Clinical Policy: Latanoprostene Bunod (Vyzulta)

Reference Number: CP.PMN.108
Effective Date: 03.01.18
Last Review Date: 02.22
Line of Business: Commercial, HIM, 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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® 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 every 30 days.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, 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 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) 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
Per SDC, modified redirection to require two alternatives consistent with the non-formulary policy.	04.30.18	
1Q 2019 annual review: no significant changes. References reviewed and updated.	11.06.18	02.19
1Q 2020 annual review: policy combined for Commercial and Medicaid lines of business; Commercial: increased number of preferred ophthalmic agents from 1 to 2; references reviewed and updated.	12.04.19	02.20
1Q 2021 annual review: no significant changes; added HIM line of business since Vyzulta is NF and policy is slightly stricter than NF policy; references to HIM.PHAR.21 revised to HIM.PA.154; 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
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.