

**Clinical Policy: Glaucoma Agents** 

Reference Number: CP.PMN.286

Effective Date: 03.01.23 Last Review Date: 11.25

Line of Business: Commercial, HIM, Medicaid Revision Log

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

#### **Description**

The following are ophthalmic agents for glaucoma requiring prior authorization:

- Prostaglandin analog: latanoprostene bunod (Vyzulta<sup>®</sup>), latanoprost (Iyuzeh<sup>™</sup>)
- Rho kinase inhibitor: netarsudil (Rhopressa®)
- Combination Rho kinase inhibitor/prostaglandin analog: netarsudil/latanoprost (Rocklatan®)
- Combination carbonic anhydrase inhibitor/alpha<sub>2</sub> adrenergic receptor agonist: brinzolamide/brimonidine tartrate (Simbrinza<sup>®</sup>)

### **FDA Approved Indication(s)**

Iyuzeh, Rhopressa, Rocklatan, Simbrinza, and Vyzulta are indicated for the reduction of elevated intraocular pressure 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<sup>®</sup> that ophthalmic agents for glaucoma are **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

- A. Open-Angle Glaucoma or Ocular Hypertension (must meet all):
  - 1. Diagnosis of open-angle glaucoma or ocular hypertension;
  - 2. Age is one of the following (a, b, or c):
    - a.  $\geq 17$  years for Vyzulta;
    - b.  $\geq$  18 years for Iyuzeh, Rhopressa, or Rocklatan;
    - c.  $\geq 2$  years for Simbrinza;
  - 3. Failure of two of the following formulary ophthalmic agents\* (*generics preferred*), each from different therapeutic classes, at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated (a-e, *see Appendix B for examples*):
    - \*For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395
    - a. Prostaglandin analog (e.g., latanoprost, tafluprost, travoprost);
    - b. Beta-blocker (e.g., betaxolol, carteolol, timolol, levonbunolol);
    - c. Alpha-2 adrenergic agonist (e.g., apraclonidine, brimonidine);
    - d. Parasympathomimetics (e.g., pilocarpine);
    - e. Carbonic anhydrase inhibitors (e.g., brinzolamide, dorzolamide);



4. Dose does not exceed the FDA-approved maximum dose (see *Section V*).

**Approval duration:** 

**Medicaid/HIM** – 12 months

**Commercial** – 12 months or duration of request, whichever is less

#### **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 or 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 the FDA-approved maximum dose (see *Section V*).

#### **Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – 12 months or duration of request, whichever is less

#### **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 2 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 policies – 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.

*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.

	and may require prior authorization.				
Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose			
Prostaglandin analog examples:  • Lumigan® (bimatoprost)  • latanoprost (Xalatan®)  • tafluprost (Zioptan®)  • travoprost (Travatan Z®)	1 drop in the affected eye(s) once daily in the evening	1 drop/eye/day			
Beta-blocker examples:  • betaxolol (Betopic-S®)  • carteolol  • timolol (Timoptic Ocudose®, Betimol®, Istalol®)	Varies	Varies			
Alpha-2 adrenergic agonist examples:  • brimonidine (Alphagan® P)  • apraclonidine 0.5% solution	1 drop in the affected eye(s) three times daily	3 drops/eye/day			
Parasympathomimetic agent example:  • pilocarpine	1 drop into the eye (s) up to four times a day	4 drops/eye/day			
Carbonic anhydrase inhibitor examples:  • brinzolamide (Azopt®)  • dorzolamide	1 drop in the affected eye(s) three times daily	3 drops/eye/day			



Drug Name	<b>Dosing Regimen</b>	Dose Limit/ Maximum Dose
<ul> <li>Combination ophthalmic agent examples:</li> <li>brimonidine tartrate-timolol maleate solution (Combigan®)</li> <li>dorzolamide-timolol solution (Cosopt®)</li> </ul>	1 drop in the affected eye(s) twice daily	2 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):
  - Known hypersensitivity to latanoprost or any other ingredients in this product (*lyuzeh only*)
  - Hypersensitivity to any component of this product, use in neonates and infants under the age of 2 years (*Simbrinza only*)
- Boxed warning(s): none reported

## V. Dosage and Administration

Drug Name	Dosing Regimen	<b>Maximum Dose</b>
Latanoprost (Iyuzeh)	1 drop in the affected eye(s) once	1 drop/eye/day
	daily in the evening	
Latanoprostene bunod (Vyzulta)	1 drop in the affected eye(s) once	1 drop/eye/day
	daily in the evening	
Netarsudil (Rhopressa),	1 drop in the affected eye(s) once	1 drop/eye/day
netarsudil/latanoprost (Rocklatan)	daily in the evening	
Brinzolamide/brimonidine	1 drop in the affected eye(s) TID	3 drops/eye/day
(Simbrinza)	-	

VI. Product Availability

Drug Name	Availability
Latanoprost (Iyuzeh)	Ophthalmic solution: 0.005% (50 mcg/mL) supplied in
	single-dose containers
Latanoprostene bunod	Ophthalmic solution: 0.024% (2.5 mL, 5 mL)
(Vyzulta)	
Netarsudil (Rhopressa)	Ophthalmic solution: 0.02% (0.2 mg/mL) in a 2.5 mL total
	volume per bottle
Netarsudil/latanoprost	Ophthalmic solution: 0.02% (0.2 mg/mL) netarsudil/
(Rocklatan)	0.005% (0.05 mg/mL) latanoprost in a 2.5 mL total
	volume per bottle
Brinzolamide/brimonidine	Ophthalmic solution: 1% (10 mg/mL) brinzolamide with
(Simbrinza)	0.2% (2 mg/mL) brimonidine tartrate in a 8 mL total
	volume bottle



#### VII. References

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- 6. American Academy of Ophthalmology Preferred Practice Pattern Glaucoma Committee. Preferred Practice Pattern® Guidelines. Primary Open-Angle Glaucoma San Francisco, CA: American Academy of Ophthalmology; November 2020. Available at: https://www.aao.org/ppp. Accessed August 27, 2025.
- 7. 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.
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- 11. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; 2025. URL: www.clinicalkeys.com/pharmacology.
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- 13. Barcharach J, Dbiner HB, Levy B, et al. Double-masked, randomized, dose-response study of AR-133324 versus latanoprost in patients with elevated intraocular pressure. Am J Ophthalmol. 2015 Feb. 122(2)302-307. doi:10.1016/j.ophtha.2014.08.022.

Reviews, Revisions, and Approvals	Date	P&T
		Approval Date
	04.06.00	
Policy created: adapted from previously approved individual drug	01.06.23	02.23
policies – CP.PMN.118 Rhopressa/ Rocklatan and CP.PMN.108		
Vyzulta (all to be retired); RT4: added newly FDA approved		
agents, Omlonti and Iyuzeh; references reviewed and updated.		



Reviews, Revisions, and Approvals	Date	P&T Approval
		Date
1Q 2024 annual review: no significant changes; references	10.16.23	02.24
reviewed and updated		
1Q 2025 annual review: removed discontinued drug Omlonti from	11.14.24	02.25
criteria; in initial approval criteria, reformatted therapeutic drug		
classes into individual rows, added example drugs in each		
therapeutic class, and revised failure of two generic ophthalmic		
agents to two formulary ophthalmic agents (generics preferred); in		
Appendix B, added example drugs for each therapeutic drug class		
and added example combination ophthalmic agents; references		
reviewed and updated.		
Added Simbrinza (adopted from HIM.PA.15, policy to retire) to	08.07.25	11.25
this policy; added step therapy bypass for IL HIM per IL HB 5395.		

### **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.

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#### 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.

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