Clinical Policy Title:	brimonidine tartrate
Policy Number:	RxA.219
Drug(s) Applied:	Mirvaso®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2021
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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of persistent facial erythema associated with rosacea;
2. Prescribed by or in consultation with a dermatologist;
3. Age ≥ 18 years;
4. 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®;
5. 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. Member is 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

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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.
azelaic acid (Finacea® 15% gel)	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 orally once daily in the morning (1 hour before or 2 hours after a meal)	40 mg/day

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

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; June 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=f6a4353f-ae69-4214-901f-e5d42a6fbde7&type=display . Accessed July 12, 2021.
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. 2013; 12(6):650- 656. Available at: https://pubmed.ncbi.nlm.nih.gov/23839181/ . Accessed July 12, 2021.
3. Micromedex® Healthcare Series [database online]. Greenwood Village, Colorado: Thomson Healthcare. Updated periodically. Accessed July 12, 2021.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: http://www.clinicalpharmacology-ip.com. Accessed July 12, 2021.
5. National Rosacea Society. Rosacea treatment algorithms. Available at: https://www.rosacea.org/physicians/treatmentalgorithms. Accessed July 12, 2021.
6. Schaller M, Almeida LMC, Bewley A, et al. Rosacea treatment update: recommendations from the global ROS acea CO nsensus (rosco) panel. *Br J Dermatol*. 2017;176(2):465-471. Available at: https://pubmed.ncbi.nlm.nih.gov/27861741/ . Accessed July 12, 2021.
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. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6624012/ . Accessed July 12, 2021.

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
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy.	07/12/2021	09/14/2021

2. Initial Approval Criteria I.A.2 was updated to include prescriber criteria, “Prescribed by or in consultation with a dermatologist…”. 3. Continued Therapy Approval Criteria II.A.1. was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. Therapeutic Alternatives verbiage was updated to “Below are suggested therapeutic alternatives based on clinical guidance.” 5. Appendix B: Therapeutic Alternatives maximum dose for doxycycline (Oracea®) was updated to remove “300 mg/day for Oracea.” 6. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 7. References were reviewed and updated.		