

Drug Monograph

Drug/Drug **Rhofade[®] (oxymetazoline hydrochloride) cream/**
Class: **Rosacea**
Prepared for: MO HealthNet
Prepared by: Conduent Heritage

New Criteria

Revision of Existing Criteria

Executive Summary

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: Rhofade[®] is available in a 1% topical cream. Each gram of cream contains 10 mg oxymetazoline hydrochloride, which is equivalent to 8.8 mg of oxymetazoline free base.

Manufacturer: Allergan, Irvine, CA 92612

Summary of Findings: Rhofade[®] was evaluated in 2 randomized, double-blind, vehicle-controlled clinical trials. In both studies, the number of patients obtaining at least a 2-grade improvement from baseline on both the 5 point clinician erythema assessment and the 5 point subject self-assessment scales on day 29 of treatment was greater with Rhofade[®] compared with vehicle. Rhofade[®] also had a greater rate of success recorded post-dose on day 29 of treatment at times of 3 hours, 6 hours, 9 hours, and 12 hours versus the vehicle cream.

Status Recommendation: Prior Authorization (PA) Required Open Access
 Clinical Edit PDL

Type of PA Criteria: Increased Risk of ADE Preferred Agent
 Appropriate Indications Non-Preferred Agent

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⁾

The National Rosacea Society estimates that approximately 16 million Americans have the disease. Persistent facial erythema is cited as the most common sign of rosacea. The redness may resemble a flushing or sunburn that does not go away. Typical triggers include sun exposure, stress, weather, food, exercise, and/or products.

Dosage Form(s) ⁽¹⁾

Rhofade® is available in a 1% topical cream. Each gram of cream contains 10 mg oxymetazoline hydrochloride, which is equivalent to 8.8 mg of oxymetazoline free base.

Manufacturer ⁽¹⁾

Allergan, Irvine, CA 92612

Indication(s) ⁽¹⁾

Rhofade® is indicated for the treatment of persistent facial erythema that is associated with rosacea in adults.

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

Rhofade® is an alpha-1A adrenoreceptor agonist that causes vasoconstriction.

Pharmacokinetics:

	Rhofade®
Protein binding	56.7% to 57.5%
Metabolism	Minimal

Rhofade® treatment for 29 days improved erythema associated with rosacea compared with a vehicle control in adults

Study 1

STUDY DESIGN	Two randomized, double-blind, vehicle-controlled clinical trials (Study 1, N=440; Study 2, N=445)
INCLUSION	Adults with persistent erythema associated with rosacea

CRITERIA	
EXCLUSION CRITERIA	Not specified
TREATMENT REGIMEN	Patients were randomized to receive Rhofade [®] cream or vehicle applied topically once daily for 29 days.
RESULTS	The proportion of patients achieving success with at least a 2 grade improvement from baseline on both the 5-point clinician erythema assessment and the 5-point subject self-assessment scales on day 29 was greater with topical Rhofade [®] compared with vehicle. The rates of success recorded post dose on day 29 for active treatment versus vehicle were 12% vs 6% at 3 hours, 16% vs 8% at 6 hours, 18% vs 6% at 9 hours, and 15% vs 6% at 12 hours for Study 1, and 14% vs 7% at 3 hours, 13% vs 5% at 6 hours, 16% vs 9% at 9 hours, and 12% vs 6% at 12 hours for Study 2
SAFETY	Not specified.

Contraindications ⁽¹⁾

- None

Warnings and Precautions ⁽¹⁾

- Blood pressure may be affected with use
- Potentiation of vascular insufficiency may occur in patients with cerebral or coronary insufficiency, Raynaud phenomenon, thromboangiitis obliterans, scleroderma, or Sjogren syndrome.
- Risk of angle closure glaucoma is increased in patients with narrow-angle glaucoma.

Adverse Effects ⁽¹⁾

Most common, ≥ 1 %	Rhofade [®] (n=489)	Vehicle (n=483)
Application site dermatitis	2%	0%
Worsening inflammatory lesions	1%	<1%
Application site pruritus	1%	1%
Application site erythema	1%	<1%
Application site pain	1%	<1%

Drug Interactions ⁽¹⁾

- Alpha adrenergic agonists
- Alpha-1 adrenergic antagonists
- Beta blockers
- Cardiac glycosides
- Monoamine oxidase inhibitors

Dosage and Administration ⁽¹⁾

The FDA recommended dose is to apply a pea-sized amount topically once daily in a thin layer to the entire face, including the forehead, nose, cheeks, and chin. Avoid the eyes and lips; wash hands immediately following application.

Cost

GENERIC NAME	BRAND NAME	MANUFACTURER	STRENGTH	COST/ PACKAGE*
Oxymetazoline	Rhofade	Allergan	1% cream, 30 g tube	\$474.90

*Maximum Allowable Cost

Conclusion

Rhofade[®] is the first alpha-1A adrenergic agonist approved for the treatment of persistent facial erythema associated with rosacea. It is a topical cream that elicits vasoconstriction. In 2 randomized clinical trials (N=885), oxymetazoline cream increased the proportion of patients with at least a 2 grade improvement from baseline on both clinician assessed and patient assessed erythema scales at each time point (3, 6, 9, and 12 hours) on day 29 when compared with a vehicle control. Rhofade[®] is applied to entire face once daily and costs \$474.90 per 30 gram tube. Caution is necessary in patients with uncontrolled cardiovascular or cerebrovascular disease due to its alpha-1 adrenergic mechanism of action.

Recommendation

The MO HealthNet Division recommends prior authorization status for this product.

References

1. Product Information: Rhofade[™], oxymetazoline hydrochloride cream. Allergan, Irvine, CA, 01/2017
2. FDA Approves Rhofade Cream for Facial Erythema Associated With Rosacea in Adults. Retrieved 5/19/2017 from: <https://www.ptcommunity.com/news/20170511/fda-approves-rhofade-cream-facial-erythema-associated-rosacea-adults>

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