Drug Coverage Policy

Effective Date.....09/01/2024
Coverage Policy Number.....IP0027
Policy Title..... Prostaglandins

Ophthalmic – Glaucoma – Prostaglandins

- Iyuzeh™ (latanoprost 0.005% ophthalmic solution [preservative-free] – Théa)
- Lumigan® (bimatoprost 0.01% ophthalmic solution – Allergan)
- Rhopressa® (netarsudil 0.02% ophthalmic solution - Alcon)
- 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)

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 Healthcare Coverage Policy

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]

Medical Necessity Criteria

Ophthalmic Prostaglandins is considered medically necessary when the following criteria are met:

FDA-Approved Indications

1. **Ocular Hypertension.** Approve for 1 year if the patient meets the following:
   A. Preferred product criteria is met for the products listed in the below tables

2. **Open-Angle Glaucoma.** Approve for 1 year if the patient meets the following:
   Note: Open-angle glaucoma includes normal-tension glaucoma, which is also referred to as low-tension glaucoma or normal-pressure glaucoma.
   A. Preferred product criteria is met for the products listed in the below tables

Employer Plans:

Product	Criteria
Iyuzeh (latanoprost 0.005% ophthalmic solution [preservative-free])	**ONE** of the following (1 or 2): 1. The patient has tried **latanoprost 0.005% ophthalmic solution (generic for Xalatan)** AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] which would result, per the prescriber, in a significant allergy or serious adverse reaction. 2. If according to the prescriber, the patient has a significant allergy/sensitivity to benzalkonium chloride [BAK] or other preservatives
Lumigan (bimatoprost	Failure, contraindication, or intolerance to **TWO** of the following: 1. latanoprost 0.005% ophthalmic solution [BAK preservative] (Xalatan)

Product	Criteria
0.01% ophthalmic solution) Contains benzalkonium chloride (BAK) as preservative	2. travoprost 0.004% ophthalmic solution [ionic buffering system preservative, no BAK] (Travatan Z) 3. tafluprost 0.0015% ophthalmic solution [preservative-free] (Zioptan)
Travatan Z (travoprost 0.004% ophthalmic solution [benzalkonium chloride-free]) Contains sofZia™ ionic buffering system as preservative, no benzalkonium chloride (BAK)	**BOTH** of the following (1 and 2): 1. The patient has tried the bioequivalent generic product, **travoprost 0.004% ophthalmic solution**, AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction. 2. Failure, contraindication, or intolerance to **ONE** of the following: A. bimatoprost 0.03% ophthalmic solution [BAK preservative] B. latanoprost 0.005% ophthalmic solution [BAK preservative] (Xalatan) C. tafluprost 0.0015% ophthalmic solution [preservative-free] (Zioptan)
Vyzulta (latanoprostene bunod 0.024% ophthalmic solution Contains benzalkonium chloride (BAK) as preservative	Failure, contraindication, or intolerance to **TWO** of the following: 1. bimatoprost 0.03 % ophthalmic solution [BAK preservative] 2. latanoprost 0.005% ophthalmic solution [BAK preservative] (Xalatan) 3. travoprost 0.004% ophthalmic solution [ionic buffering system preservative, no BAK] (Travatan Z) 4. tafluprost 0.0015% ophthalmic solution [preservative-free] (Zioptan)
Xalatan (latanoprost 0.005% ophthalmic solution) Contains benzalkonium chloride as preservative (BAK)	The patient has tried the bioequivalent generic product, **latanoprost 0.005% ophthalmic solution**, AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction.
Xelpros (latanoprost 0.005% ophthalmic emulsion)	**ONE** of the following (1 or 2): 1. The patient has tried **latanoprost 0.005% ophthalmic solution (generic for Xalatan)** AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] which would result, per the prescriber, in a significant allergy or serious adverse reaction.

