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 May 1, 2017**

*(Unless noted otherwise below)*

**Effective dates are pending CMS approval**

### Class Reviews

#### Ophthalmic Steroid Agents Formulary Class Review

The following ophthalmic steroid drugs and ophthalmic steroid combinations were reviewed: dexamethasone drops, Durezol® (difluprednate) drops, (fluorometholone) drops suspension, FML Forte® (fluorometholone) drops suspension, FLM S.O.P.® (fluorometholone) ointment, Flarex® (fluorometholone acetate) drops suspension, Lotemax® (loteprednol etabonate) drops suspension/ointment/drops gel, Alrex® (loteprednol etabonate) drops suspension, prednisolone acetate drops suspension, prednisolone sodium phosphate suspension, Pred Mild® (prednisolone acetate) drops suspension, Vexol® (rimexolone) drops suspension, neomycin-polymyxin-hc (neomycin sulfate/polymyxin B sulfate/hydrocortisone) drops suspension, Maxitrol® (neomycin/polymyxin B sulfate/dexamethasone) ointment/drops suspension, neo-polycin-hc (neomycin sulfate/bacitracin zinc/polymyxin B/hydrocortisone) ointment, sulfacetamide-prednisolone (sulfacetamide sodium/prednisolone sodium phosphate) drops, Blephamide® S.O.P. (sulfacetamide sodium/prednisolone acetate) ointment, Blephamide® (sulfacetamide sodium/prednisolone acetate) drops suspension, Tobradex® (tobramycin/dexamethasone) drops suspension/ointment, Zylet® (tobramycin/loteprednol etabonate) drops suspension, and Pred-G® (gentamicin sulfate/prednisolone acetate) ointment/drops suspension.

No changes recommended.

#### Ophthalmic Glaucoma Agents Formulary Class Review

The following ophthalmic beta-blocker drugs were reviewed: betaxolol hcl drops, Combigan® (brimonidine/timolol) drops, carteolol hcl drops, Cosopt® (dorzolamide/timolol) drops, Cosopt® PF (dorzolamide/timolol) dropperette, Betagan® (levobunolol hcl) drops, metipranolol drops, Betimol® (timolol) drops, timolol maleate drops, Istaol® (timolol maleate) drop daily, Timoptic-XE® (timolol maleate) sol-gel, Timoptic® (timolol maleate) drops, and Timoptic® Ocudose (timolol maleate/PF) dropperette.
The following ophthalmic prostaglandin drugs were reviewed: bimatoprost 0.03% drops, Lumigan® 0.01% (bimatoprost) drops, Xalatan® (latanoprost) drops, Travatan Z® (travoprost) drops, travoprost (benzalkonium) drops, Rescula® (unoprostone isopropyl) drops, and Zioptan® (tafluprost/PF) droperette.

The following ophthalmic miotic drugs were reviewed: Miostat® (carbachol) vial, and Isopto® Carpine (pilocarpine hcl) drops.

The following ophthalmic cholinesterase inhibitor drugs were reviewed: Phospholine Iodide® (echothiophateiodide) drops.

The following ophthalmic carboni anhydrase inhibitor drugs were reviewed: Azopt® (brinzolamide) drops suspension, and Trusopt® (dorzolamide hcl) drops.

The following ophthalmic alpha-2 agonists and combo drugs were reviewed: Iopidine® (apraclonidine hcl) drops, droperette, brimonidine 0.15% drops, brimonidine 0.2% drops, Alphagan® P (brimonidine tartrate) drops, and Simbrinza (brimonidine/brimonidine tartrate) drops suspension.

Bimatoprost
- Remove the quantity limit.

