Pharmacy Medical Necessity Guidelines: Glaucoma Medications
Effective: January 14, 2019

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>√</th>
<th>Type of Review – Care Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Covered</td>
<td></td>
<td>Type of Review – Clinical Review</td>
</tr>
<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>RX</td>
<td>Department to Review</td>
</tr>
</tbody>
</table>

These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**
- Tufts Health Plan Commercial products – large group plans
- Tufts Health Plan Commercial products – small group and individual plans
- Tufts Health Freedom Plan products – large group plans
- Tufts Health Freedom Plan products – small group plans
- CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**
- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
- Tufts Health RITogether – A Rhode Island Medicaid Plan

**Fax Numbers:**
RXUM: 617.673.0988

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

**OVERVIEW**

**FDA-APPROVED INDICATIONS**
The ophthalmic alpha adrenergic agonists, carbonic anhydrase inhibitors and prostaglandin agonists are indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

The following table summarizes the formulary status for Tufts Health Together Members.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>PDL Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alpha-adrenergic Agonists</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brimonidine 0.2% * (Alphagan)</td>
<td>Brimonidine</td>
<td>Tier 1</td>
</tr>
<tr>
<td>Brimonidine 0.15% (Alphagan P)</td>
<td>Brimonidine</td>
<td>PA; Tier 1</td>
</tr>
<tr>
<td>Alphagan P 0.1%</td>
<td>Brimonidine</td>
<td>PA; Tier 2</td>
</tr>
<tr>
<td><strong>Carbonic Anhydrase Inhibitors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dorzolamide 2% * (Trusopt)</td>
<td>Dorzolamide</td>
<td>Tier 1</td>
</tr>
<tr>
<td>Azopt 1%</td>
<td>Brinzolamide</td>
<td>PA; Tier 2</td>
</tr>
<tr>
<td><strong>Prostaglandin Agonists</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latanoprost 0.005%* (Xalatan)</td>
<td>Latanoprost</td>
<td>Tier 1</td>
</tr>
<tr>
<td>Lumigan 0.01%, 0.03%</td>
<td>Bimatoprost</td>
<td>PA; Tier 2</td>
</tr>
<tr>
<td>Zioptan 0.0015%</td>
<td>Tafluprost</td>
<td>PA; Tier 2</td>
</tr>
<tr>
<td>Travatan Z 0.004%</td>
<td>Travoprost</td>
<td>PA; Tier 2</td>
</tr>
<tr>
<td>Rescula 0.15%</td>
<td>Unoprostone Isopropyl</td>
<td>PA; Tier 2</td>
</tr>
<tr>
<td>Vyzulta 0.024%</td>
<td>Latanaprostene Bunod</td>
<td>PA; Tier 2</td>
</tr>
<tr>
<td>Xelpros 0.005%</td>
<td>Latanoprost</td>
<td>PA; Tier 2</td>
</tr>
<tr>
<td><strong>Rho Kinase Inhibitor</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rhopressa 0.02%</td>
<td>Netarsudil</td>
<td>PA; Tier 2</td>
</tr>
<tr>
<td><strong>Combination Medications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dorzolamide/Timolol 2-0.5%* (Cosopt)</td>
<td>Dorzolamide HCl-Timolol</td>
<td>Tier 1</td>
</tr>
<tr>
<td>Combigan 0.2/0.5%</td>
<td>Brimonidine +Timolol</td>
<td>PA; Tier 2</td>
</tr>
<tr>
<td>Simbrinza 1-0.2%</td>
<td>Brinzolamide-Brimonidine</td>
<td>PA; Tier 2</td>
</tr>
</tbody>
</table>

*Preferred medications covered without prior authorization

Brand name medications with AB-rated generics are non-covered. They are included in the table to serve as a reference. Requests for the brand-name products, with AB-rated generics, will also require review according to Brand Name criteria.

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Pharmacy Medical Necessity Guidelines:
Glaucoma Medications
**COVERAGE GUIDELINES**

The plan may authorize coverage of a nonpreferred ophthalmic medication for Members when the following criterion for a particular regimen is met and limitations do not apply:

**For brimonidine 0.1% (Alphagan P) or 0.15%,**
1. The member tried and failed therapy with brimonidine 0.2%, or the provider indicates clinical inappropriateness of therapy with brimonidine 0.2%

**For Azopt (brinzolamide),**
1. The member tried and failed therapy with dorzolamide, or the provider indicates clinical inappropriateness of therapy with dorzolamide

**For a prostaglandin agonist (Lumigan 0.01% and 0.03%, Zioptan 0.0015%, Travatan Z 0.004%, Rescula 0.15%, Vyzulta 0.024%, Xelpros 0.005%),**
1. The member tried and failed therapy with generic latanoprost (Xalatan), or the provider indicates clinical inappropriateness of therapy with generic latanoprost (Xalatan).

**For Rhopressa (netarsudil),**
1. The member tried and failed therapy with at least two agents used for the treatment of glaucoma, each from a different class (e.g., alpha-adrenergics, carbonic anhydrase inhibitors, prostaglandin agonists)

**For a combination product (Combigan or Simbrinza)**
1. The member tried and failed concomitant therapy with brimonidine 0.2% and an alternative agent, or the provider indicates clinical inappropriateness of concomitant therapy with brimonidine 0.2% and an alternative agent, such as timolol or dorzolamide.

**LIMITATIONS**
1. Requests for brand-name products, with AB-rated generics, will also be reviewed according to Brand Name criteria.

**CODES**
None

**REFERENCES**
2. FDA News and Events. FDA approves Zioptan to treat elevated eye pressure. fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm291966.htm
19. Xelpros (latanoprost 0.005%) [prescribing information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc: September 2018.

APPROVAL HISTORY
June 4, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. March 10, 2015: Approval duration modified to one year.
3. January 1, 2016: Administrative change to rebranded template.
4. January 12, 2016: No changes.
7. January 9, 2018: No changes.
8. April 10, 2018: Added Vyzulta (latanoprostene bunod) to the MNG.
9. August 7, 2018: Added Rhopressa (netarsudil) to the MNG.
10. January 8, 2019: Added Xelpros (latanoprost) to the MNG. For the criteria for the nonpreferred prostaglandin agonists, specified that the preferred latanoprost agent is generic Xalatan. Administrative changes made to template.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION
Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.