

# Drug Policy

<b>Policy:</b>	<b>Rhofade® (oxymetazoline 1% hydrochloride cream – EPI Health)</b> <b>Prior Approval Criteria</b>	<b>Annual Review Date: 05/16/2024</b>  <b>Last Revised Date: 05/16/2024</b>
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## OVERVIEW

Rhofade, an  $\alpha_{1A}$ -adrenergic agonist, is indicated for the topical treatment of persistent **facial erythema associated with rosacea** in adults.<sup>1</sup>

Rhofade has been shown to decrease the erythema associated with rosacea and has not been shown to exert any beneficial effects on inflammatory lesions.<sup>1-3</sup>

## POLICY STATEMENT

This policy involves the use of Rhofade. Prior authorization is recommended for pharmacy benefit coverage of Rhofade. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

**Automation:** When available, ICD-10 codes for Rosacea (ICD-10: L71.\*) will be used for automation to allow approval for Rhofade for patients at least 18 years of age.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rhofade is recommended in those who meet the following criteria:

### Food and Drug Administration (FDA)-Approved Indications

- 1. Facial Erythema.** Approve for 1 year if the patient meets both of the following criteria (A and B):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has facial erythema associated with rosacea.

### Initial Approval/ Extended Approval.

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**A) Initial Approval:** 1 year (365 days)

**B) Extended Approval:** 1 year (365 days)

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## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Rhofade has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

- 1. Erythema Caused by Conditions Other Than Rosacea.** Rhofade is indicated for the treatment of persistent facial erythema associated with rosacea.
- 2.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

- Rhofade® cream for topical use [prescribing information]. Charleston, SC: EPI Health; November 2019.
- Del Rosso JQ, Thiboutot D, Gallo R, et al. Consensus recommendations from the American Acne & Rosacea Society on the management of rosacea, part 2: a status report on topical agents. *Cutis*. 2013;92(6):277-284.
- Del Rosso JQ, Thiboutot D, Gallo R, et al. Consensus recommendations from the American Acne & Rosacea Society on the management of rosacea, part 5: a guide on the management of rosacea. *Cutis*. 2014;93(3):134-138.