**Ophthalmic NSAIDs Formulary Class Review**

The following drugs were reviewed: Bromday® (bromfenac 0.09%) drops, Prolensa® (bromfenac 0.07%) drops, Bromsite® (bromfenac 0.075%) drops, diclofenac drops, Ocufem® (flurbiprofen) drops, Nevanac® (nepafenac 0.1%) drops suspension, Ileuro® (nepafenac 0.3%) drops suspension, Acular® LS (ketorolac 0.4%) drops, Acular® (ketorolac 0.5%) drops, and Acuvail® (ketorolac/PF) droperette.

No changes recommended.

**Ophthalmic Antibiotic Agents Formulary Class Review**

The following drugs were reviewed: Azasite® (azithromycin) drops, Besivance® (besifloxacin hcl) drops suspension, polycin (bacitracin/polymyxin B sulfate) ointment, neosporin (neomycin/polymyxin B sulfate/gramicidin D) drops, neo-polycin (neomycin/bacitracin/polymyxin B) ointment, Ciloxan® (ciprofloxacin hcl) drops/oointment, Iotycin® (erythromycin base) ointment, gentak (gentamicin sulfate) drops/oointment, levofloxacin drops, Mozeza® (moxifloxacin hcl) drops visc, Vigamox® (moxifloxacin hcl) drops, Natacyn® (natamycin) drops suspension, Ocuflox® (ofloxacin) drops, Polytrim® (polyoxin B sulfate/trimethoprim) drops, sulfacetamide sodium ointment, Sulfamide® (sumfacetamide sodium) drops, Tobrex® (tobramycin) drops, and Viroptic® (trifluridine) drops.

No changes to current formulary status.

**Urinary Anti-Spasmodics Formulary Class Review**

The following drugs were reviewed: bethanechol chloride, Enablex® (darifenacin hydrobromide), flavoxate HCL, Toviaz® (fesoterodine fumarate), Myrbetriq® (mirabegron), Oxytrol® for Women (oxybutynin), Glenique® (oxybutynin), oxybutynin – tablet/syrup, Ditropan® XL (oxybutynin chloride), Vesicare® (solifenacin succinate), Detrol® (tolterodine tartrate), Detrol® LA (tolterodine tartrate), Trospium® ER (trosipium chloride), and trospium.

No recommended changes to current formulary status.

**New Drugs and Combinations:**

Spinraza® (nusinersen) vial
- Indication: For the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.
Part B Benefit, Prior Authorization

Prior Authorization Criteria:
- Diagnosis of SMA with genetic testing confirmation
  AND
- Patient is presymptomatic or has symptoms with an onset at age <30 years
  AND
- Documentation of baseline motor function, with a standardized test appropriate based on the patient’s age and level of function: CHOP-INTEND, HINE, HFMSE, RULM, or 6MWT

NOTE the following guidance on selecting an appropriate test:
Walkers (adults): 6MWT, RULM
Non-walkers (adults): RULM
6MWT: six-minute walk test
RULM: revised upper limb module

Reauthorization: Improvement or maintenance of motor function, evidenced by follow-up results of motor function test performed at baseline.

Zinplava® (bezlotoxumab) vial
- Indication: Prophylaxis for recurrent *Clostridium difficile* infection in patients who are at high risk of recurrence.

Part B Benefit, Prior Authorization
Prior Authorization Criteria:
All of the following criteria must be met for Clostridium difficile infection (CDI):
1. Must be used in combination with standard of care oral antibiotics for treatment (e.g., oral vancomycin, fidaxomicin, metronidazole)
2. One of the following:
   a. At least three episodes of mild to moderate CDI that have not responded to six to eight weeks of treatment with antibiotics, including a vancomycin taper
   b. Have had at least two episodes of severe CDI that required them to be admitted to the hospital

Reauthorization:
1. Previous dose was at least six (6) months ago
2. Patient must have had documented benefit from previous infusion, defined as reduction in frequency of recurrences of CDI from baseline

