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/](https://premera.com/medicare-advantage/pharmacy-services/). You can also check the Premera MA Formulary using [Epocrates.com](http://epocrates.com):

- To download the formulary from [epocrates.com](http://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 April 1, 2107**

(Unless noted otherwise below)

Effective dates are pending CMS approval

**Class Reviews:**

<table>
<thead>
<tr>
<th>Vaginal Anti-Infectives/Antifungals Formulary Class Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>The following anti-infective drugs were reviewed: Cleocin® (clindamycin phosphate), Clindesse® (clindamycin phosphate), Cleocin Ovule® (clindamycin phosphate), and Vandazole® (metronidazole).</td>
</tr>
</tbody>
</table>

The following antifungal drugs were reviewed: Gyne-Lotrimin® ( clotrimazole), Monistat® (miconazole nitrate), miconazole 3 (miconazole nitrate), Vagistat®-1 (tioconazole), Gynazole® (butoconazole nitrate), Terazol® (terconazole), terconazole, and AVC® (sulfanilamide).

No formulary changes.

<table>
<thead>
<tr>
<th>Vaginal Estrogens, Progestins, and Miscellaneous Formulary Class Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>The following vaginal estrogen drugs were reviewed: Estring® (estradiol), Vagifem® (estradiol), Estrace® (estradiol), Femring® (estradiol acetate), and Premarin® (estrogens, conjugated).</td>
</tr>
</tbody>
</table>

The following vaginal progestin drugs were reviewed: Crinone® 4% (progesterone, micronized), Crinone® 8% (progesterone, micronized), and Endometrin® (progesterone, micronized).

The following vaginal miscellaneous drugs were reviewed: Fem pH® (acetic acid/ oxyquinoline sulfate) and Relagard® (acetic acid/ oxyquinoline sulfate).

No formulary changes.

<table>
<thead>
<tr>
<th>Urinary Anti-infectives Formulary Class Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>The following drugs were reviewed: Hiprex® (methenamine hippurate), methenamine mandelate, Furadantin® (nitrofurantoin), Macroductin® (nitrofurantoin macrocrystal), Macrobid® ( nitrofurantoin monohydrate/macrocrys)</td>
</tr>
</tbody>
</table>
Monurol® (fosfomycin tromethamine), and methenamine combinations.

No formulary changes.

Miscellaneous Genitourinary Agents Formulary Class Review

The following Acidifiers and Alkalinizers drugs were reviewed: Cytra®-2 (citric acid/sodium citrate), Cytra®-3 (sodium/potassium/potassium citrate/sodium citrate/citric acid), Cytra®-K (potassium citrate/citric acid), Virtrate®-K (potassium citrate/citric acid), Urocit®-K (potassium citrate), potassium monohydrate – powder/granules, Oracit® (citric acid/sodium citrate), Renacidin® (citric acid/glucuronolactone/magnesium carbonate), Tricitrates® (sodium/potassium/potassium citrate/sodium citrate/citric acid), and K-Phos®-2 (sodium phosphate, monobasic/potassium phosphate, monobasic).

The following Urinary Analgesics, Cystinosis Agents, and Interstitial Cystitis drugs were reviewed: Cystagon® (cysteamine bitartrate), Procysbi® (cysteamine bitartrate), Elmiron® (pentosane polysulfate sodium), Romso®-50 (dimethyl sulfoxide), and phenazopyridine.

The following Urinary Stone Agent drugs were reviewed: Lithostat® (acetohydroxamic acid), and Thiola® (tiopronin).

The following Prostatic Hypertrophy drugs were reviewed: Uroxatral® (alfuzosin hcl), Avodard® (dutasteride), Cardura® XR (doxazosin mesylate), Jalyn® (dutasteride/tamsulosin hcl), Proscar® (finasteride), Rapaflo® (silodosin), and Flomax® (tamsulosin hcl).

No formulary changes.

New Drugs and Combinations:

Zurampic® (lesinurad) tablet

- Indication: Used in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone.

Formulary, Non-preferred drug, Prior Authorization

Lartruvo® (olaratumab solution) injection

- Indication: Used in combination with doxorubicin, for the treatment of adult patients with soft tissue sarcoma (STS) with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery.

Part B Benefit, Prior Authorization

Prior Authorization Criteria:
A prior authorization form and relevant chart notes documenting medical rationale are required. For continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

Reauthorization requires documentation of adequate response to the medication must be provided.

