RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	latanoprostene bunod
Policy Number:	RxA.566
Drug(s) Applied:	Vyzulta®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
latanoprostene bunod (Vyzulta®)	Open-angle glaucoma, Ocular hypertension	1 drop in the affected eye(s) once daily in the evening	1 bottle/30 days

Dosage Forms

- 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
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy ;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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

- Contraindication(s):
  - None reported

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information
None

References

1. Vyzulta® Prescribing Information. Bridgewater, NJ: Bausch & Lomb Incorporated; May 2019. Available at: https://www.vyzulta.com/ . Accessed September 22, 2020
2. Primary Open-Angle Glaucoma Preferred Practice Pattern® Guidelines. Available at: www.aaojournal.org. Accessed September 22, 2020.
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 September 22, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title was updated 2. Line of business policy applies to was updated to All lines of business 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Reference reviewed and updated.	09/22/2020	12/07/2020