

Pharmacy Medical Necessity Guidelines: Glaucoma Medications

Effective: January 12, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans <ul style="list-style-type: none"> CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan			<p>Fax Numbers: RXUM: 617.673.0988</p>

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 RITogether Members.

Brand Name	Generic Name	PDL Status
Alpha-adrenergic Agonists		
Brimonidine 0.2%* (Alphagan)	Brimonidine	Covered
Brimonidine 0.15% (Alphagan P)	Brimonidine	PA
Alphagan P 0.1%	Brimonidine	PA
Carbonic Anhydrase Inhibitors		
Dorzolamide 2%* (Trusopt)	Dorzolamide	Covered
Azopt 1%	Brinzolamide	PA
Prostaglandin Agonists		
Latanoprost 0.005%* (Xalatan)	Latanoprost	Covered
Lumigan 0.01%, 0.03%	Bimatoprost	PA
Zioptan 0.0015%	Tafluprost	PA
Travoprost 0.004% (Travatan Z)	Travoprost	PA
Rescula 0.15%	Unoprostone Isopropyl	PA
Vyzulta 0.024%	Latanoprostene Brunod	PA
Xelpros 0.005%	Latanoprost	PA
Rho Kinase Inhibitor		
Rhopressa 0.02%	Netarsudil	PA
Combination Medications		
Dorzolamide/Timolol 2-0.5%* (Cosopt)	Dorzolamide HCl-Timolol	Covered
Combigan 0.2/0.5%	Brimonidine -Timolol	PA
Simbrinza 1-0.2%	Brinzolamide-Brimonidine	PA

* 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.

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:

Brimonidine 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%

Brimonidine 0.1% (Alphagan P)

1. The member tried and failed therapy with brimonidine 0.2% and brimonidine 0.15%, or the provider indicates clinical inappropriateness of therapy with brimonidine 0.2% and brimonidine 0.15%

Azopt (brinzolamide)

1. The member tried and failed therapy with dorzolamide, or the provider indicates clinical inappropriateness of therapy with dorzolamide

Prostaglandin agonist: Lumigan 0.01% and 0.03%, Zioptan 0.0015%, travoprost 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).

Rhopressa (netarsudil)

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

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
3. Chabi A, et al. Randomized Clinical Trial of the Efficacy and Safety of Preservative-free Tafluprost and Timolol in Patients With Open-Angle Glaucoma or Ocular Hypertension. *Am J Ophthalmol.* 2012 Jun;153(6):1187-96. [Abstract]
4. Uusitalo H, et al. Efficacy and safety of tafluprost 0.0015% versus latanoprost 0.005% eye drops in open-angle glaucoma and ocular hypertension: 24-month results of a randomized, double-masked phase III study. *Acta Ophthalmol.* 2010 Feb;88(1):12-9. [Abstract]
5. Hommer A, et al. Switching patients from preserved prostaglandin-analog monotherapy to preservative-free tafluprost. *Clin Ophthalmol.* 2011;5:623-31. Epub 2011 May 17.
6. Ranno S, et al. A Prospective Study Evaluating IOP Changes after Switching from a Therapy with Prostaglandin Eye Drops Containing Preservatives to Nonpreserved Tafluprost in Glaucoma Patients. *ScientificWorldJournal*; 2012:804730.
7. American Academy of Ophthalmology Glaucoma Panel. Preferred Practice Pattern Guidelines. Primary Open-Angle Glaucoma. American Academy of Ophthalmology, 2010. Available from: one.aao.org/preferred-practice-pattern/primary-openangle-glaucoma-ppp--october-2010
8. European Glaucoma Society. Terminology and Guidelines for Glaucoma: 3rd Edition. May 2008. Available from: eugs.org/eng/reguser.asp
9. Sucampo Pharma Americas, LLC, Rescula product information. Bethesda, MD. November 2012.
10. Nordmann JP, et al. A double-masked randomized comparison of the efficacy and safety of unoprostone with timolol and betaxolol in patients with primary openangle glaucoma including pseudoexfoliation glaucoma or ocular hypertension. 6 month data. *Am J Ophthalmol.* 2002;133:1-10.
11. Hommer A, et al. Unoprostone as adjunctive therapy to timolol: a double masked randomized study versus brimonidine and dorzolamide. *Br J Ophthalmol.* 2003;87:592-598.

12. Stewart WC, et al. The safety and efficacy of unoprostone 0.15% versus brimonidine 0.2%. *Acta Ophthalmol Scand.* 2004;82:161-165.
13. Stewart WC, et al. Additive efficacy of unoprostone isopropyl 0.12% (Rescula) to latanoprost 0.005%. *Am J Ophthalmol.* 2001;131:339-344.8.
14. American Academy of Ophthalmology Glaucoma Panel. Preferred Practice Pattern® Guidelines. Primary Open-Angle Glaucoma. San Francisco, CA: American Academy of Ophthalmology; 2010. Available at: aao.org/ppp.
15. Vyzulta (latanoprostene bunod) [prescribing information]. Bridgewater, NJ: Bausch and Lomb; June 2019.
16. Rhopressa (netarsudil) [prescribing information]. Irvine, CA: Aerie Pharmaceuticals, Inc.; March 2019.
17. Xelpros (latanoprost 0.005%) [prescribing information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc: September 2018.
18. Zioptan (tafluprost) [prescribing information]. Lake Forest, IL: Oak Pharmaceuticals, Inc; November 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.
2. September 16, 2015: Approval duration approved for life of plan.
3. January 1, 2016: Administrative change to rebranded template.
4. January 12, 2016: No changes.
5. January 10, 2017: No changes.
6. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Updated criteria for brimonidine 0.1%, requiring a trial and failure with brimonidine 0.15% and brimonidine 0.2%.
7. January 9, 2018: No changes.
8. April 10, 2018: Added Vyzulta (latanoprostene brunod) to the MNG.
9. August 7, 2018: Added Rhopressa (netarsdil) to the MNG.
10. January 8, 2019: Added Xelpros (latanoprost 0.005%) 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.
11. January 14, 2020: No changes.
12. January 12, 2021: No changes.

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.