Basaglar® (insulin glargine, human recombinant analog) injection

- Indication: To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.
- Formulary Alternatives: Lantus®, Toujeo®, Tresiba®, Levemir®, NPH insulin

Limitations of Use: Not recommended for treating diabetic ketoacidosis.

Non-formulary

Rubraca® (rucaparib camsylate) tablet

- Indication: For ovarian cancer as monotherapy in advanced disease with deleterious BRCA mutations (germline and/or somatic), with 2 or more previous chemotherapies.
- Formulary Alternatives: olaparib (Lynparza®)
Formulary, Specialty, Prior Authorization

Prior Authorization Criteria:

- Relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
- Must be prescribed by, or in consultation with an oncologist.

Reauthorization requires documentation of an adequate response to the medication.

New Indications:

**Tarceva® (erlotinib hydrochloride)**

NEW FDA-APPROVED INDICATION:

The treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen.

Reviewed new indication. No update needed as policy is based upon current National Comprehensive Cancer Network (NCCN) compendia. Notify via MD Alert.

**Keytruda® (pembrolizumab)**

NEW FDA-APPROVED INDICATION:

- Patients with metastatic NSCLC whose tumors have high PD-L1 expression \([\text{Tumor Proportion Score (TPS)} \geq 50\%]\) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, and no prior systemic chemotherapy treatment for metastatic NSCLC.
- Patients with metastatic NSCLC whose tumors express PD-L1 \([\text{TPS} \geq 1\%]\) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda®.

Reviewed new indication. No policy current currently, therefore no additional action necessary at this time. Notify via MD Alert.

**Selzentry® (maraviroc)**

NEW FDA-APPROVED INDICATION:

- The treatment of only CCR5-tropic HIV-1 infection in patients 2 years of age and older weighing at least 10 kg.

Reviewed new indication. No policy current currently, therefore no additional action necessary at this time. Notify via MD Alert.

**Opdivo® (nivolumab)**

NEW FDA-APPROVED INDICATION:

- Indicated as a single agent for recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after a platinum-based therapy.

Reviewed new indication. No update needed as policy is based upon current NCCN compendia. Notify via MD alert.

**Darzalex® (daratumumab)**

NEW FDA-APPROVED INDICATION:

- Use in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.

Reviewed new indication. No update needed as policy is based upon current NCCN compendia. Notify via MD alert.

**Renvela® (sevelamer carbonate)**
NEW FDA-APPROVED INDICATION:
- Control of serum phosphorus in adults and children 6 years of age and older with chronic kidney disease on dialysis.

Reviewed new indication. No update needed as policy is based upon current NCCN compendia. Notify via MD alert.

Drug Safety Monitoring

Direct-Acting Antivirals for Hepatitis C: Drug Safety Communication - Risk of Hepatitis B Reactivating

ISSUE:
The FDA is warning about the risk of hepatitis B virus (HBV) becoming an active infection again in any patient who has a current or previous infection with HBV and is treated with certain direct-acting antiviral (DAA) medicines for hepatitis C virus. In a few cases, HBV reactivation in patients treated with DAA medicines resulted in serious liver problems or death. HBV reactivation usually occurred within 4-8 weeks.

As a result, FDA is requiring a Boxed Warning about the risk of HBV reactivation to be added to the drug labels of these DAAs directing healthcare professionals to screen and monitor for HBV in all patients receiving DAA treatment. This warning will also be included in the patient information leaflet or Medication Guides for these medicines.

FDA identified 24 cases of HBV reactivation reported to FDA and from the published literature in HCV/HBV co-infected patients treated with DAAs during the 31 months from November 22, 2013 to July 18, 2016. Of the cases reported, two patients died and one required a liver transplant. HBV reactivation was not reported as an adverse event in the clinical trials submitted for the DAA approvals because patients with HBV co-infection were excluded from the trials.

RECOMMENDATION:
Healthcare professionals should screen all patients for evidence of current or prior HBV infection before starting treatment with DAAs, and monitor patients using blood tests for HBV flare-ups or reactivation during treatment and post-treatment follow-up.

