BlueCross BlueShield Arizona

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PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**8/02/2018**
LAST REVIEW DATE:	**5/20/2021**
LAST CRITERIA REVISION DATE:	**5/20/2021**
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

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 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. A confirmed diagnosis of **ONE** of the following:
     a. Ocular hypertension with an intraocular pressure (IOP) greater than 22 mmHg on two instances
     b. Open-angle glaucoma with optic neuropathy and progressive peripheral visual field loss

  4. Individual has failure, contraindication per FDA label, or intolerance to **BOTH** of the following:
     a. Two trials of an ophthalmic prostaglandin analog (i.e., Lumigan, Xalatan, Vyzulta, Zioptan, Travatan Z)
     b. Two trials of an ophthalmic beta-blocker (i.e., Betagan, Betoptic-S, Timolol etc.)

  Initial approval duration: 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 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
     a. Response is defined as:
        i. Achieved and maintains at least a 25% reduction in IOP over baseline

  3. Individual has been adherent with the medication

  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 a Non-Cancer Medications**

  2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

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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.

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. 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 (IOP): 8-21 mmHg

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Ocular Hypertension:

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

Open-angle Glaucoma:

- 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				

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Resources:

Rhopressa (netarsudil) product information, revised by Aerie Pharmaceuticals, Inc. 03-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on April 07, 2021.

Jacobs DS. Open-angle glaucoma: Epidemiology, clinical presentation, and diagnosis. In: UpToDate, Gardiner MF, Givens J (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on April 08, 2021.

Jacobs DS. Open-angle glaucoma: Treatment. In: UpToDate, Gardiner MF, Givens J (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on April 08, 2021.