

<b>Clinical Policy Title:</b>	netarsudil, netarsudil/latanoprost
<b>Policy Number:</b>	RxA.269
<b>Drug(s) Applied:</b>	Rocklatan®, Rhopressa®
<b>Original Policy Date:</b>	02/07/2020
<b>Last Review Date:</b>	09/14/2020
<b>Line of Business Policy Applies to:</b>	All lines of business

## Background

Netarsudil (Rhopressa®) is a Rho kinase inhibitor.

Netarsudil and latanoprost (Rocklatan®) is a fixed dose combination of netarsudil and latanoprost, a prostaglandin analogue.

Rhopressa® and Rocklatan® are indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

## Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
netarsudil (Rhopressa®), netarsudil/latanoprost (Rocklatan®)	Open-angle glaucoma or ocular hypertension	1 drop into the affected eye(s) once daily in the evening	1 drop/eye/day

## Dosage Forms

Drug Name	Availability
Netarsudil (Rhopressa®)	Ophthalmic solution: Netarsudil 0.02% (0.2 mg/mL) in a 2.5 mL total volume per bottle
Netarsudil/Latanoprost (Rocklatan®)	Ophthalmic solution: Netarsudil 0.02% (0.2 mg/mL) and Latanoprost 0.005% (0.05 mg/mL) in a 2.5 mL total volume per bottle

## Clinical Policy

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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 or Ocular Hypertension (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. Medication should be prescribed by, or in consultation with ophthalmologist;
5. Dose does not exceed 1 drop/eye/day +.

**Approval Duration**

**Commercial:** 12 months

**Medicaid:** 12 months

**II. Continued Therapy Approval**

**A. Open-Angle Glaucoma or 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 1 drop/eye/day .

**Approval Duration**

**Commercial:** 12 months

**Medicaid:** 12 months

**III. Appendices**

**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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
brimonidine (Alphagan® P)	1 drop in the affected eye(s) three times daily	3 drops/eye/day
pilocarpine (Isopto 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

**APPENDIX D: General Information**

- none

**References**

1. Rhopressa® Prescribing Information. Irvine, CA: Aerie Pharmaceutical, Inc.; March 2019. Available at: [www.rhopressa.com](http://www.rhopressa.com). Accessed July 10, 2020.
2. Rocklatan® Prescribing Information. Irvine, CA: Aerie Pharmaceuticals, Inc.; June 2020 Available at: [www.rocklatan.com](http://www.rocklatan.com). Accessed July 10, 2020.
3. Prum BE, Lim MC, Mansberger SL, et al. Primary Open-Angle Glaucoma Suspect Preferred Practice Pattern (®) Guidelines. Ophthalmology. 2016 Jan;123(1):P112-51. Accessed July 11, 2020.
4. 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: Rho Kinase Elevated IOP Treatment Trial 1 and 2 (ROCKET-1 and ROCKET-2). Am J Ophthalmol. February 2018; 186:116-127. Accessed July 11, 2020.
5. Barcharach J, Dubiner HB, Levy B, et al. Double-masked, randomized, dose-response study of AR-13324 versus latanoprost in patients with elevated intraocular pressure. Am J Ophthalmol. 2015 Feb. 122(2)302-307. Accessed July 11, 2020.
6. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: <http://www.clinicalkey.com>. Updated January 14, 2020. Accessed July 11, 2020.
7. Netarsudil, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: <http://online.lexi.com>. Accessed July 11, 2020.
8. Netarsudil/Latanoprost, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: <http://online.lexi.com>. Accessed July 11, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Policy title table was updated: Clinical Policy Title was updated to " Netarsudil, Netarsudil/Latanoprost". Drug(s) Applied was updated to "Rocklatan®, Rhopressa®". Line of Business Policy Applies to was updated to "All".</li> <li>2. Dosage Forms was updated to "Netarsudil 0.02% (0.2 mg/mL) and Latanoprost 0.005% (0.05 mg/mL)".</li> <li>3. Clinical policy was updated: Approval duration was updated for both Initial and Continued Approval Criteria; Prescriber has been specified as ophthalmologist; Continued Approval was rephrased to "Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy".</li> <li>4. Isopto Carpine® has been corrected in Appendix C.</li> <li>5. Appendix D has been updated to none.</li> <li>6. References were updated.</li> </ol>	07/11/2020	09/14/2020