

**Clinical Policy: Brimonidine Tartrate (Mirvaso), Oxymetazoline (Rhofade)**

Reference Number: CP.PMN.86

Effective Date: 11.16.16

Last Review Date: 05.18

[Revision Log](#)

Line of Business: Commercial, HIM, Medicaid

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

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

Oxymetazoline (Rhofade<sup>™</sup>) is a topical alpha receptor agonist.

*\*For Health Insurance Marketplace (HIM), Rhofade is non-formulary and cannot be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.*

**FDA approved indication**

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

Rhofade is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

**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 Centene Corporation<sup>®</sup> that Mirvaso and Rhofade are **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. If papules or pustules are present, a failure of a trial 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;
3. Dose does not exceed 30 mg (1 tube) per month.

**Approval duration:****Medicaid** - 12 Months**HIM** - Mirvaso for 12 months (*refer to HIM.PA.103 for Rhofade*)**Commercial** - Length of Benefit**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): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

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

1. Currently receiving medication via Centene Corporation or member has previously met initial approval criteria;
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:**

**Medicaid** - 12 Months

**HIM** - Mirvaso for 12 months (*refer to HIM.PA.103 for Rhofade*)

**Commercial** - Length of Benefit

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**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): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and 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 policies – CP.CPA.09 for commercial for commercial, HIM.PHAR.21 for health insurance marketplace, and 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.*

<b>Drug</b>	<b>Dosing Regimen</b>	<b>Dose/Limit/Maximum Dose</b>
metronidazole (Metrocream <sup>®</sup> 0.75%, Metrogel <sup>®</sup> 1%, Metro lotion <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.

<b>Drug</b>	<b>Dosing Regimen</b>	<b>Dose/Limit/Maximum Dose</b>
Finacea <sup>®</sup> (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) <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 PO; 40 mg PO/day for Oracea

*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: 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**

Mirvaso, Rhofade		
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 QD

**VI. Product Availability**

Drug	Availability
Brimonidine tartrate (Mirvaso)	Gel (30 gm tube or pump): 0.33%
Oxymetazoline (Rhofade)	Cream (30 gm tube): 1%

**VII. References**

1. Mirvaso Prescribing Information. Fort Worth, TX: Galderma Laboratories; July 2016. Available at: [www.mirvaso.com](http://www.mirvaso.com). Accessed February 8, 2018.
2. Rhofade Prescribing Information. Irvine, CA: Allergan; January 2017. Available at: [www.rhofade.com](http://www.rhofade.com). Accessed February 8, 2018.
3. 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.
4. Micromedex® Healthcare Series [database online]. Greenwood Village, Colorado: Thomson Healthcare. Updated periodically. Accessed February 8, 2018.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: <http://www.clinicalpharmacology-ip.com>. Accessed January 17, 2017.
6. Mirvaso. American Hospital Formulary Service Drug Information. Available at: <http://www.medicinescomplete.com/mc/ahfs/current/>. Accessed January 17, 2017.
7. National Rosacea Society. Rosacea treatment algorithms. Available at: <https://www.rosacea.org/physicians/treatmentalgorithms>. Accessed February 2017.
8. 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
Converted to new template. Clinical changes to Criteria: Clarify redirection only for rosacea with papules or pustules.	06.17	11.17
Added Rhofade to Mirvaso policy per 05/30/17 SDC decision.	07.17	11.17
2Q 2018 annual review: added quantity limit of 30 gm (1 tube) per month; combined commercial and HIM lines of business with Medicaid line of business policy; references reviewed and updated.	02.08.18	05.18

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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