PRIOR AUTHORIZATION POLICY

POLICY: Topical Alpha-Adrenergic Agonists for Rosacea – Brimonidine Prior Authorization with Step Therapy Policy

- Mirvaso® (brimonidine gel, 0.33% – Galderma, generic)

REVIEW DATE: 01/25/2023

OVERVIEW

Brimonidine 0.33% gel (Mirvaso, generic) 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

Prior Authorization is recommended for prescription benefit coverage of Mirvaso/brimonidine 0.33% gel. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Mirvaso/brimonidine 0.33% gel is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Facial Erythema.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has facial erythema due to rosacea; AND
   - **C)** Patient meets one of the following criteria (i or ii):
     - **i.** Generic brimonidine 0.33% gel is requested; OR
     - **ii.** Patient meets both of the following criteria (a and b):
       - **a)** Patient has tried generic brimonidine 0.33% gel; AND
       - **b)** Patient cannot use generic brimonidine 0.33% gel due to a formulation difference in the inactive ingredient(s) [e.g., buffers, emollients, emulsifiers, preservatives, surfactants] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Mirvaso/brimonidine 0.33% gel is not recommended in the following situations:

1. **Erythema Caused by Conditions Other Than 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.

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REFERENCES

1. Mirvaso® topical gel [prescribing information]. Fort Worth, TX: Galderma; November 2017.
2. 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.
3. 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.

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