

Commercial/Healthcare Exchange PA Criteria

Effective: July 25, 2018

Prior Authorization: Rhopressa - Rocklatan

Products Affected: Rhopressa (netarsudil) ophthalmic solution, Rocklatan (netarsudil and latanoprost) ophthalmic solution

Medication Description:

Rhopressa (netarsudil) a Rho kinase (ROCK) inhibitor has been approved by the U.S. Food and Drug Administration in December 18, 2017 to reduce intraocular pressure (IOP) in patients who have ocular hypertension (OHT) or open-angle glaucoma (OAG). Glaucoma affects approximately 2.3 million people in the United States (US). It is the second most common cause of permanent blindness in the US and the most common cause of blindness among African Americans and Hispanics. Two major types of glaucoma have been identified: open-angle and closed-angle. In OAG, there is reduced flow through the trabecular meshwork. OAG accounts for the majority of cases. OHT can be used as a generic term referring to any situation in which IOP is >21 mmHg, the widely accepted upper limit of normal IOP in the general population. OHT has a 10 to 15 times greater prevalence than primary OAG. A 20% reduction in IOP target in people with OHT has been shown to delay or prevent the onset of glaucoma, but treatment goals should be individualized.

Rocklatan (netarsudil/latanoprost) is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. In 2 randomized trials, the average intraocular pressure (IOP) lowering effect of netarsudil 0.02%/latanoprost 0.005% was 1 to 3 mmHg greater than monotherapy with either netarsudil 0.02% or latanoprost 0.005%.

The American Academy of Ophthalmology (AAO) preferred practice guidelines (2015) for the treatment of glaucoma note that the initial therapy choice, prostaglandin analogues are the most frequently used initial eye drops for lowering IOP in patients with glaucoma. The guidelines also state that prostaglandin analogues are the most effective drugs at lowering IOP and that they can be considered as initial medical therapy. The range of IOP reductions reported for each ophthalmic drug class are: prostaglandin analogues, 25% to 33%; beta-blockers, 20% to 25%; alpha-adrenergic agonists, 20% to 25%; and carbonic anhydrase inhibitors, 15% to 20%.⁸ If IOP is inadequately controlled with either a topical beta-blocker or a prostanoid, a topical agent from a different class is typically substituted or added.

Covered Uses: The reduction of intraocular pressure (IOP) in patients who have ocular hypertension (OHT) or open-angle glaucoma (OAG).

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. History of previous therapy tried/failed

Age Restrictions: 18 years of age or older

Coverage Duration: 12 months

Other Criteria:

Approve if the patient meets the following criteria (A AND B):

- A. Patient has a diagnosis of Intraocular pressure (IOP)/ocular hypertension (OHT) or open-angle glaucoma; AND
- B. Patient has had an adequate trial and failure of a prostaglandin inhibitor (eg, latanoprost, bimatoprost, etc.) AND beta-adrenergic antagonist (eg, timolol, betaxolol, etc.).

References:

1. Rhopressa® ophthalmic solution [prescribing information]. Irvine, CA: Aerie Pharmaceuticals, Inc; December 2017.
2. Lu LJ, Tsai JC, Liu J. Novel pharmacologic candidates for treatment of primary open-angle glaucoma. *Yale J Biol Med.* 2017;90(1):111-118.
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: rho kinase elevated IOP treatment trial 1 and 2 (ROCKET-1 and ROCKET-2). *Am J Ophthalmol.* 2018;186:116-127.
4. Data on file (Aerie Pharmaceuticals). A double-masked, randomized, multi-center, active-controlled, parallel group, 6-month study assessing the ocular hypotensive efficacy and safety of netarsudil ophthalmic solution, 0.02% QD compared with timolol maleate ophthalmic solution, 0.5% BID [abstract 170098]. Presented at: the American Academy of Optometry (AAOPT) meeting; Chicago, IL; October 11-14, 2017.
5. Bacharach J, Dubiner HB, Levy B, et al. Double-masked, randomized, dose-response study of AR-13324 versus latanoprost in patients with elevated intraocular pressure. *Ophthalmology.* 2015;122:302-307.
6. Fiscella RG, Lesa TS, Edward D. Glaucoma. In: DiPiro JT, Talbert RL, Yee GC, et al., (Eds). *Pharmacotherapy – A Pathophysiologic Approach.* 7th ed. New York, NY: McGraw-Hill. 2008:1551-1564.
7. Product Information: ROCKLATAN(TM) ophthalmic solution, netarsudil latanoprost ophthalmic solution. Aerie Pharmaceuticals Inc (per manufacturer), Irvine, CA, 2019.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	07/17/2018
2	Update	Addition of new drug: Rocklatan	Prior Authorization Products Affected	08/12/2019