Rhofade™ (oxymetazoline)

Policy # 00568
Original Effective Date: 06/21/2017
Current Effective Date: 06/20/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Rhofade™‡ (oxymetazoline) to be **eligible for coverage** when the patient selection criteria are met.

Patient Selection Criteria
Coverage eligibility for Rhofade (oxymetazoline) will be considered when the following criteria are met:

- Patient has a diagnosis of persistent facial erythema associated with rosacea; AND
- Patient is 18 years of age or older; AND
- Patient has tried and failed generic topical metronidazole (only if papulopustular), unless there is clinical evidence or patient history that suggests the use of generic topical metronidazole (only if papulopustular) will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.*
- Patient has tried and failed Mirvaso®‡ (brimonidine) unless there is clinical evidence or patient history that suggests the use of Mirvaso (brimonidine) will be ineffective or cause an adverse reaction to the patient
  *(Note: This criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.*

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of Rhofade (oxymetazoline) when the patient has NOT tried and failed both generic topical metronidazole (only is papulopustular) AND Mirvaso (brimonidine) to be **not medically necessary.****

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Rhofade (oxymetazoline) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary****) to be **investigational.***

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Background/Overview

Rhofade is an alpha 1a adrenoceptor agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults. It is available in a 1% cream. The package insert dosing says to apply a pea-sized amount once daily in a thin layer to cover the entire face (forehead, nose, each cheek, and chin) avoiding the eyes and lips.

Erythema Associated with Rosacea

Prior to the launch of Rhofade, Mirvaso was the only drug approved for the treatment of persistent (non-transient) facial erythema of rosacea in adults. In papulopustular rosacea, drugs that are used to treat the underlying condition (e.g. topical metronidazole products) may also have benefit in the reduction of facial erythema. There are currently no head to head studies between Rhofade and Mirvaso, therefore no superiority claims can be made between the two.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

Rationale/Source

The efficacy of Rhofade was established in two identical vehicle controlled trials. In the first trial, the proportion of patients achieving the primary endpoint at day 29 was statistically significant in the Rhofade group versus the vehicle group. The results of the assessments at the following time points were: hour 3 (11.9% vs. 5.5%), hour 6 (15.5% vs. 8.3%), hour 9 (17.7% vs. 6.0%), and hour 12 (14.8% vs. 6.0%). The same can be said about trial 2 with the following results: hour 3 (14.3% vs. 7.4%), hour 6 (13.4% vs. 4.8%), hour 9 (15.5% vs. 8.5%), and hour 12 (12.3% vs. 6.1%). Longer term data showed continued efficacy over 52 weeks.

The patient selection criteria presented in this policy takes into consideration the FDA approved indication of this drug as well as other therapeutic alternatives that currently exist for this condition. There have been no direct, head to head comparisons of Rhofade to other drugs in this treatment category (e.g. Mirvaso) that would indicate Rhofade is more efficacious than any of the existing treatment modalities.

References

1. Rhofade Drug Evaluation. Express Scripts. Updated March 2017.
2. Rhofade [package insert]. Allergan. Irvine, California. Updated January 2017.
3. Mirvaso [package insert]. Galderma Laboratories. Fort Worth, Texas. Updated August 2013.

Policy History

Original Effective Date: 06/21/2017
Current Effective Date: 06/20/2018
06/01/2017 Medical Policy Committee review

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06/21/2017 Medical Policy Implementation Committee approval. New policy.
06/07/2018 Medical Policy Committee review
06/20/2018 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 06/2019

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.