Xultophy® (insulin degludec/ liraglutide) injection
- Indication: Type 2 Diabetes Mellitus inadequately controlled on basal insulin (less than 50 units daily) or liraglutide (less than or equal to 1.8 mg daily)
- Formulary Alternatives:
  - insulin degludec (Tresiba®), insulin detemir (Levemir®), insulin glargine (Lantus®, Basaglar®), liraglutide (Victoza®), exenatide (Byetta® and Bydureon®)

Non-formulary

Soliqua® (insulin glargine/lixisenatide) insulin pen
- Indication: Treatment of Type 2 Diabetes Mellitus (T2DM) in adults inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide.
- Formulary Alternatives: insulin glargine, liraglutide, exenatide
Non-formulary, Prior Authorization, Quantity Limit (6 pens per 30 days)

**Rayaldee® (calcifediol) capsule**
- Indication: Secondary hyperparathyroidism in adult patients with stage 3 or 4 chronic kidney disease and serum total 25-hydroxyvitamin D levels <30 ng/mL.
- Formulary Alternatives: calcitriol, doxercalciferol, paricalcitol

Non-formulary, Prior Authorization for Part B vs Part D

**Vemlidy® (tenofovir alafenamide) tablet**
- Indication: For the treatment of chronic hepatitis B virus infection in adults with compensated liver disease. Do not use with HIV infection.
- Formulary Alternatives: tenofovir disoproxil fumerate (Viread®) and entecavir

Formulary, Non-preferred drug, Quantity Limit (1 tablet per day)

**Adlyxin® (lixisenatide) pen injector**
- Indication: For type 2 diabetes.
- Formulary Alternatives: exenatide (Byetta®), exenatide extended-release (Bydureon®), and liraglutide (Victoza®)

Non-formulary

**Eucrisa® (crisaborole) ointment**
- Indication: Topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.
- Formulary Alternatives: tacrolimus 0.03% and 0.1%, betamethasone 0.05 % ointment, clobetasol 0.05% ointment, mometasone 0.1% ointment

New Strengths and Formulations:

**Ameluz® (aminolevulinic acid) topical**
- Indication: Lesion-directed and field-directed treatment of actinic keratoses (AKs) of mild-to-moderate severity on the face and scalp in combination with photodynamic therapy (PDT).

