



PRIOR AUTHORIZATION POLICY

- POLICY:** Ophthalmic – Glaucoma – Prostaglandins Prior Authorization Policy
- Bimatoprost 0.03% ophthalmic solution – generic only
 - Lumigan® (bimatoprost 0.01% ophthalmic solution – Allergan)
 - Rocklatan™ (netarsudil 0.02%/latanoprost 0.005% ophthalmic solution – Aerie)
 - Travatan® Z (travoprost 0.004% ophthalmic solution [benzalkonium chloride-free] – Novartis, generic)
 - Vyzulta™ (latanoprostene bunod 0.024% ophthalmic solution – Bausch + Lomb)
 - Xalatan® (latanoprost 0.005% ophthalmic solution – Pfizer, generic)
 - Xelpros™ (latanoprost 0.005% ophthalmic emulsion – Sun)
 - Zioptan® (tafluprost 0.0015% ophthalmic solution – Théa, generic)

REVIEW DATE: 05/15/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

The various ophthalmic prostaglandin products are indicated for the reduction of elevated intraocular pressure (IOP) in patients with **open-angle glaucoma** or **ocular hypertension**.¹⁻⁸ All of these are single-entity products, except Rocklatan, which is a combination product containing a rho kinase inhibitor (netarsudil) and a prostaglandin analog (latanoprost). Bimatoprost 0.03% ophthalmic solution is also marketed as Latisse®, indicated to treat hypotrichosis of the eyelashes by increasing their growth including length, thickness, and darkness.⁹ Of note, Latisse is not included in this policy.

Glaucoma, a disease that damages the eye's optic nerve, is the leading cause of blindness in people > 60 years old.¹⁰ Reduction of IOP, regardless of the pretreatment IOP, reduces the

risk of disease progression.¹¹ In addition, IOP reduction may prevent the onset to early glaucoma in patients with ocular hypertension.

Normal-tension glaucoma is a form of open-angle glaucoma with a presenting iOP in the normal range. IOP is generally between 11 and 12 mmHg; but a cut-off of 21 mmHg is often applied to define this condition.¹² Normal-tension glaucoma is also referred to as normal or low-pressure glaucoma. Additionally, the American Academy of Ophthalmology guidelines on primary open-angle glaucoma include normal-tension glaucoma in the recommendations for care, stating that lowering IOP reduces the risk of developing primary open-angle glaucoma and slows the progression of primary open-angle glaucoma, including normal-tension open-angle glaucoma.¹¹

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of ophthalmic prostaglandins for patients < 60 years of age. This age edit (for patients < 60 years of age) is used to monitor for appropriate use and to screen for cosmetic use. Prescription benefit coverage of these products for cosmetic conditions is not recommended. All approvals are provided for the duration noted below. For patients ≥ 60 years of age, coverage will be approved at the point of service. Prior Authorization and prescription benefit coverage is not recommended for Latisse.

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- **Zioptan® (tafluprost 0.0015% ophthalmic solution – Théa, generic)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

- 1. Ocular Hypertension.** Approve for 1 year.
- 2. Open-Angle Glaucoma.** Approve for 1 year.
Note: Open-angle glaucoma includes normal-tension glaucoma, which is also referred to as low-tension glaucoma or normal-pressure glaucoma.

CONDITIONS NOT COVERED

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is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 1. Cosmetic Conditions** (e.g., eyelash growth). Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical pharmacy benefit.
- Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

- Xalatan® ophthalmic solution [prescribing information]. New York, NY: Pfizer; December 2022.
- Lumigan® ophthalmic solution [prescribing information]. Madison, NJ: Allergan; March 2022.
- Travatan® Z ophthalmic solution [prescribing information]. East Hanover, NJ: Novartis; May 2020.
- Zioptan® ophthalmic solution [prescribing information]. France: Théa; May 2022.
- Vyzulta® ophthalmic solution [prescribing information]. Bridgewater, NJ: Bausch + Lomb; May 2019.
- Bimatoprost 0.03% ophthalmic solution [prescribing information]. Somerset, NJ: Micro Labs; January 2023.
- Rocklatan™ ophthalmic solution [prescribing information]. Irvine, CA: Aerie; June 2020.
- Xelpros® ophthalmic emulsion [prescribing information]. Cranbury, NJ: Sun; June 2022.
- Latisse® ophthalmic solution [prescribing information]. Madison, NJ: Allergan; August 2021.
- Boyd K. Glaucoma. Available at: <https://www.aao.org/eye-health/diseases/what-is-glaucoma>. Last reviewed on December 4, 2023. Accessed on May 2, 2024.
- Gedde SJ, Vinod K, Wright MW, et al. Primary open-angle glaucoma Preferred Practice Pattern® guidelines. The American Academy of Ophthalmology. 2020. Available at: <http://www.aao.org/guidelines-browse?filter=preferredpracticepatterns>. Accessed on May 2, 2024.
- Gosling D, Meyer JJ. Normal tension glaucoma. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK576377/#:~:text=Normal%2Dtension%20glaucoma%20is%20a,visual%20morbidity%20in%20most%20patients>. Last update, December 12, 2022. Accessed on May 2, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria change.	04/26/2023

Annual Revision	No criteria change.	05/15/2024
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