MEDICAL MUTUAL®

Drug Policy

Policy:	**Topical Alpha-Adrenergic Agonists for Rosacea** **Prior Approval Criteria**	**Annual Review Date: 05/19/2022** **Last Revised Date: 05/19/2022**

OVERVIEW

The topical alpha-adrenergic agonists, Mirvaso and Rhofade, are indicated for the topical treatment of persistent facial erythema associated with rosacea in adults ≥ 18 years of age. Mirvaso is an alpha$_2$-adrenergic agonist and Rhofade is an alpha$_{1A}$-adrenergic agonist. Both products have been shown to decrease the erythema associated with rosacea; neither has been shown to exert any beneficial effects on inflammatory lesions.

Rosacea, a chronic, inflammatory facial skin disorder, affects approximately 16 million people in the US. The hallmark of rosacea is centrofacial persistent erythema, typically affecting the cheeks, chin, forehead, and nose; the perioral and periocular regions are generally unaffected. Patients with rosacea typically present with clinical manifestations that include flushing, persistent facial edema, dryness, burning and stinging skin, inflammatory papules and pustules, telangiectasia or dilation of blood vessels, and watery or irritated eyes. Diffuse centrofacial erythema is almost universally present in all patients with rosacea; it generally intensifies in magnitude during a flare and persists between flares at less intensity.

The American Acne & Rosacea Society (AARS) published consensus guidelines on the management of rosacea in 2014. The panel notes that a gentle skin care and photoprotection regimen is recommended for all patients. A topical alpha-adrenergic agonist is recommended for use as monotherapy in patients with centrofacial erythema without papulopustular lesions or in combination with an anti-inflammatory (e.g., topical metronidazole, Finacea® [azelaic acid]) in patients with centrofacial erythema and papulopustular lesions. The topical alpha-agonists should not be considered as alternatives to anti-inflammatory therapies.

POLICY STATEMENT

This policy involves the use of Rhofade or Mirvaso. Prior authorization is recommended for pharmacy benefit coverage of Rhofade or Mirvaso. 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.

Drugs Affected:

- Mirvaso® (brimonidine gel, 0.33% – Galderma)
- Rhofade™ (oxymetazoline hydrochloride cream, 1% – Allergan)

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Automation: When available, the following ICD-10 code(s) and corresponding approval durations will be used for automation to allow approval of the requested medication:

1. **L71.*;** 1 year in adults only

RECOMMENDED AUTHORIZATION CRITERIA

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

Food and Drug Administration (FDA)-Approved Indications

1. **Facial Erythema Due to Rosacea in Adults ≥ 18 years of age.** Approve.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year (365 days)
B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Neither Mirvaso or 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**. Mirvaso and Rhofade are 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

- Mirvaso® topical gel [prescribing information]. Fort Worth, TX: Galderma Laboratories; June 2018.
- Rhofade™ cream for topical use [prescribing information]. Irvine, CA: Allergan; January 2017.
- 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.
- Sarnoff DS. Therapeutic update on rosacea. *J Drugs Dermatol*. 2014;13(1):10-1.
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- Del Rosso JQ, Thiboutot D, Gallo R, et al. Consensus recommendations from the American Acne & Rosacea Society on the management of rosacea, part 1: a status report on the disease state, general measures, and adjunctive skin care. *Cutis*. 2013;92(5):234-40.