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 document at premera.com/medicare-advantage/pharmacy-services/. Pharmacy policies are updated and available on the secure provider Medicare Advantage website at premera.com/wa/provider/medicare-advantage/; simply click on the Get Started button.

You can find the Premera Medicare Advantage (MA) Formulary (List of Covered Drugs) 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 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.

**Effective June 1, 2015**

(Unless noted otherwise below)

**Effective dates are pending CMS approval**

**Class Reviews:**

**GLP1 update**

The following medications were reviewed: exenatide (Byetta®), exenatide extended-release (Bydureon®), liraglutide (Victoza®), dulaglutide (Trulicity®), albiglutide (Tanzeum®)

- The American Diabetes Association (ADA) Standards of Care discusses the supporting evidence for the use of GLP-1 agonists; ADA stance still is that metformin is the gold standard of care.
- PHP suggests these agents should be more readily accessible for diabetes patients, naming Victoza®, Byetta®, and Bydureon® as preferred agents and Tanzeum® and Trulicity® as non-preferred agents.

**Preferred Agents:** Victoza®, Byetta®, and Bydureon®

- Formulary, Tier 3 (preferred brand)
Non-preferred Agents: Tanzeum®, Trulicity®
• Non-Formulary

Idiopathic Pulmonary Fibrosis Agents
The following medications were reviewed: nintendanib (Ofev®) and pirfenidone (Esbriet®)
• Nintendanib (Ofev®) and pirfenidone (Esbriet®) represent the first FDA-approved medications for the treatment of idiopathic pulmonary fibrosis.
• While the evidence (for both agents) shows statistically significant benefit for slowing the progression of this disease, they don’t represent a cure and the cost is significant.

For both Esbriet® and Ofev®
• Formulary, Tier 6 (specialty), with prior authorization

Policy Criteria:
• Confirmed diagnosis of idiopathic pulmonary fibrosis and presence of a histological pattern associated with usual interstitial pneumonia (UIP) on high-resolution computed tomography or lung biopsy

Hematological Agents
The following medications were reviewed: C1 esterase inhibitor (Berinert®, Cinryze®, ), C1 esterase inhibitor, recomb (Ruconest®), icatibant acetate (Firazyr®), ecallantide (Kalbitor®)
• Indicated for the treatment of acute hereditary angioedema (HAE) attacks.
• First-line recommended by various international and US guidelines for the treatment of acute HAE attacks include Berinert®, Cinryze®, Kalbitor®, Firazyr®.

No change to current products: Berinert®, Cinryze®, Firazyr®, and Kalbitor®
For Ruconest:
Medical (Part B) with prior authorization; Non-formulary (Part D)

Chenodiol (Chenodal®) tablet (MUE)
• Indicated for gallstone dissolution with radiolucent stones in well-opacifying gallbladders when surgery would be indicated except for the presence of increased surgical risk due to systemic disease or age.
• Used off-label to treat a rare condition called cerebrotendinous xanthomatosis (CTX).

Formulary, Tier 6 (specialty), with Prior Authorization

New Drugs and Combinations:

Alemtuzumab (Lemtrada®) vial
• Indicated for the treatment of relapsing forms of multiple sclerosis (MS) in patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. Specifically, alemtuzumab may be most valuable in patients who are refractory or considered non-candidates to other standard Disease-Modifying Therapy and/or in patients where disease is rapidly progressing where the short-term benefit outweighs the long-term risk.

Medical (Part B) with Prior Authorization; Non-formulary (Part D)

**Nivolumab (Opdivo®) vial**

• Indicated for the treatment of unresectable or metastatic melanoma following progression on ipilimumab and if BRAF V600 mutation positive, a BRAF inhibitor.
• The National Comprehensive Cancer Network (NCCN) recommends the use of nivolumab as first-line treatment for patients with metastatic or unresectable melanoma.

Medical (Part B) with Prior Authorization; Non-formulary (Part D)

**Palbociclib (Ibrance®) capsule**

• FDA-approved in combination with letrozole for the treatment of postmenopausal women with ER-positive, HER2-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease.
• Palbociclib (Ibrance®) is first in class, oral selective cyclin-dependent kinase (CDK) 4/6 inhibitor.

Formulary, Tier 6 (specialty), with Prior Authorization

**Peramivir (Rapivab®) vial**

• Indicated for treatment of uncomplicated influenza at a one-time dose of 600mg intravenously starting within 48 hours of symptom onset.
• For patients unable to tolerate or absorb orally or enterically administered oseltamivir, peramivir IV or zanamivir should be considered.

