RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title: **Latanoprostene Bunod (Vyzulta)**
Policy Number: **RxA.566**
Drug(s) Applied: **Latanoprostene bunod (Vyzulta®)**
Last Review Date: **01/2020**
Line of Business: **Commercial**

Background

Latanoprostene bunod (Vyzulta®) is a prostaglandin analog that is metabolized into two moieties, latanoprost acid and a butanediol mononitrate which releases nitric oxide.
It is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

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

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

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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 a generic ophthalmic prostaglandin analog (e.g., latanoprost), ophthalmic beta-blocker (e.g., timolol), or ophthalmic alpha-2 adrenergic agonist (e.g., brimonidine) unless contraindicated or clinically significant adverse events are experienced;
4. Dose does not exceed one bottle every 30 days.

Approval duration: Length of Benefit

II. Continued Therapy

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

1. Currently receiving medication via RxAdvance benefit 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 every 30 days.

Approval duration: Length of Benefit

III. Appendices

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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
latanoprost (Xalatan®)	1 drop in the affected eye(s) once daily 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

References

1. Vyzulta Prescribing Information. Bridgewater, NJ: Bausch & Lomb Incorporated; June 2018. Available at: www.bausch.com. Accessed November 6, 2018.
2. Primary Open-Angle Glaucoma Preferred Practice Pattern® Guidelines. Available at: www.aaojournal.org. Accessed November 6, 2018.
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 November 6, 2018.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	03/06/2020