Clinical Policy: Oxymetazoline (Rhofade)

Reference Number: PA.CP.PMN.86
Effective Date: 4.17.19
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Revision Log

Description
Oxymetazoline (Rhofade™) is a topical alpha-1a adrenoreceptor agonist.

FDA Approved Indication(s)
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 PA Health & Wellness® that Rhofade 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 ≥ 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:
Medicaid – 12 Months
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): 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: 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

Cream (30 gm tube): 1%

VII. References

1. Rhofade Prescribing Information. Irvine, CA: Allergan; January 2017. Available at: www.rhofade.com. Accessed 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® 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. Accessed 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
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