Medical (Part B); Non-formulary (Part D)

**Elvitegravir (Vitekta®) tablet**

• Indication: For the treatment of HIV-1 infection in antiretroviral treatment-experienced adults.

Formulary, Tier 6 (specialty)

**Atazanavir Sulfate Cobicistat (Evotaz®) tablet**

• Indications: For the use in combination with other antiretroviral agents for the treatment
<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>Formulary Tier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Darunavir Cobicistat (Prezco®) tablet</td>
<td>Indication: In combination with other antiretroviral agents for the treatment of HIV-1 infection.</td>
<td>6 (specialty)</td>
</tr>
<tr>
<td>Lenvatinib mesylate (Lenvima®) capsule</td>
<td>Indication: For the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer.</td>
<td>6 (specialty), with prior authorization</td>
</tr>
<tr>
<td>New Vaccines - meningococcal B vaccines</td>
<td>Indication: For active immunization to prevent invasive disease caused by Neisseria meningitides serogroup B.</td>
<td>5 (injectable)</td>
</tr>
<tr>
<td>Ferric Citrate (Auryxia®) tablet</td>
<td>Indication: Phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.</td>
<td>4 (brand), with prior authorization</td>
</tr>
<tr>
<td><strong>New Strengths and Formulations:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tiotropium (Spiriva Respimat®) mist inhaler</td>
<td>Indication: For the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. It is indicated to reduce exacerbations in COPD patients.</td>
<td>3 (preferred brand)</td>
</tr>
<tr>
<td>Antihemophilic Factor VIII (Obizur®) vial</td>
<td>Indications: For the treatment of bleeding episodes in adults with acquired hemophilia A.</td>
<td>Medical (Part B); Non-formulary (Part D)</td>
</tr>
</tbody>
</table>
### Factor XIII A-Subunit, Recomb (Tretten®) vial
- **Indications:** Preventing bleeding in patients with congenital factor XIII (FXIII) A-subunit deficiency.

Non-formulary

### Budesonide Foam (Uceris®) foam
- **Indications:** Rectal foam indicated for the induction of remission in patients with active mild to moderate distal ulcerative colitis extending up to 40 cm from the anal verge.

Non-formulary

### Doxycycline Hyclate (Acticlate®) tablet
- **Indications:** For Rickettsia infections, sexually transmitted infections, respiratory tract infections, specific bacterial infections, ophthalmic infections, anthrax, including inhalational anthrax (post-exposure), alternative treatment for selected infections when penicillin is contraindicated, adjunctive therapy in acute intestinal amebiasis and severe acne.

Non-formulary

### New Indications:

#### Lisdexamfetamine Dimesylate (Vyvanse®) capsule
- **New FDA-approved indication:** Moderate to severe binge eating disorder (BED)
- **Action:** Update policy with new indication.

#### Irutinib (Imbruvica®) capsule
- **New FDA-approved indication:** Waldenström’s macroglobulinemia (WM).
- **Action:** Update policy with new indication.

#### Rufinamide (Banzel®) tablet, oral supsension
- **Expanded FDA-approved indication:** Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in pediatric patients 1 year of age and older, and in adults.
- **Action:** Update policy with new indication.
### Azelastine Hydrochloride; Fluticasone Propionate (Dymista®) spray/pump

Expanded FDA-approved indication: The relief of symptoms of seasonal allergic rhinitis in patients 6 years of age and older who require treatment with both azelastine hydrochloride and fluticasone propionate for symptomatic relief

**Action:** Update policy with new indication

### Lenalidomide (Revlimid®) capsule

Modified FDA-approved indication:
- Multiple myeloma (MM), in combination with dexamethasone
- Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities.
- Mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

**Action:** Update policy with new indication.

### Clinical Policy Changes

<table>
<thead>
<tr>
<th>Clinical Policy Name</th>
<th>Change Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zetia</td>
<td>Require the use of both formulary high-intensity statin agents (atorvastatin and rosuvastatin) prior to approval.</td>
</tr>
</tbody>
</table>
| Nuedexta             | Changes for 2016 for Part D where it is more restrictive
- Remove the following criteria due to updates on FDA labeling: A diagnosis of comorbid diagnosis of multiple sclerosis or ALS
- Add the following reauthorization criteria: documented response to therapy is required, defined as a reduction in episodes of inappropriate laughing, crying, or emotional ability due to pseudobulbar effect. |
| Chenodal             | New Clinical Policy:
- For use in cerebrotendinous xanthomatosis: must be prescribed by, or in consultation with, a genetics or metabolism specialist.
- For use in gallstone dissolution:
  - Must be prescribed by a gastroenterologist
  - Documentation that the patient is not a candidate for surgery
  - Documentation of trial and failure, contraindication or intolerance to ursodiol |
| Harvoni              | Part D policy created:
- Require genotype, baseline viral load, prior |

