

## CLINICAL POLICY

Brimonidine Tartrate

### Clinical Policy: Brimonidine Tartrate (Mirvaso)

Reference Number: PA.CP.PMN.192

Effective Date: 04/2019

Last Review Date: 04/2024



#### Description

Brimonidine Tartrate (Mirvaso<sup>®</sup>) is an alpha-2 adrenergic agonist topical gel. It may reduce erythema through direct vasoconstriction.

#### FDA Approved Indication(s)

Mirvaso is indicated for the topical treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age or older.

#### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness<sup>®</sup> that Mirvaso is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Facial Erythema Associated with Rosacea (must meet all):

1. Diagnosis of persistent facial erythema associated with rosacea;
2. Age  $\geq$  18 years;
3. If papules or pustules are present, failure of, or concomitant treatment with, any of the following agents, unless clinically significant adverse effects are experienced or all are contraindicated: topical metronidazole, oral doxycycline, ivermectin cream, Finacea<sup>®</sup>;
4. Dose does not exceed 30 grams (1 tube) per month.

**Approval duration: 12 months**

##### B. Other diagnoses/indications:

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

#### II. Continued Therapy

##### A. Facial Erythema Associated with Rosacea (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 30 grams (1 tube) per month.

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

**Approval duration: Duration of request or 12 months (whichever is less);** or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
metronidazole (Metrocream <sup>®</sup> 0.75%, Metrogel <sup>®</sup> 1%, Metrolotion <sup>®</sup> 0.75% )	Apply thin film topically to affected area QD for 1% and BID for 0.75%	No maximum dosage information is available.
azelaic acid 15% gel (Finacea <sup>®</sup> )	Apply in a thin film topically to the affected area BID Reassess if no improvement in 12 weeks.	No maximum dosage information is available.
doxycycline (Oracea) <sup>®</sup>	Lesions (papules and pustules): 40 mg PO once daily in the morning (1 hour before or 2 hours after a meal)	300 mg/day; 40 mg/day for Oracea
ivermectin cream 1% (Soolantra <sup>®</sup> )	Apply a pea-size amount to the affected areas of the face (forehead, chin, nose, each cheek) once daily. Spread as a thin layer, avoiding the eyes and lips.	4 oz/topical application

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): hypersensitivity

- Boxed warning(s): none reported

*Appendix D: General Information*

- Tetracycline agents, including doxycycline and minocycline exhibit anti-inflammatory activities at doses < 50 mg. Anti-inflammatory dose doxycycline does not exert antibiotic selection pressure and thus does not induce antibiotic resistance; its mechanism of action in rosacea appears to relate to the anti-inflammatory and biological activities of doxycycline.

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Facial erythema associated with rosacea	Apply a pea-size amount topically QD to each of the five areas of the face (forehead, chin, nose, each cheek) avoiding the eyes and lips.	One application/day

**VI. Product Availability**

Gel (30 gm tube or pump): 0.33%

**VII. References**

1. Mirvaso Prescribing Information. Fort Worth, TX: Galderma Laboratories; November 2017. Available at: [https://www.mirvaso.com/themes/custom/mirvaso\\_basic/pdfs/MirvasoPI.pdf](https://www.mirvaso.com/themes/custom/mirvaso_basic/pdfs/MirvasoPI.pdf). Accessed January 12, 2024.
2. Thiboutot D, Anderson R, Cook-Bolden F, et al. Standard management options for rosacea: the 2019 update by the National Rosacea Society expert committee. *J Am Acad Dermatol.* 2020; 82(6): 1501-1510. doi: 10.1016/j.jaad.2020.01.077.
3. Shaller M, Almeida LMC, Bewley A, et al. Recommendations for rosacea diagnosis, classification and management: update from the global ROSacea COnsensus 2019 panel. *Br J Dermatol.* 2020; 182:1090-1091. doi: 10.1111/bjd.18420.
4. Hampton PJ, Berth-Jones J, Duarte Williamson CE, et al. British Association of Dermatologists' Clinical Standards Unit. British Association of Dermatologists guidelines for the management of people with rosacea 2021. *Br J Dermatol.* 2021 Oct;185(4):725-735. doi: 10.1111/bjd.20485.

Reviews, Revisions, and Approvals	Date
Policy created. 2Q 2019 annual review: policy split from PA.CP.PMN.86 Brimonidine (Mirvaso), Oxymetazoline (Rhofade) into individual drug policies; added age limit; references reviewed and updated.	04/2019
2Q 2020 annual review: references reviewed and updated.	04/2020
2Q 2021 annual review: added ivermectin 1% cream as an option for failure; references reviewed and updated.	04/2021
2Q 2022 annual review: references reviewed and updated.	04/2022
2Q 2023 annual review: no significant changes; references reviewed and updated.	04/2023
2Q 2024 annual review: no significant changes; references reviewed and updated.	04/2024