



## CLINICAL POLICY

### Brimonidine Tartrate

### Clinical Policy: Brimonidine Tartrate (Mirvaso)

Reference Number: PA.CP.PMN.192

Effective Date: 4.17.19

Last Review Date: 04.19



[Revision Log](#)

#### Description

Brimonidine Tartrate (Mirvaso®) is a relatively selective 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 health plans affiliated with PA Health & Wellness® 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, a failure of or concomitant treatment with any of the following agents, unless contraindicated or clinically significant adverse effects are experienced: topical metronidazole, oral doxycycline or Finacea;
4. Dose does not exceed 30 mg (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 mg (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 for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
metronidazole (Metrocream® 0.75%, Metrogel® 1%, Metrolotion® 0.75% )	Apply thin film topically to affected area QD for 1% and BID for 0.75%	No maximum dosage information is available.
Finacea® (15% gel) (azelaic acid)	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)®	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

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

*Appendix C: Contraindications/Boxed Warnings*

*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: [www.mirvaso.com](http://www.mirvaso.com). Accessed January 31, 2019.
2. Fowler J Jr, et al. Efficacy and safety of once-daily topical brimonidine tartrate gel 0.5% for the treatment of moderate to severe facial erythema of rosacea: results of two randomized, double-blind, and vehicle-controlled pivotal studies. *J Drugs Dermatol*. Jun 2013; 12(6):650-6.
3. Micromedex<sup>®</sup> Healthcare Series [database online]. Greenwood Village, Colorado: Thomson Healthcare. Updated periodically. Accessed January 31, 2019.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: <http://www.clinicalpharmacology-ip.com>. Accessed January 31, 2019.
5. National Rosacea Society. Rosacea treatment algorithms. Available at: <https://www.rosacea.org/physicians/treatmentalgorithms>. January 31, 2019.
6. Scaller M, et al. Rosacea treatment update: Recommendations from the global ROSacea Consensus (ROSCO) panel. *Br J Dermatol* 2016. Epub ahead of print. doi: 10.1111/bjd.15173.

Reviews, Revisions, and Approvals	Date	P&T Approval 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.	04.17.19	