Netarsudil Ophthalmic Products (Rhopressa®, Rocklatan®)

Policy # 00652
Original Effective Date: 12/19/2018
Current Effective Date: 09/14/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the netarsudil ophthalmic products, Rhopressa®‡ and Rocklatan®‡, for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for the netarsudil ophthalmic products, Rhopressa and Rocklatan, will be considered when the following criteria are met:

- Patient is using the requested drug for the reduction of elevated intraocular pressure due to open-angle glaucoma OR for the reduction of elevated intraocular pressure due to ocular hypertension; AND
- Patient is 18 years of age or older; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) a generic ophthalmic prostaglandin (e.g., latanoprost, bimatoprost, travoprost) after at least one month of therapy unless there is clinical evidence or patient history that suggests the required generic products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has tried and failed (e.g., intolerance or inadequate response) a generic ophthalmic beta-adrenergic blocker or combination product (e.g., betaxolol, carteolol, levobunolol, metipranolol, timolol, dorzolamide plus timolol) after at least one month of therapy unless

there is clinical evidence or patient history that suggests the use of the required generic products will be ineffective or cause an adverse reaction to the patient.
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of the netarsudil ophthalmic products, Rhopressa or Rocklatan, when the patient has NOT tried and failed a generic ophthalmic prostaglandin AND a generic ophthalmic beta blocker/combo after at least one month of therapy with each product to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of the netarsudil ophthalmic products, Rhopressa or Rocklatan, when the requested drug is used for a non-FDA approved indication OR in patients younger than 18 years of age to be **investigational.***

Background/Overview

Rhopressa and Rocklatan are both indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Rhopressa is a rho kinase inhibitor, which is believed to reduce intraocular pressure by increasing the outflow of aqueous humor through the trabecular meshwork route. Rocklatan contains the same active ingredient, netarsudil, as Rhopressa with the addition of an ophthalmic prostaglandin, latanoprost. Rhopressa and Rocklatan are both dosed as one drop into the affected eye(s) once daily.

Open angle glaucoma is an optic neuropathy characterized by progressive peripheral visual loss. The peripheral vision loss is often followed by central field loss. Open angle glaucoma is typically accompanied by intraocular pressure increases caused by increased aqueous production and/or decreased aqueous outflow. Ocular hypertension is distinguished from glaucoma in that there are no detectable changes in vision, no evidence of visual field loss, and no damage to the optic nerve.

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Patients diagnosed with ocular hypertension are at an increased risk of developing glaucoma. Typical treatments for open angle glaucoma and ocular hypertension include drug classes such as ophthalmic prostaglandins (e.g. latanoprost) and ophthalmic beta blockers (e.g. timolol), both of which have generic products available in the respective class. Both Rocklatan and Rhopressa provide minimal additional value as compared to the current products available on the market. Therefore, post marketing experience is necessary before any definitive recommendations are available for Rhopressa and Rocklatan and their place in therapy.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Rhopressa was approved in late 2017 for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Rocklatan was approved for the same indication in March of 2019.

Rationale/Source

Rhopressa 0.02% was evaluated in three randomized and controlled clinical trials in patients with open-angle glaucoma or ocular hypertension. The three studies demonstrated up to 5 mmHg (millimeters of mercury) reductions in intraocular pressure for subjects treated with Rhopressa 0.02% once daily in the evening. For patients with baseline intraocular pressure < 25 mmHg, the intraocular pressure reductions with Rhopressa 0.02% dosed once daily were similar to those with timolol 0.5% dosed twice daily. For patients with baseline intraocular pressure equal to or above 25 mmHg, Rhopressa 0.02% resulted in smaller mean intraocular pressure reductions at the morning time points than timolol 0.5% for study visits on days 43 and 90. The difference in mean intraocular pressure reduction between the two treatment groups was as high as 3 mmHg, favoring timolol.

Rocklatan was evaluated in 2 randomized and controlled clinical trials (Study 301 and 302) in patients with open-angle glaucoma and ocular hypertension. Studies 301 and 302 compared intraocular pressure lowering effect of Rocklatan dosed once daily to individually administered Rhopressa once daily and latanoprost once daily. The treatment duration was 12 months for Study 301 and 3 months for Study 302. The average intraocular pressure lowering effect of Rocklatan was 1 to 3 mmHg greater than monotherapy with either Rhopressa or latanoprost throughout 3 months.

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The purpose of this policy is to enforce the FDA approved indication and to promote the utilization of the generically available products for treatment of these conditions.

References

1. Rhopressa [package insert]. Aerie Pharmaceuticals, Incorporated. Irvine, California. Updated December 2017.
2. Open-angle glaucoma treatment. UpToDate. Accessed August 2018.
3. Rocklatan [package insert]. Aerie Pharmaceuticals, Incorporated. Irvine, California. Updated March 2019.

Policy History

Original Effective Date: 12/19/2018
Current Effective Date: 09/14/2020

12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. New policy.
08/01/2019	Medical Policy Committee review
08/14/2019	Medical Policy Implementation Committee approval. Changed title to Netarsudil Ophthalmic Products (Rhopressa, Rocklatan). Added Rocklatan to the policy.
08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. Travatan Z is now available as a generic. Changed Travatan Z to generic travoprost in the policy.

Next Scheduled Review Date: 08/2021

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety,

effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company

recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.