MEDICAL MUTUAL®

Drug Policy

Policy:	Brimonidine 0.33% gel Prior Authorization	Annual Review Date: 05/16/2024 Last Revised Date: 05/16/2024

OVERVIEW

Brimonidine 0.33% gel, an alpha$_2$-adrenergic agonist, is indicated for the topical treatment of persistent (non transient) **facial erythema of rosacea** in patients ≥ 18 years of age.[1]

Brimonidine 0.33% gel has been shown to decrease the erythema associated with rosacea; brimonidine 0.33% gel has not been shown to exert any beneficial effects on inflammatory lesions.[1-3]

POLICY STATEMENT

This policy involves the use of brimonidine 0.33% gel. Prior authorization is recommended for pharmacy benefit coverage of brimonidine 0.33% gel. 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of brimonidine 0.33% gel 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 the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has facial erythema due to rosacea.

Initial Approval/ Extended Approval.

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

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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Brimonidine 0.33% gel 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**. Brimonidine 0.33% gel 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

- Mirvaso® topical gel [prescribing information]. Fort Worth, TX: Galderma; November 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.