Clinical Policy: Netarsudil (Rhopressa)

Reference Number: PA.CP.PMN.118
Effective Date: 02.13.18
Last Review Date: 04.17.19

Revision Log

Description
Netarsudil (Rhopressa®) is a Rho kinase inhibitor.

FDA Approved Indication(s)
Rhopressa is 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® that Rhopressa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of open-angle glaucoma or ocular hypertension;
2. Age ≥ 18 years;
3. Failure of two of the following generic ophthalmic agents, each from different therapeutic classes, at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced: prostaglandin analog (e.g., latanoprost), ophthalmic beta-blocker (e.g., timolol), ophthalmic alpha-2 adrenergic agonist (e.g., brimonidine), parasympathomimetics (e.g., pilocarpine), or carbonic anhydrase inhibitors (e.g. dorzolamide);
4. Dose does not exceed 1 drop/eye/day (2 bottles or 5 mL/30 days).

Approval duration: 12 months

B. Other diagnoses/indications

1. Currently receiving medication via PA Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53.

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 drop/eye/day (2 bottles or 5 mL/30 days.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53.

III. 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.

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) twice daily	2 drops/eye/day
brimonidine (Alphagan® P)	1 drop in the affected eye(s) three times daily	3 drops/eye/day
pilocarpine (Isoto Carpine®)	1 drop into the eye (s) up to four times a day	4 drops/eye/day
dorzolamide (Trusopt®)	1 drop in the affected eye(s) three times daily	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

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Open-angle glaucoma	1 drop into the affected eye(s) once daily in the evening	1 drop/eye/day

V. Product Availability

Ophthalmic solution: 0.02% (0.2 mg/mL) in a 2.5 mL total volume per bottle

VI. References

1. Rhopressa Prescribing Information. Irvine, CA: Aerie Pharmaceutical, Inc.; October 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208254lbl.pdf. Accessed February 5, 2019.
2. Prum BE, Lim MC, Mansberger SL, et al. Primary Open-Angle Glaucoma Suspect Preferred Practice Pattern® Guidelines. Ophthalmology. 2016 Jan;123(1):P112-51. doi: 10.1016/j.ophtha.2015.10.055.
3. Serle JB, Katz LJ, Mclaurin E, et al. Two Phase 3 clinical trials comparing the safety and efficacy of netarsudil to timolol in patients with elevated intraocular pressure. Am J Ophthalmol. 2017 Nov 30. pii: S0002-9394(17)30513-5. doi: 10.1016/j.ajo.2017.
4. 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
Policy created.	02.13.18	04.18.18
2Q 2019 annual review: references reviewed and updated.	04.17.19	