BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

**PHARMACY COVERAGE GUIDELINE**

# RHOPRESSA® (netarsudil dimesylate) ophthalmic solution Generic Equivalent (if available)

**This Pharmacy Coverage Guideline (PCG):**
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

**Scope**
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

**Instructions & Guidance**
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

## Criteria:

➢ **Criteria for initial therapy:** Rhopressa (netarsudil demethylase) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Ophthalmologist or Optometrist

2. Individual is 18 years of age or older

3. Individual has a confirmed diagnosis of elevated intraocular pressure (IOP) and **ONE** of the following:
   a. An individual with open-angle glaucoma (optic neuropathy with atrophy of optic nerve head)

   b. An individual with ocular hypertension (no optic nerve damage)

4. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
    a. **Two** trials of an ophthalmic prostaglandin analog (i.e., bimatoprost, latanoprost, latanoprostene bunod, tafluprost, travoprost)
    b. **Two** trials of an ophthalmic beta-blocker (i.e., levobunolol, betaxolol hcl, timolol, etc.)

5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

**Initial approval duration**: 6 months

- **Criteria for continuation of coverage (renewal request):** Rhopressa (netarsudil demethylase) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Ophthalmologist or Optometrist

2. Individual's condition has responded while on therapy with response defined as achieved and maintains at least a 25% reduction in IOP

3. Individual has been adherent with the medication

4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

**Renewal duration**: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

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**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.

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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 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. Normal-tension glaucoma is a form of open-angle glaucoma with a presenting IOP in the normal range. Normal-tension glaucoma is also referred to as normal or low-pressure glaucoma. Glaucoma is diagnosed in patients with characteristic nerve damage on fundus examination and visual field testing.

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.

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**Definitions:**

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

**Normal Intraocular Pressure (IOP)**: 8-21 mmHg

**Ocular Hypertension:**

- Abnormally high IOP with no evidence of glaucoma, that is, no field loss or abnormality of the optic nerve

**Open-angle Glaucoma:**

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- Characteristic optic nerve (optic neuropathy) and progressive peripheral visual field loss followed by central visual filed loss, with or without elevated IOP
- An elevated IOP alone does not establish the diagnosis of open-angle glaucoma

**Agents that reduce IOP:**

| Agents for Glaucoma | | | | |
|---|---|---|---|---|
| **Drug** | **Strength** | **Duration** | **Decrease aqueous production** | **Increase aqueous outflow** |
| **Alpha-2 Adrenergic Agonists** | | | | |
| Iopidine (apraclonidine) | 0.5-1% | 7 to 12 h | √ | NR |
| Alphagan (brimonidine) | 0.1%, 0.15%,0.2% | 6 to 8 h | √ | √ |
| **Beta-Blockers** | | | | |
| Betoptic-S (betaxolol) | 0.25-0.5% | >12 h | √ | NR |
| Carteolol | 1% | 12 h | √ | ~ |
| Betagan (levobunolol) | 0.25-0.5% | 24 h | √ | ~ |
| Metipranolol | 0.3% | 24 h | √ | ~ |
| Betimol, Istalol, Timoptic, Timoptic Ocudose, Timoptic XE (timolol) | 0.25-0.5% | 24 h | √ | ~ |
| **Carbonic Anhydrase Inhibitors** | | | | |
| Azopt (brinzolamide) | 1% | ≈ 8 h | √ | NR |
| Trusopt (dorzolamide) | 2% | 8 to 12 h | √ | NR |
| **Docosanoid** | | | | |
| Rescula (unoprostone) | 0.15% | 12 h | NR | √ |
| **Miotics, Cholinesterase Inhibitors** | | | | |
| Phospholine Iodide (echothiophate) | 0.125% | Days/wks | NR | √ |
| **Miotics, Direct-Acting** | | | | |
| Miostat (carbachol) | 0.01% | 4-8 h | NR | √ |
| Isopto Carpine (pilocarpine) | 1%, 2%,4% | 4-12 h | NR | √ |
| **Prostaglandin Analogues** | | | | |
| Lumigan (bimatoprost) | 0.01-0.03% | 24 h | NR | √ |
| Xalatan, Xelpros (latanoprost) | 0.005% | 24 h | NR | √ |
| Vyzulta (latanoprostene bunod) | 0.024% | 24 h | NR | √ |
| Zioptin (tafluprost) | 0.0015% | 24 h | NR | √ |
| Travatan Z (travoprost) | 0.004% | 24 h | NR | √ |
| **Rho Kinase Inhibitor** | | | | |
| Rhopressa (netarsudil) | 0.02% | ND | | √ |
| **Fixed Combinations** | | | | |
| Combigan (brimonidine-timolol) | 0.2%/0.5% | 24 h | √ | √ |

| | | | | |
|---|---|---|---|---|
| Simbrinza (brinzolamide-brimonidine) | 1%/0.2% | 8 h | √ | √ |
| Cosopt, Cosopt PF (dorzolamide-timolol) | 2%/0.5% | 24 h | √ | NR |
| Rocklatan (netarsudil-latanoprost) | 0.02%/0.005% | 24 h | | √ |
| ~: possible activity; ND: no data; NR: no activity reported | | | | |

## Resources:

Rhopressa (netarsudil) product information, revised by Alcon Laboratories, Inc. 09-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 18, 2025.

Jacobs DS. Open-angle glaucoma: Epidemiology, clinical presentation, and diagnosis. In: UpToDate, Gardiner MF, Li H (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through February 2025. Topic last updated October 16, 2024. Accessed March 08, 2025.

Jacobs DS. Open-angle glaucoma: Treatment. In: UpToDate, Gardiner MF, Li H (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through February 2025 Topic last updated January 08, 2025. Accessed March 08, 2025.

Weizer JS. Angle-closure glaucoma: Treatment. In: UpToDate, Jacobs DS, Li H (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through February 2025.Topic last updated October 30, 2023. Accessed March 08, 2025.

Gedde SJ, Vinod K, Wright MW, et al. Primary open-angle glaucoma Preferred Practice Pattern® guidelines. The American Academy of Ophthalmology. 2020. Available at: http://www.aao.org/guidelines-browse?filter=preferredpracticepatterns. Accessed March 08, 2025.