

**TOPICAL ROSACEA AGENTS**

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

**RATIONALE FOR INCLUSION IN PA PROGRAM****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).

**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

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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