RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	brimonidine tartrate
Policy Number:	RxA.219
Drug(s) Applied:	Mirvaso®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Brimonidine tartrate (Mirvaso®) is a relatively selective alpha-2 adrenergic agonist topical gel. It may reduce erythema through direct vasoconstriction. It is indicated for the topical treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age or older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Brimonidine tartrate (Mirvaso®)	Persistent (nontransient) facial erythema associated with rosacea	Apply a pea-size amount topically once daily to each of the five areas of the face (forehead, chin, nose, each cheek) avoiding the eyes and lips.	One application/day

Dosage Forms

- Gel (30 gm tube or pump): 0.33%

Clinical Policy

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

I. Initial Approval Criteria

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

1. Diagnosis of persistent facial erythema associated with rosacea;
2. Age ≥ 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
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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	Maximum Dose
metronidazole (Metrocream® 0.75%, Metrogel® 1%, Metrolotion® 0.75%)	Apply thin film topically to affected area once daily for 1% and twice daily for 0.75%	No maximum dosage information is available.
Finacea® (15% gel) (azelaic acid)	Apply in a thin film topically to the affected area twice daily. 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

- 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.

References

1. Mirvaso Prescribing Information. Fort Worth, TX: Galderma Laboratories; November 2017. Available at: www.mirvaso.com. Accessed June 25, 2020.
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® Healthcare Series [database online]. Greenwood Village, Colorado: Thomson Healthcare. Updated periodically. Accessed June 25, 2020.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: http://www.clinicalpharmacology-ip.com. Accessed June 25, 2020.
5. National Rosacea Society. Rosacea treatment algorithms. Available at: https://www.rosacea.org/physicians/treatmentalgorithms. Accessed June 25, 2020.
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.
7. Del Rosso JQ, Tanghetti E, Webster G, Stein Gold L, Thiboutot D, Gallo RL. Update on the Management of Rosacea from the American Acne & Rosacea Society (AARS). *J Clin Aesthet Dermatol*. 2019;12(6):17-24.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated. 2. Indication updated to specify "persistent (nontransient)". 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. QD/BID was updated to spell out. 5. Approval duration was updated in Initial and Continued therapy approval to include Commercial and Medicaid designation. 6. References were updated.	07/22/2020	09/14/2020