Effective Feb. 19, 2015
### Other Formulary Changes:

<table>
<thead>
<tr>
<th>Drug/Policy Name</th>
<th>Change Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diltiazem HCL (Cardizem LA®) 120mg tablet</td>
<td>Add to formulary without prior authorization.</td>
</tr>
<tr>
<td>Octreotide Acetate (Sandostatin®), ampul</td>
<td>This product was added to the formulary.</td>
</tr>
<tr>
<td>Albuterol (Proventil®), inhaler</td>
<td>Currently processing as Tier 2 (generic) not Tier 4 (non-preferred tier). Change to Tier 2 for 2015 until we can resubmit and process drug at Tier 4 as desired to maximum rebate opportunities for 2016.</td>
</tr>
<tr>
<td>Ribavirin (Ribosphere®) 400mg tablet</td>
<td>Change from non-preferred brand (tier 4) to generic (tier 2).</td>
</tr>
<tr>
<td>Solifenacin Succinate (Vesicare®) tablet</td>
<td>Add to formulary (preferred brand).</td>
</tr>
<tr>
<td>Mirabegron (Myrbetriq®) tablet</td>
<td>Remove prior authorization and change to preferred brand (tier 3).</td>
</tr>
<tr>
<td>Olmesartan/Hydrochlorothiazide (Benicar® HCTZ) 40-12.5mg, 40-25mg tablet</td>
<td>Currently non-formulary, add prior authorization.</td>
</tr>
<tr>
<td>Nebivolol (Bystolic®) tablet</td>
<td>Add to formulary (brand-tier 4) with prior authorization.</td>
</tr>
<tr>
<td>Mometasone/formoterol (Dulera®)</td>
<td>Add to formulary (brand-tier 4).</td>
</tr>
</tbody>
</table>
HFA aerosol

Ezetimibe (Zetia®) tablet      Add to formulary, Tier 4, with prior authorization.

Chenodiol (Chenodal®) tablet  Add to Formulary, Tier 6 (specialty), with prior authorization, limited access.

The following prior authorization policies are retired effective June 1, 2015.
- Cycloset
- Vivitrol
- Nulojix
- Samsca

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**MedWatch Safety Alerts**  
**Jan. 1, 2015 – Feb. 28, 2015**

1. **ISSUE:** FDA is aware of and understands the concerns arising from recent reports questioning the safety of prescription and over-the-counter (OTC) pain medicines when used during pregnancy. As a result, FDA evaluated research studies published in the medical literature and determined they are too limited to make any recommendations based on these studies at this time. Because of this uncertainty, the use of pain medicines during pregnancy should be carefully considered. FDA urges pregnant women to always discuss all medicines with their healthcare professionals before using them.

Severe and persistent pain that is not effectively treated during pregnancy can result in depression, anxiety, and high blood pressure in the mother. Medicines including nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, and acetaminophen can help treat severe and persistent pain. However, it is important to carefully weigh the benefits and risks of using prescription and OTC pain medicines during pregnancy.

**BACKGROUND:** The published studies FDA-reviewed reported on the potential risks associated with the following three types of pain medicines used during pregnancy:

- Prescription NSAIDs and the risk of miscarriage in the first half of pregnancy. Examples of prescription NSAIDs include ibuprofen, naproxen, diclofenac, and celecoxib.
- Opioids, which are available only by prescription, and the risk of birth defects of the brain, spine, or spinal cord in babies born to women who took these products during the first trimester of pregnancy. Examples of opioids include oxycodone, hydrocodone, hydromorphone, morphine, and codeine.
• Acetaminophen in both OTC and prescription products and the risk of attention deficit hyperactivity disorder (ADHD) in children born to women who took this medicine at any time during pregnancy. Acetaminophen is a common pain reducer and fever reducer found in hundreds of medicines including those used for colds, flu, allergies, and sleep.

RECOMMENDATION: Healthcare professionals should talk with each patient about the benefits and risks of analgesic use during pregnancy, which may differ among patients and by treatment indication. Continue to follow the existing recommendations in current drug labels regarding the use of analgesics during pregnancy.