Product	Criteria
Contains potassium sorbate 0.47% as preservative, no benzalkonium chloride (BAK)	2. If according to the prescriber, the patient has a significant allergy/sensitivity to benzalkonium chloride [BAK]
Zioptan (tafluprost 0.0015% ophthalmic solution Preservative-free	**BOTH** of the following (1 and 2): 1. The patient has tried the bioequivalent generic product, **tafluprost 0.0015% ophthalmic solution**, AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction. 2. Failure, contraindication, or intolerance to **ONE** of the following: A. bimatoprost 0.03 % ophthalmic solution [BAK preservative] B. latanoprost 0.005% ophthalmic solution [BAK preservative] (Xalatan) C. travoprost 0.004% ophthalmic solution [ionic buffering system preservative, no BAK] (Travatan Z)

Individual and Family Plans:

Product	Criteria
Iyuzeh (latanoprost 0.005% ophthalmic solution [preservative-free])	**ONE** of the following (1 or 2): 1. The patient has tried **latanoprost 0.005% ophthalmic solution (generic for Xalatan**) AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] which would result, per the prescriber, in a significant allergy or serious adverse reaction. 2. If according to the prescriber, the patient has a significant allergy/sensitivity to benzalkonium chloride [BAK] or other preservatives
Lumigan (bimatoprost 0.01% ophthalmic solution) Contains benzalkonium chloride (BAK) as preservative	Failure, contraindication, or intolerance to **TWO** of the following: 1. latanoprost 0.005% ophthalmic solution [BAK preservative] (Xalatan) 2. travoprost 0.004% ophthalmic solution [ionic buffering system preservative, no BAK] (Travatan Z) 3. tafluprost 0.0015% ophthalmic solution [preservative-free] (Zioptan) [may require prior authorization]
Rhopressa (netarsudil 0.02% ophthalmic solution)	Failure, contraindication, or intolerance to **BOTH** of the following: 1. **ONE** ophthalmic prostaglandin analog Note: Examples include: bimatoprost 0.03% ophthalmic solution, bimatoprost [Lumigan] 0.01% ophthalmic solution [may require prior authorization], latanoprost [Xalatan]

Product	Criteria
	0.005% ophthalmic solution, tafluprost [Zioptan] 0.0015% ophthalmic solution[may require prior authorization], travoprost [Travatan Z] 0.004% ophthalmic solution) 2. **EITHER** of the following (1 or 2): A. Trial of another class of therapy (for example, ophthalmic beta-blockers, alpha agonists, parasympathomimetics, topical or oral carbonic anhydrase inhibitors) B. Trial of a second prostaglandin analog (for example, bimatoprost 0.03% ophthalmic solution, bimatoprost [Lumigan] 0.01% ophthalmic solution [may require prior authorization], latanoprost [Xalatan] 0.005% ophthalmic solution, tafluprost [Zioptan] 0.0015% ophthalmic solution [may require prior authorization], travoprost [Travatan Z] 0.004% ophthalmic solution)
Rocklatan (netarsudil 0.02%/latanoprost 0.005% ophthalmic solution)	Inability to use single agents Rhopressa [may require prior authorization] AND latanoprost 0.005% ophthalmic solution [Xalatan] concurrently
tafluprost 0.0015% ophthalmic solution	**ONE** of the following: 1. **Patient without benzalkonium chloride sensitivity:** Failure, contraindication, or intolerance to **TWO** of the following: A. bimatoprost 0.03 % ophthalmic solution [BAK preservative] B. latanoprost 0.005% ophthalmic solution [BAK preservative] (Xalatan) C. travoprost 0.004% ophthalmic solution [ionic buffering system preservative, no BAK] (Travatan Z) 2. **Patient with benzalkonium chloride sensitivity:** Failure, contraindication or intolerance to travoprost 0.004% ophthalmic solution [ionic buffering system preservative, no BAK] (Travatan Z) 3. Patient has sensitivity to ophthalmic preservatives other than benzalkonium chloride (for example, potassium sorbate or ionic buffering systems like sofZia™)
Travatan Z (travoprost 0.004% ophthalmic solution [benzalkonium chloride-free] Contains sofZia™ ionic buffering system as preservative, no	**BOTH** of the following (1 and 2): 1. The patient has tried the bioequivalent generic product, **travoprost 0.004% ophthalmic solution**, AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction. 2. Failure, contraindication, or intolerance to **ONE** of the following: A. bimatoprost 0.03% ophthalmic solution [BAK preservative]

