BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 8/02/18
LAST REVIEW DATE: 8/02/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

RHOPRESSA® (netarsudil dimesylate) ophthalmic solution

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

RHOPRESSA® (netarsudil dimesylate) ophthalmic solution (cont.)

Criteria:

- **Criteria for initial therapy:** Rhopressa (netarsudil demethylase) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is an Ophthalmologist or Optometrist
  2. Individual is 18 years of age or older
  3. A confirmed diagnosis of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension
  4. Intraocular pressure is > 21 mmHg
  5. Individual has failure, contraindication or intolerance to **ALL** the following preferred step therapy agents:
     - Two trials of an ophthalmic prostaglandin analog (i.e. Lumigan, Xalatan, Vyzulta, Zioptan, Travatan Z)
     - Two trials of an ophthalmic beta-blocker (i.e. Betagan, Betoptic-S, Timolol etc.)

  Initial approval duration: Two 2.5 mL bottle per 30 days for 6 months

- **Criteria for continuation of coverage (renewal request):** Rhopressa (netarsudil demethylase) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by an Ophthalmologist or Optometrist
  2. Individual's condition has responded while on therapy
     - Response is defined as:
       - Achieved and maintains at least a 25% reduction in IOP over baseline
  3. Individual has been adherent with the medication

  Renewal duration: Two 2.5 mL bottle per 30 days for 12 months

Description:

Rhopressa (netarsudil demethylase) is a Rho kinase inhibitor indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Rhopressa (netarsudil demethylase) is believed to reduce IOP by increasing the outflow of aqueous humor through the trabecular meshwork route, however the exact mechanism is unknown.

Glaucoma is a general term used for a group of eye diseases characterized by IOP. However, glaucoma should be referred to as an optic neuropathy rather than a disease of high IOP. Optic nerve damage results in a

RHOPRESSA® (netarsudil dimesylate) ophthalmic solution (cont.)

progressive loss of retinal ganglion cell axons, manifested initially as visual field loss and, ultimately, irreversible blindness if left untreated.

There are three types of glaucoma: open-angle glaucoma, angle-closure glaucoma, and developmental glaucoma. Glaucoma can also be referred as acute, subacute, and chronic.

Open-angle glaucoma is characterized initially by progressive peripheral field loss, followed by central field loss. It is usually but not always seen with increases in IOP. Elevated IOP alone does not establish the diagnosis of open-angle glaucoma. Glaucoma is diagnosed in patients with characteristic nerve damage on fundus examination and visual field testing, usually in the presence of elevated IOP.

Evidence for optic nerve damage is from either or both of the following: optic disc or retinal nerve fiber layer structural abnormalities (e.g., thinning, cupping, or notching of the disc rim, progressive change, nerve fiber layer defects); reliable and reproducible visual field abnormalities (e.g., arcuate defect, nasal step paracentral scotoma, generalized depression) in the absence of other causes or explanations for a field defect.

IOP is thought to be due to increased aqueous humor production and/or reduced outflow of aqueous humor. Lowering IOP has been shown to reduce the risk of progression of visual field loss and/or optic disc changes and is the primary goal of therapy. There is no clear consensus regarding a threshold IOP for the initiation of open-angle glaucoma treatment. There is also no standard guideline for an optimal IOP. If there is evidence of nerve damage occurring despite reaching a specified target IOP value, the IOP must be reduced further. Dose or use of other additional medications should be adjusted based on follow-up visual fields and evaluation for cup progression. Also patients with more advances disc damage and field loss need lower target IOP. Data from Early Manifest Glaucoma Trial (EMGT) and the Collaborative Initial Glaucoma Treatment Study (CIGTS) have suggested a target IOP of ≥ 25-30% below initial IOP

Topical prostaglandins are considered first-line therapy for open-angle glaucoma. Use of combination therapy with other agents from different classes can result in greater reductions in IOP. Pharmacotherapy for glaucoma often requires multiple medications. Topical medications work either by increasing aqueous outflow or by decreasing aqueous production.

Definitions:

Normal Intraocular Pressure:
8-21 mmHg

Agents that reduce IOP:

Agents for Glaucoma				
Drug	**Strength**	**Duration**	**Decrease aqueous production**	**Increase aqueous outflow**
Alpha-2 Adrenergic Agonists				
Apraclonidine	0.5-1%	7 to 12 h	√	NR
Brimonidine	0.1%, 0.15%,0.2%	6 to 8 h	√	√
Beta-Blockers				

RHOPRESSA® (netarsudil dimesylate) ophthalmic solution (cont.)

Betaxolol	0.25-0.5%	>12 h	√	NR
Carteolol	1%	12 h	√	~
Levobunolol	0.25-0.5%	24 h	√	~
Metipranolol	0.3%	24 h	√	~
Timolol	0.25-0.5%	24 h	√	~
Carbonic Anhydrase Inhibitors				
Brinzolamide	1%	≈ 8 h	√	NR
Dorzolamide	2%	8 to 12 h	√	NR
Docosanoid				
Unoprostone	0.15%	12 h	NR	√
Miotics, Cholinesterase Inhibitors				
Echothiophate	0.125%	Days/wks	NR	√
Miotics, Direct-Acting				
Carbachol	0.01%	4-8 h	NR	√
Pilocarpine	1%, 2%,4%	4-12 h	NR	√
Prostaglandin Analogues				
Bimatoprost	0.01-0.03%	24 h	NR	√
Latanoprost	0.005%	24 h	NR	√
Latanoprostene bunod	0.024%	24 h	NR	√
Tafluprost	0.0015%	24 h	NR	√
Travoprost	0.004%	24 h	NR	√
Rho Kinase Inhibitor				
Netarsudil	0.02%	ND		√
Fixed Combinations				
Brimonidine-Timolol	0.2%/0.5%	24 h	√	ND
Brinzolamide-Brimonidine	1%/0.2%	8 h	√	ND
Dorzolamide-Timolol	2%/0.5%	24 h	√	ND
~ = possible activity; ND = no data; NR = no activity reported				

Resources:

Rhopressa. Package Insert. Revised by manufacturer 12/2017. Accessed 4/06/18.

Rhopressa product information accessed 05-03-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7d4f0e3a-5b86-4c43-982a-813b22ae7e22

UpToDate: Open-angle glaucoma: Epidemiology, clinical presentation, and diagnosis. Current through Apr, 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/open-angle-glaucoma-epidemiology-clinical-presentation-and-diagnosis?search=open%20angle%20glaucoma&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

RHOPRESSA® (netarsudil dimesylate) ophthalmic solution (cont.)

UpToDate: Open-angle glaucoma: Treatment. Current through Apr, 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/open-angle-glaucoma-treatment?search=open%20angle%20glaucoma&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.