Patients should tell their healthcare professional if they have a history of hepatitis B infection or other liver problems before being treated for hepatitis C. Contact your healthcare professional immediately if you develop fatigue, weakness, loss of appetite, nausea and vomiting, yellow eyes or skin, or light-colored stools, as these may be signs of serious liver problems. 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.

Testosterone and Other Anabolic Androgenic Steroids (AAS): FDA Statement - Risks Associated With Abuse and Dependence

ISSUE: FDA approved class-wide labeling changes for all prescription testosterone products, adding a new warning and updating the “Abuse and Dependence” section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other AAS.

The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act. Testosterone and other AAS are abused by adults and adolescents, including athletes and body builders. Abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. Examples of these conditions include failure of the testicles to produce testosterone because of genetic problems, or damage to the testicles from chemotherapy or infection.

RECOMMENDATION:
Healthcare professionals should discuss the risks of testosterone use with patients prior to initiating therapy. 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.

### Health Plan Other Formulary Changes:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Change Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yuvafem (Vagifem®) vaginal tablet</td>
<td>Generic will be non-formulary due to rebate incentives received for covering brand only.</td>
</tr>
<tr>
<td>Dofetilide (Tikosyn®) capsule</td>
<td>Medicare Part D: Change dofetilide from Tier 4 (non-preferred drug tier) to Tier 2 (generic tier) due to complexity of the disease and challenge in administering tiering exception.</td>
</tr>
<tr>
<td>Zarfio® (filgrastim-sndz) syringe</td>
<td>• Medicare Part B: Prior Authorization</td>
</tr>
<tr>
<td></td>
<td>• Medicare Part D: Non-Formulary</td>
</tr>
<tr>
<td>Duloxetine capsule</td>
<td>Remove quantity limitations due to low cost of drugs and low risk of overutilization.</td>
</tr>
<tr>
<td>Metronidazole 1% pump/gel</td>
<td>Add to formulary, non-preferred drug tier for Medicare Part D.</td>
</tr>
<tr>
<td>Trospium extended-release (Sanctura XR®) capsule</td>
<td>Add to formulary, non-preferred generic tier for Medicare Part D.</td>
</tr>
<tr>
<td>Bevacizumab syringe</td>
<td>Medicare: Part B Benefit.</td>
</tr>
<tr>
<td>Aprepitant (Emend®) 40 mg capsule</td>
<td>Medicare Part D: Formulary, Non-Preferred Drug, Quantity Limit (8 capsules per 30 days).</td>
</tr>
<tr>
<td>Epinephrine vial</td>
<td>Add to formulary, non-preferred generic.</td>
</tr>
<tr>
<td>Atovaquone/proguanil (Malarone®) tablet</td>
<td>Add to formulary, non-preferred drug for Medicare.</td>
</tr>
<tr>
<td>Monural® (fosfomycin tromethamine) packet</td>
<td>Add to formulary, preferred brand.</td>
</tr>
<tr>
<td>Reclast® (zoledronic acid/mannito-water) infusion</td>
<td>Add to formulary, non-preferred drug, B vs D for Medicare.</td>
</tr>
<tr>
<td>Relistor® tablets</td>
<td>Clarification from December meeting: Medicare: Non-formulary.</td>
</tr>
</tbody>
</table>

### New Generic Medications

#### First- time generics to market

- **Quetiapine ER (Seroquel®) tablet**: Not a true generic
  - Formulary, Preferred Brand
- **Ropivacaine (Naropin®) vial**:
  - Part B Benefit
- **Esomeprazole DR capsules**: Line extend as a generic
  - Non-Formulary
- **Venlafaxine hcl ER 225 mg tablet**: Line extend as a generic
  - Formulary, Non-Preferred Generic, Quantity Limit (1 tablet per day)
- **Mycophenolate (Cellcept®) vial**:
  - Part B Benefit
- **Armodafinil (Nuvigil®) tablet**: Now considered a true generic
  - Formulary, Non-Preferred Generic, Prior Authorization, Quantity Limit (150 mg, 200 mg, 250 mg: 1 tablet per day; 50 mg: 2 tablets per day)
- **Tigecycline (Tygacil®) vial**: Line extend as a brand
  - Formulary, Non-Preferred Drug
- **Metoprolol ER-HCTZ (Dutoprol®) tablet**: Line extend as a brand
  - Formulary, Non-Preferred Drug
- **Doripenem (Doribax®) vial**
  - Formulary, Non-Preferred Drug