

Pharmacy Medical Necessity Guidelines: Glaucoma Step Therapy

Effective: July 1, 2020

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> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" 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 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

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Latanoprost, Lumigan (bimatoprost), travoprost, Vyzulta (latanoprostene bunod), Xelpros (latanoprost), and Zioptan (tafluprost) are prostaglandin analogues indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Rhopressa (netarsudil) is a Rho kinase inhibitor and Rocklatan (netarsudil and latanoprost) is a combination Rho kinase inhibitor, prostaglandin analogue indicated for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension.

COVERAGE GUIDELINES

Note: Prescriptions that meet the initial step therapy requirements, will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit prior authorization requests to the plan using the Universal Pharmacy Medical Review Request Form for members who do not meet the step therapy criteria at the point of service.

Please refer to the table below for formularies and medications subject to this policy:

Drug	Tufts Health Plan Large Group Plans	Tufts Health Plan Small Group and Individual Plans
Step-1		
latanoprost	Covered	Covered
Step-2		
bimatoprost 0.03%	Requires prior use of a drug on Step-1 or Step-2	Requires prior use of a drug on Step-1 or Step-2
Lumigan® 0.01%		
travoprost 0.004%		
Vyzulta™		
Zioptan™		
Xelpros™		
Step-3		
Rhopressa®	Requires prior use of a drug on Step-2 or Step-3	Requires prior use of a drug on Step-2 or Step-3

Rocklatan™		
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Automated Step Therapy Coverage Criteria

The following stepped approach applies to coverage of the Step-2 and Step-3 medications by the plan:

Step 1: Medications on Step-1 are covered without prior authorization.

Step 2: The plan may cover medications on Step-2 if the following criteria are met:

The Member has had a trial of one (1) Step-1, Step-2, or Step-3 medication within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by the plan.

Step 3: The plan may cover Step-3 medications if the following criteria are met:

The Member has had a trial of a Step-2 or Step-3 medication within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by the plan.

Note: The plan may cover medications on Step-2 or Step-3 if a Member has received a **non-covered** medication within the previous 180 days listed below under the limitations section as evidenced by physician documented use, excluding the use of samples.

Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

The following stepped approach applies to glaucoma medications covered by the plan:

Step 2: The plan may cover medications on Step-2 if the following criteria are met:

- The Member has had a trial of a Step-1, Step-2, or Step 3 medication as evidenced by physician documented use, excluding the use of samples

OR

- The Member has a physician documented contraindication or intolerance to a Step-1 medication

Step 3: The plan may cover medications on Step-3 if the following criteria are met:

- The Member has had a trial of a Step-2 or Step-3 medication as evidenced by physician's documented use, excluding the use of samples

OR

- The Member has a physician documented contraindication or intolerance to a Step-2 or Step-3 medication

Note: The plan may cover medications on Step-2 or Step-3 if a Member has received a **non-covered** medication, listed below under the limitations section, as evidenced by physician documented use, excluding the use of samples.

LIMITATIONS

- Medications on Step-2 and Step -3 are not covered unless the above step therapy criteria are met.
- Non-covered glaucoma medications for all Commercial formularies include the following brand-name products: Travatan Z and Xalatan. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives and submit a formulary exception request to the plan as indicated.
- Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.

CODES

None

REFERENCES

1. American Academy of Ophthalmology. Preferred practice pattern: primary open-angle glaucoma. October 2010. URL: one.aao.org/CE/PracticeGuidelines/PPP.aspx?sid=ca9ec1b5-2567-4e85-96f6-b6540e5ac5a1. Available from Internet. Accessed 2012 May 30.
2. American Glaucoma Society. Glaucoma basics & frequently asked questions. URL: americanglaucomasociety.net/patients/faqs. Available from Internet. Accessed 2016 April 21.
3. Lumigan (bimatoprost) [prescribing information]. Irvine, CA: Allergan, Inc.; 2016 August.
4. Rhopressa (netarsudil) [prescribing information]. Irvine, CA: Aerie Pharmaceuticals, Inc.; 2017 December.
5. Rocklatan™ (netarsudil and latanoprost) [prescribing information]. Irvine, CA: Aerie Pharmaceuticals, Inc.; 2019 March.

6. Travatan Z (travoprost) [prescribing information]. Fort Worth, TX: Alcon Laboratories, Inc.; 2017 September.
7. Uusitalo H, Pillunat L, Ropo A. 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;88:12-9.
8. Vyzulta prescribing information. Bridgewater, NJ: Bausch & Lomb Incorporated; 2017 November.
9. Xalatan (latanoprost) [prescribing information]. New York, NY: Pfizer Inc.; 2017 April.
10. Zioptan (tafluprost) [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; 2014 August.

APPROVAL HISTORY

September 13, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 12, 2012: Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs. Added Zioptan to Step-2 of the Glaucoma Step Therapy program
2. May 14, 2013: No changes
3. October 8, 2013: Administrative update: Removed requirement of 30-day trial and replaced with just a previous trial of the medication.
4. April 1, 2014: Administrative Update: Removed language pertaining to the Generic Focused Formulary and added the EHB MA/RI Formulary.
5. May 13, 2014: No changes
6. May 12, 2015: No changes
7. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
8. May 10, 2016: Added the Automated Step Therapy Coverage Criteria. Added limitation #2: "Non-covered glaucoma medications for all Commercial formularies include the following brand-name products: Xalatan. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives and submit a formulary exception request to the plan as indicated."
9. November 15, 2016: Due to discontinuation of Lumigan® 0.03%, administrative update to clarify that Lumigan® 0.01% and generic bimatoprost 0.03% are Step-2 medications.
10. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
11. November 14, 2017: No changes
12. April 10, 2018: Added Vyzulta to the list of step 2 medications
13. August 7, 2018: Added Rhopressa to step 3 and added criteria for step 3 drugs, and added criteria under Step-2 criteria allowing authorization if the Member has a physician documented contraindication or intolerance to a Step-1 medication, and added the use of samples or vouchers/coupons for brand name medications as a limitation.
14. February 12, 2019: Administrative update to template. Revised the step-therapy language. Added Xelpros to Step 2 drugs.
15. September 10, 2019: Added Rocklatan to the list of step 3 medications.
16. April 14, 2020: Effective July 1, 2020: Travatan Z will be non-covered for all Commercial and Direct Plans. The generic is listed on step-2.

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.