Clinical Policy: Latanoprostene Bunod (Vyzulta)

Reference Number: ERX.NPA.61
Effective Date: 03.01.18
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Latanoprostene bunod (Vyzulta®) is a prostaglandin analog that is metabolized into two moieties, latanoprost acid and a butanediol mononitrate which releases nitric oxide.

FDA Approved Indication(s)
Vyzulta is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Vyzulta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Open-Angle Glaucoma, Ocular Hypertension (must meet all)**:**

1. Diagnosis of open-angle glaucoma or ocular hypertension;
2. Age ≥ 17 years;
3. Failure of two of the following generic ophthalmic agents, each from a different therapeutic class, at up to maximally indicated doses, unless clinically significant adverse events are experienced or all are contraindicated: prostaglandin analog (e.g., latanoprost), ophthalmic beta-blocker (e.g., timolol), ophthalmic alpha-2 adrenergic agonist (e.g., brimonidine);
4. Dose does not exceed one bottle per 30 days.

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Open-Angle Glaucoma, Ocular Hypertension (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one bottle per 30 days.

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
IOP: intraocular pressure

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
latanoprost (Xalatan®)	1 drop in the affected eye(s) QD in the evening	1 drop/eye/day
timolol (Timoptic®)	1 drop in the affected eye(s) BID	2 drops/eye/day
brimonidine (Alphagan® P)	1 drop in the affected eye(s) TID	3 drops/eye/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Open-angle glaucoma, ocular hypertension	1 drop in the affected eye(s) qPM	1 bottle/30 days

VI. Product Availability

Ophthalmic solution: 0.024% (2.5 mL, 5 mL)

VII. References

1. Vyzulta Prescribing Information. Bridgewater, NJ: Bausch & Lomb Incorporated; June 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/207795s002lbl.pdf. Accessed October 4, 2021.
2. Primary Open-Angle Glaucoma Preferred Practice Pattern® Guidelines. 2021. Available at: https://www.aaojournal.org/article/S0161-6420(20)31024-1/fulltext. Accessed October 4, 2021.
3. Weinreb R, Sforzolini B, Vittitow J, et al. Latanoprostene bunod 0.024% versus timolol maleate 0.5% in subjects with open-angle glaucoma or ocular hypertension: the APOLLO study. *Ophthalmology*. 2016; 123(5):965-973.
4. Medeiros F, Martin K, Peace J, et al. Comparison of latanoprostene bunod 0.024% and timolol maleate 0.5% in open-angle glaucoma or ocular hypertension: the LUNAR study. *Am J Ophthalmol.* 2016; 168:250-259.
5. Weinreb R, Ong T, Sforzolini B, et al. A randomized, controlled comparison of latanoprostene bunod and latanoprost 0.005% in the treatment of ocular hypertension and open angle glaucoma: the VOYAGER study. *Br J Ophthalmol.* 2015; 99:738-745.

6. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed October 4, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	12.12.17	02.18
1Q 2019 annual review: no significant changes; references reviewed and updated.	11.06.18	02.19
1Q 2020 annual review: added Medicaid line of business with 12 month approval durations; increased required number of preferred ophthalmic agents from 1 to 2; references reviewed and updated.	12.18.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	10.22.20	02.21
1Q 2022 annual review: no significant changes; specified that the requirement for the prior trial of the two generic ophthalmic agents be for agents from different therapeutic classes; references reviewed and updated.	10.04.21	02.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.