Clinical Policy Title:	oxymetazoline hydrochloride
Policy Number:	RxA.267
Drug(s) Applied:	Rhofade®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Rhofade® is a topical alpha-1a adrenoreceptor agonist. It is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
oxymetazoline HCl (Rhofade®)	Facial erythema associated with rosacea	Apply a pea-size amount once daily in a thin layer to cover the entire face (forehead, chin, nose, and each cheek) avoiding the eyes and lips.	One application/day

Dosage Forms

- Cream: 1%

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 provisions of the pharmacy benefit administer 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. Age of 18 years or older;
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 azelaic acid;
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. Member is currently receiving medication that has been authorized by RxAdvance or the member has 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%, Noritate® 1%, Rosadan® 0.75%)	Apply thin film topically to affected area once daily for 1% and BID for 0.75%.	No maximum dosage information is available.
azelaic acid (Finacea®15% gel, Azelex® 20% cream)	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 monohydrate (Oracea)®	Lesions (papules and pustules): 40 mg PO once daily in the morning (1 hour before or 2 hours after a meal).	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):
  - None reported.

- 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. Rhofade Prescribing Information. Irvine, CA: Allergan; November 2019. Available at: www.rhofade.com. Accessed April 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. Jun 2013; 12(6):6506.
3. Micromedex® Healthcare Series [database online]. Greenwood Village, Colorado: Thomson Healthcare. Updated periodically. Accessed April 12, 2021.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: http://www.clinicalpharmacology-ip.com. Accessed April 12, 2021.
5. National Rosacea Society. Rosacea treatment algorithms. Available at: https://www.rosacea.org/physicians/treatmentalgorithms. Accessed April 12, 2021.
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

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was updated. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Commercial approval duration and Medicaid approval duration updated. 6. Updated APPENDIX B: Therapeutic Alternatives to include Noritate® 1%, Rosadan® 0.75% as new brands of metronidazole. Added Azelex® 20% as brand for azelaic acid, updated doxycycline to include monohydrate and removed max dose of 300 mg/day 7. References were updated. 8. Reworded dosing regimen to: “Apply a pea-size amount once daily in a thin layer to cover the entire face	07/13/2020	09/14/2020

(forehead, chin, nose, and each cheek) avoiding the eyes and lips." 9. Updated Initial Approval Criteria #3 – removed Finacea and added azelaic acid 10. Removed package size under dosage form		
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Background was updated. 3. Continued therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance.." 4. References were reviewed and updated.	04/12/2021	06/10/2021