Drug Monograph

Drug/Drug Class:	**Rhopressa® (netarsudil) drops/ Glaucoma Agents**
Prepared for:	MO HealthNet
Prepared by:	Conduent

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary [1]

Purpose:	The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be made available on an open access basis to prescribers, require a clinical edit or require prior authorization for use.
Dosage Forms & Manufacturer:	Rhopressa® is available in an ophthalmic solution containing 0.2 mg/ml of netarsudil. Manufactured for: Aerie Pharmaceuticals, Inc., Irvine, CA 92614
Summary of Findings:	Results from three randomized, clinical trials found that Rhopressa® was associated with a reduction in intraocular pressure of up to 5mmHg. The results were similar between groups treated with Rhopressa® 0.02% dosed once daily compared to those treated with timolol 0.5% dosed twice daily in patients with a baseline intraocular pressure <25 mmHg.
Status Recommendation:	☐ Prior Authorization (PA) Required ☐ Open Access ☐ Clinical Edit ☒ PDL
Type of PA Criteria:	☐ Increased Risk of ADE ☐ Preferred Agent ☐ Appropriate Indications ☒ Under Solicitation

Purpose

The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be considered a prior authorization drug, a clinical edit drug or an open access drug. While prescription expenditures are increasing at double-digit rates, payers are evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. This review will assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class.

Introduction [2,3]

Open angle glaucoma, the most common form of glaucoma, accounts for at least 90% of all glaucoma cases. It is caused by the slow clogging of the drainage canals, resulting in increased eye pressure. Its presentation displays a wide and open angle between the iris and cornea. Open angle glaucoma develops slowly and is a lifelong condition that has symptoms and damage that are typically unnoticed. Open angle glaucoma is also called primary or chronic glaucoma. It affects about three million Americans.

Dosage Form(s) [1]

Rhopressa® is available in an ophthalmic solution containing 0.2 mg/ml of netarsudil.

Manufacturer [1]

Manufactured for: Aerie Pharmaceuticals, Inc., Irvine, CA 92614

Indication(s) [1]

Rhopressa® is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension.

Clinical Efficacy [1,2] (mechanism of action/pharmacology, comparative efficacy)

Rhopressa® is a rho kinase inhibitor, which is believed to reduce IOP by increasing the outflow of aqueous humor through the trabecular meshwork route.

Pharmacokinetics:

	Rhopressa®
Absorption	Systemic exposures are very minimal
Metabolism	Metabolized by esterases in the eye

Clinical Trials Experience

STUDY DESIGN	3 randomized, controlled clinical trials
INCLUSION	Patients with open angle glaucoma or ocular hypertension. The first two

CRITERIA	trials enrolled subjects with IOP lower than 27 mmHg and the third enrolled subjects with IOP lower than 30 mmHg.
EXCLUSION CRITERIA	Not specified.
TREATMENT REGIMEN	Patients were randomized to receive Rhopressa® 0.02% once daily in the evening or timolol 0.5% dosed twice daily.
RESULTS	The three studies demonstrated up to 5 mmHg reductions in IOP for subjects treated with Rhopressa® 0.02% once daily in the evening. For patients with IOP < 25 mmHg, the IOP reductions with Rhopressa® were similar to those with timolol. For patients with baseline IOP ≥ 25 mmHg, however, Rhopressa® resulted in smaller mean IOP reductions at the morning time points than timolol for study visits on Day 43 and 90; the difference in mean IOP reduction between the two treatment groups was as high as 3 mmHg, favoring timolol.
SAFETY	Not specified.

Contraindications [(1)]

- None

Warnings and Precautions [(1)]

- There have been reports of bacterial keratitis associated with the use of multiple dose containers of topical ophthalmic products
- Contact lenses should be removed prior to instillation of Rhopressa® and may be reinserted 15 minutes following its administration

Adverse Effects [(1)]

The most common adverse reaction observed in controlled clinical studies with Rhopressa® dosed once daily was conjunctival hyperemia which was reported in 53% of patients. Other common (approximately 20%) ocular adverse reactions reported were: corneal verticillata, instillation site pain, and conjunctival hemorrhage. Instillation site erythema, corneal staining, blurred vision, increased lacrimation, erythema of eyelid, and reduced visual acuity were reported in 5-10% of patients.

Drug Interactions [(1)]

- None

Dosage and Administration [(1)]

The recommended dosage is one drop in the affected eye(s) once daily in the evening.

Cost [(3)]

GENERIC NAME	BRAND NAME	MANUFACTURER	DOSE	COST/ 25 DAYS
Netarsudil	Rhopressa	Aerie Pharmaceuticals	One drop in each eye daily	$229*
Travoprost	Travatan Z	Alcon	Once drop in each eye daily	$170.25*

* Wholesale Acquisition Cost

Conclusion

Rhopressa® 0.02% is a novel eye drop indicated for lowering elevated intraocular pressure in patients with glaucoma and ocular hypertension. Rhopressa® is a rho kinase inhibitor that was FDA approved in December 2017. The approval was based on results from 3 randomized trials that demonstrated up to 5 mmHg reductions in IOP for patients treated with Rhopressa® 0.02% once daily in the evening. The results also showed that for those patients with a baseline IOP of < 25 mmHg, reductions were similar between grouped treated with Rhopressa® 0.02% dosed once daily and those treated with timolol 0.5% dosed twice daily. Furthermore, the results showed that patient with baseline IOP ≥ 25 mmHg; timolol 0.5% twice daily had a greater reduction in morning time points than Rhopressa® 0.02% once daily. The difference in IOP reduction between the two treatment groups was as high as 3 mmHg, favoring timolol.

Recommendation

This drug is being considered for inclusion in the state specific Preferred Drug List (PDL).

References

1) Rhopressa. Retrieved 8/21/2018 from: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7d4f0e3a-5b86-4c43-982a-813b22ae7e22&audience=consumer
2) New Drug Rhopressa Now Available for Open-Angle Glaucoma. Retrieved 8/21/2018 from: https://www.glaucoma.org/news/new-drug-rhopressa-now-available-for-open-angle-glaucoma.php
3) Types of Glaucoma. Retrieved 8/21/2018 from: https://www.glaucoma.org/glaucoma/types-of-glaucoma.php

Prepared by: Luke Boehmer PharmD

Date: August 21, 2018