Part B Benefit

### Health Plan Other Formulary Changes:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Change Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selzentry® (maraviroc) tablet</td>
<td>Add to formulary, preferred brand</td>
</tr>
<tr>
<td>Thiola® (tiopronin) tablet</td>
<td>Add to formulary, specialty, limited access</td>
</tr>
<tr>
<td>Octagam® (immune gamma globulin)</td>
<td>Add to formulary, specialty, with prior authorization (IGG PA Program)</td>
</tr>
<tr>
<td>Restasis® (cyclosporine) ophthalmic multi-dose</td>
<td>Add to formulary, non-preferred drug tier, quantity limit 5.5 mL per 28 days</td>
</tr>
<tr>
<td>Sandostatin LAR® (octreotide) vial</td>
<td>Add to formulary, specialty, with prior authorization (Octreotide PA Program)</td>
</tr>
<tr>
<td>Heparin 5,000 unit syringe</td>
<td>Non-Formulary</td>
</tr>
<tr>
<td>Synjardy® XR (empagliflozin/metformin hcl) tablet</td>
<td>Formulary, Non-Preferred Drug, Prior Authorization</td>
</tr>
<tr>
<td>Policy Name</td>
<td>Change Summary</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Aczone</td>
<td>The policy criteria was updated and clarified to align with more recent guidelines from the American Academy of Dermatology guidelines for the treatment of acne.</td>
</tr>
<tr>
<td>Topical Acne Products</td>
<td>Benzaclin® pump is now available as a generic medication with similar costs to formulary agents. Therefore, the prior authorization will be retired for this agent. As there are several clindamycin/benzoyl peroxide formulations, Acanya® and Onexton® gel will be moved to the &quot;New Medications and Formulations without Established Benefit&quot; policy. The Neuac kit is considered a benefit exclusion effective 1/1/17, so will be removed from this policy and added to exclusion lists.</td>
</tr>
<tr>
<td>Evzio, Narcan</td>
<td>The prior authorization for Narcan® nasal spray was removed. The criterion for documentation of training for patient and caregiver was removed due to difficulty in operational review of this criterion. Narcan® will continue to have quantity limitations and this policy will be used to evaluate requests for exceptions to the quantity limits.</td>
</tr>
<tr>
<td>Signifor, Signifor LAR</td>
<td>The policy criteria were updated to reflect current practice guidelines from the Endocrine Society for treatment of acromegaly. In addition, a requirement of trial of octreotide therapy was added before initiation with this agent.</td>
</tr>
<tr>
<td>Testosterone Replacement Therapy (TRT)</td>
<td>Injectable testosterone formulations will be added to the policy. The policy criteria were made more restrictive to align with recent guidelines. For initial approval, patients must show signs and symptoms of low testosterone that do not include sexual dysfunctions (e.g. decreased libido). In addition, confirmation of low testosterone will be required through two separate morning levels.</td>
</tr>
<tr>
<td>Octreotide, Sandostatin, Sandostatin LAR</td>
<td>The policy criteria were updated to reflect current practice guideline from the Endocrine Society for treatment of acromegaly. In addition, criteria for approval were removed for off-label indications without appropriate evidence for support (inoperable bowel obstruction and short bowel syndrome).</td>
</tr>
<tr>
<td>Somavert</td>
<td>The policy criteria were updated to reflect current practice guidelines from the Endocrine Society for treatment of acromegaly.</td>
</tr>
<tr>
<td>Human Growth Hormones for Adults</td>
<td>Dosing guidelines were added to the policy for dose optimization due to risk of side effects and cost of medications.</td>
</tr>
<tr>
<td>PCSK9 Inhibitors</td>
<td>The criterion for ezetemibe therapy was changed to be needed only when the patient has a LDL level that is &lt;30% above the desired goal LDL (70 or 100 mg/dL).</td>
</tr>
<tr>
<td>New Medications and Formulations without Established Benefit</td>
<td>Xultophy® and Soliqua® were added to this policy as they both contain two medications that have formulary alternatives, and the combination products have not established a clinical benefit. In addition, Acanya®, Zembrace®, and Onexton® were added as there are several strengths and formulations of clindamycin/benzoyl gel available that are more cost-effective and have comparable efficacy.</td>
</tr>
<tr>
<td>Lumizyme</td>
<td>This policy was updated to reflect maximum recommended</td>
</tr>
</tbody>
</table>
doses of 20mg/kg/2weeks as this is supported by the package insert. A review of current literature does not support using doses above 20mg/kg/2weeks at this time.

**Millipred**
The criteria were updated to add coverage for use in alcoholic hepatitis and a Maddrey Discriminant Function (MDF) score is ≥32. This regimen is recommended by AASLD guidelines. A trial showed that patients with severe liver impairment did not convert prednisone to the active metabolite, prednisolone, as effectively as those with only mild hepatic impairment.

**Tanzeum, Trulicity**
Adlyxin® was added to this policy (see full review). Otherwise, the policy was reviewed without significant changes.

**Therapeutic Immunomodulators_Commercial**
Policy wording was changed to reflect requirements of rebate contracts. No clinical information was changed. There are medical drug dosing guidelines that were added to provide clinical reviewers with dose optimization guidelines.

The following policies were retired effective 6/1/2017.
- Cystaran

### New Generic Medications

**First time generics to market**
- **Prednisolone solution (Millipred®):** Line extend as a generic.
  - Non-formulary
- **Dexmethylphenidate HCL ER (Focalin® XR) CPBP 50-50:** Line extend as a generic.
  - Non-formulary
- **Flurandrenolide (Cordan®) ointment:**
  - Non-formulary
- **Multivitamin-Iron-Fluoride (Poly-Vi-Flor®) drops:**
  - Non-formulary