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Section:	Prescription Drugs	**Effective Date:**	October 1, 2023
Subsection:	Topical Products	**Original Policy Date:**	July 15, 2016
Subject:	Topical Rosacea Agents	**Page:**	1 of 6

Last Review Date: September 8, 2023

Topical Rosacea Agents

Description

Finacea (azelaic acid), Mirvaso (brimonidine), Noritate (metronidazole), Rhofade (oxymetazoline), Soolantra (ivermectin)

Background
Finacea (azelaic acid), Mirvaso (brimonidine), Noritate (metronidazole), Rhofade (oxymetazoline) and Soolantra (ivermectin) are used for the topical treatment of rosacea. Rosacea is a chronic relapsing inflammatory skin disorder which mostly affects the central face. Persistent facial redness is cited as the most common sign of rosacea and may resemble a flushing or sunburn that does not go away. Mirvaso and Rhofade are alpha adrenergic agonists that can reduce facial redness through direct cutaneous vasoconstriction. The mechanisms by which Finacea, Noritate and Soolantra act in reducing inflammatory lesions of rosacea are unknown (1-6).

Regulatory Status
FDA-approved indications: (1-5)

- Finacea is indicated for the topical treatment of inflammatory papules and pustules of mild to moderate rosacea.
- Mirvaso is indicated for the topical treatment of persistent (non-transient) facial erythema of rosacea in adults.
- Noritate is indicated for the topical treatment of inflammatory lesions and erythema of rosacea.
- Rhofade is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

- Soolantra is indicated for the topical treatment of inflammatory lesions of rosacea.

Safety and effectiveness of the topical rosacea agents in pediatric patients under 18 years of age has not been established (1-5).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Topical rosacea agents may be considered **medically necessary** if the conditions indicated below are met.

Topical rosacea agents may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Rosacea

AND ALL of the following:

1. Completion of a baseline rosacea assessment
2. Patients with inflammatory lesions (e.g., papules, pustules) must have an inadequate treatment response, intolerance, or contraindication to **ONE** of the following:
    a. Doxycycline
    b. Topical generic metronidazole
3. Prescribed by a dermatologist or patient will be referred to a dermatologist
4. **NO** dual therapy with another PA topical rosacea agent (see Appendix 1)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Rosacea

AND ALL of the following:

1. Re-evaluation of rosacea for improvement
2. **NO** dual therapy with another PA topical rosacea agent (see Appendix 1)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 180 units per 90 days

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity 180 units per 90 days

Duration 12 months

Rationale

Summary

Finacea (azelaic acid), Mirvaso (brimonidine), Noritate (metronidazole), Rhofade (oxymetazoline) and Soolantra (ivermectin) are used for the topical treatment of rosacea. Rosacea is a chronic relapsing inflammatory skin disorder which mostly affects the central face. Persistent facial redness is cited as the most common sign of rosacea and may resemble a flushing or sunburn that does not go away. Mirvaso and Rhofade are alpha adrenergic agonists that can reduce facial redness through direct cutaneous vasoconstriction. The mechanisms by which Finacea, Noritate and Soolantra act in reducing inflammatory lesions of rosacea are

unknown. Safety and effectiveness of the topical rosacea agents in pediatric patients under 18 years of age has not been established (1-6).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of topical rosacea agents while maintaining optimal therapeutic outcomes.

References

1. Finacea [package insert]. Madison, NJ: LEO Pharma Inc.; December 2020.
2. Mirvaso [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; November 2017.
3. Noritate [package insert]. Bridgewater, NJ: Bausch Health US, LLC; June 2020.
4. Rhofade [package insert]. Charleston, SC: EPI Health, LLC; November 2019.
5. Soolantra [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; July 2018.
6. Rivero AL, Whitfeld M. An update on the treatment of rosacea. *Aust Prescr*. 2018;41(1):20-24. doi:10.18773/austprescr.2018.004

Policy History

Date	Action
July 2016	Addition to PA
December 2016	Annual review and reference update
February 2017	Addition of Rhofade to PA and completion of a baseline erythema assessment and no dual therapy with other topical alpha adrenergic agonists
June 2017	Annual review
September 2018	Annual review and reference update
September 2019	Annual review and reference update
September 2020	Annual review and reference update
January 2021	Addition of Finacea, Noritate, and Soolantra to policy. Revised initiation t/f options to doxycycline or topical generic metronidazole. Revised dual therapy statement and added Appendix 1. Added PA quantity limit of 180 units per 90 days.
March 2021	Annual review and reference update
September 2022	Annual review
January 2023	Modified initiation and continuation requirements to rosacea assessment from erythema assessment
March 2023	Annual review

April 2023	Per SME, added initiation requirement that the medication be prescribed by or recommended by a dermatologist and also added the caveat that the t/f only applies to patients with inflammatory lesions
September 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.

Appendix 1 - List of PA Topical Rosacea Agents

Generic Name	Brand Name
azelaic acid	Finacea
brimonidine	Mirvaso
ivermectin	Soolantra
metronidazole	Noritate
oxymetazoline	Rhofade