

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 checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input 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 Together Members.

Brand Name	Generic Name	PDL Status
Alpha-adrenergic Agonists		
Brimonidine 0.2%* (Alphagan)	Brimonidine	Tier 1
Brimonidine 0.15% (Alphagan P)	Brimonidine	PA; Tier 1
Alphagan P 0.1%	Brimonidine	PA; Tier 2
Carbonic Anhydrase Inhibitors		
Dorzolamide 2%* (Trusopt)	Dorzolamide	Tier 1
Azopt 1%	Brinzolamide	PA; Tier 2
Prostaglandin Agonists		
Latanoprost 0.005%* (Xalatan)	Latanoprost	Tier 1
Bimatoprost 0.03%* (Lumigan)	Bimatoprost	Tier 1
Travoprost 0.004%* (Travatan Z)	Travoprost	Tier 1
Rho Kinase Inhibitor		
Rhopressa 0.02%	Netarsudil	PA; Tier 2
Combination Medications		
Dorzolamide/Timolol 2-0.5%* (Cosopt)	Dorzolamide HCl-Timolol	Tier 1
Combigan 0.2/0.5%	Brimonidine -Timolol	PA; Tier 2
Simbrinza 1-0.2%	Brinzolamide-Brimonidine	PA; Tier 2

* 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 0.1% (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%

Azopt (brinzolamide)

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

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)

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

1. FDA News and Events. FDA approves Zioptan to treat elevated eye pressure. fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm291966.htm
2. 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]
3. 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]
4. 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.
5. 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.
6. Zioptan Formulary Submission Dossier. Merck Global Medical Information. Merck & Co., Inc. North Wales, PA. January 2014.
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/requser.asp
9. Sucampo Pharma Americas, LLC, Rescula product information. Bethesda, MD. November 2012.
10. Rescula Formulary Submission Dossier. Clinical and Economic Data Supporting Formulary Consideration of Rescula. Sucampo Pharma Americas, LLC, Bethesda, MD August 2013.
11. 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.
12. 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.
13. Stewart WC, et al. The safety and efficacy of unoprostone 0.15% versus brimonidine 0.2%. *Acta Ophthalmol Scand*. 2004;82:161-165.
14. Stewart WC, et al. Additive efficacy of unoprostone isopropyl 0.12% (Rescula) to latanoprost 0.005%. *Am J Ophthalmol*. 2001;131:339-344.8.
15. 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.

16. Vyzulta (latanoprostene bunod) [prescribing information]. Bridgewater, NJ: Bausch and Lomb; November 2017.
17. Rhopressa (netarsudil) [prescribing information]. Irvine, CA: Aerie Pharmaceuticals, Inc.; 2017 December.
18. Xelpros (latanoprost 0.005%) [prescribing information]. Cranbury, NJ: Sun Pharmaceuticals Industrices, 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.
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, Adding Tufts Health RITogether to the template.
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.
11. October 15, 2019: Effective 1/1/2020, latanoprost 0.005% (generic Xalatan) and Zioptan (tafluprost) are preferred prostaglandin agents and Lumigan 0.01%, Rescula, Travatan Z, and Xelpros are Not Covered. Generic bimatoprost 0.03% criteria updated to require trial and failure with either generic Xalatan or Zioptan.
12. January 14, 2020: No changes.
13. September 15, 2020: Effective 1/1/2021, Updated MNG to indicate that latanoprost 0.005%, travoprost 0.004%, and bimatoprost 0.03% will be preferred in the ophthalmic prostaglandins class.
14. 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.