treatment immediately if a patient reports serious side effects, and switch to a non-fluoroquinolone antibacterial drug to complete the patient’s treatment course.

**RECOMMENDATION:** Notify prescribers via MD Alert.

**Decision:** All recommendation approved by the committee

Canagliflozin (Invokana, Invokamet): Drug Safety Communication - Clinical Trial Results Find Increased Risk of Leg and Foot Amputations

**ISSUE:**
FDA is alerting the public about interim safety results from an ongoing clinical trial that found an increase in leg and foot amputations, mostly affecting the toes, in patients treated with the diabetes medicine canagliflozin (Invokana, Invokamet). FDA has not determined whether canagliflozin increases the risk of leg and foot amputations. FDA is currently investigating this new safety issue and will update the public when we have more information.

**RECOMMENDATION:**
Healthcare professionals should follow the recommendations in the canagliflozin drug labels. Monitor patients for the signs and symptoms described above and advise patients to seek medical advice if they experience them.

Patients should not stop or change their diabetes medicines without first talking to their healthcare professional. Doing so can lead to uncontrolled blood sugar levels that can be harmful. Over time, this can
cause serious problems, including blindness, nerve and kidney damage, and heart disease. Patients taking canagliflozin should notify their healthcare professionals right away if they notice any new pain or tenderness, sores or ulcers, or infections in their legs or feet.

**RECOMMENDATION:** Notify prescribers via MD Alert.

**Decision:** All recommendation approved by the committee

### Health Plan Other Formulary Changes:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Change Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viibryd® (vilazodone hcl) 10-20 mg titration pack</td>
<td>Add to Formulary to align with other strengths. Formulary, Non-Preferred Brand, Prior Authorization.</td>
</tr>
<tr>
<td>Allzital® (butalbital/acetaminophen) 25 mg-325 mg tablet</td>
<td>Non-Formulary.</td>
</tr>
<tr>
<td>Adzenys® XR ODT (dextroamphetamine/amphetamine) tablet</td>
<td>New Strength and Dosage Form. Non-Formulary.</td>
</tr>
<tr>
<td>Dyanavel® XR ((dextroamphetamine/amphetamine) suspension</td>
<td>New Strength and Dosage Form. Non-Formulary.</td>
</tr>
<tr>
<td>Quillichew® (methylphenidate hcl) tablet</td>
<td>New Strength and Dosage Form. Non-Formulary.</td>
</tr>
<tr>
<td>Tivicay® (dolutegravir sodium ) tablet</td>
<td>New Strength. Formulary, Specialty.</td>
</tr>
</tbody>
</table>

### Health Plan Clinical Policies – Major Changes:

The following policies were retired **effective Oct. 1, 2016.**

- Banzel

### New Generic Medications

**First-time generics to market**

- **Rosuvastatin calcium (Crestor®) tablet:** Line extend as a generic
  - Formulary, Non-Preferred Generic
- **Clindamycin-Benzoyl Peroxide (Benzaclin®) 1-5% pump:** Line extend as generic.
  - Non-Formulary
- **Miglitol (Glyset®) tablet:** Line extend as generic
  - Non-Formulary
- **Doxycycline hyclate DR (Doryx®) tablet:** Not a true generic. Line extend as brand
  - Non-Formulary