Product	Criteria
benzalkonium chloride (BAK)	B. latanoprost 0.005% ophthalmic solution [BAK preservative] (Xalatan) C. tafluprost 0.0015% ophthalmic solution [preservative-free] (Zioptan) [may require prior authorization]
Vyzulta (latanoprostene bunod 0.024% ophthalmic solution Contains benzalkonium chloride (BAK) as preservative	Failure, contraindication, or intolerance to **TWO** of the following: 1. bimatoprost 0.03 % ophthalmic solution [BAK preservative] 2. latanoprost 0.005% ophthalmic solution [BAK preservative] (Xalatan) 3. travoprost 0.004% ophthalmic solution [ionic buffering system preservative, no BAK] (Travatan Z) 4. tafluprost 0.0015% ophthalmic solution [preservative-free] (Zioptan) [may require prior authorization]
Xalatan (latanoprost 0.005% ophthalmic solution) Contains benzalkonium chloride as preservative (BAK)	The patient has tried the bioequivalent generic product, **latanoprost 0.005% ophthalmic solution**, AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction.
Xelpros (latanoprost 0.005% ophthalmic emulsion) Contains potassium sorbate 0.47% as preservative, no benzalkonium chloride (BAK)	**ONE** of the following (1 or 2): 1. The patient has tried **latanoprost 0.005% ophthalmic solution (generic for Xalatan**) AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] which would result, per the prescriber, in a significant allergy or serious adverse reaction. 2. If according to the prescriber, the patient has a significant allergy/sensitivity to benzalkonium chloride [BAK]
Zioptan (tafluprost 0.0015% ophthalmic solution Preservative-free	**BOTH** of the following (1 and 2): 1. The patient has tried the bioequivalent generic product, **tafluprost 0.0015% ophthalmic solution** [may require prior authorization], AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction 2. Failure, contraindication, or intolerance to **ONE** of the following: A. bimatoprost 0.03 % ophthalmic solution [BAK preservative]

Product	Criteria
	B. latanoprost 0.005% ophthalmic solution [BAK preservative] (Xalatan) C. travoprost 0.004% ophthalmic solution [ionic buffering system preservative, no BAK] (Travatan Z)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered not medically necessary, 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.

References

1. Xalatan® ophthalmic solution [prescribing information]. New York, NY: Pfizer; December 2022.
2. Lumigan® ophthalmic solution [prescribing information]. Madison, NJ: Allergan; March 2022.
3. Travatan® Z ophthalmic solution [prescribing information]. East Hanover, NJ: Novartis; May 2020.
4. Zioptan® ophthalmic solution [prescribing information]. France: Théa; May 2022.
5. Vyzulta® ophthalmic solution [prescribing information]. Bridgewater, NJ: Bausch + Lomb; May 2019.
6. Bimatoprost 0.03% ophthalmic solution [prescribing information]. Somerset, NJ: Micro Labs; January 2023.
7. Rocklatan™ ophthalmic solution [prescribing information]. Irvine, CA: Aerie; June 2020.
8. Xelpros® ophthalmic emulsion [prescribing information]. Cranbury, NJ: Sun; June 2022.
9. Latisse® ophthalmic solution [prescribing information]. Madison, NJ: Allergan; August 2021.
10. 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.
11. 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.
12. 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.

Revision Details

Type of Revision	Summary of Changes	Date

Annual Revision	**Policy Name Change: Updated** Policy Name from "Ophthalmic Glaucoma Agents - Prostaglandin Analogs and Rho Kinase Inhibitors" to "Ophthalmic – Glaucoma – Prostaglandins." **No criteria changes.**	09/01/2024

The policy effective date is in force until updated or retired.