

Reference number(s)

1486-A

Initial Prior Authorization Rosacea Products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Emrosi	minocycline hydrochloride extended-release
Finacea	azelaic acid
Mirvaso	brimonidine
Noritate	metronidazole
Rhofade	oxymetazoline
Soolantra	ivermectin

Indications

FDA-approved Indications

Emrosi

Emrosi (minocycline hydrochloride extended-release) is indicated to treat inflammatory lesions (papules and pustules) of rosacea in adults.

Limitation of Use

- This formulation of minocycline has not been evaluated in the treatment or prevention of infections.
- To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, use Emrosi only as indicated.

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Finacea Gel

Finacea Gel, 15% is indicated for topical treatment of the inflammatory papules and pustules of mild to moderate rosacea.

Limitations of Use

Although some reduction of erythema which was present in patients with papules and pustules of rosacea occurred in clinical studies, efficacy for treatment of erythema in rosacea in the absence of papules and pustules has not been evaluated.

Finacea Foam

Finacea Foam, 15% is indicated for topical treatment of the inflammatory papules and pustules of mild to moderate rosacea.

Mirvaso

Mirvaso (brimonidine) topical gel, 0.33% is an alpha adrenergic agonist indicated for the topical treatment of persistent (nontransient) erythema of rosacea in adults 18 years of age or older.

Noritate

Noritate is indicated for the topical treatment of inflammatory lesions and erythema of rosacea.

Rhofade

Rhofade (oxymetazoline hydrochloride) cream, 1% is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

Soolantra

Soolantra cream is indicated for the treatment of inflammatory lesions of rosacea.

Coverage Criteria

Rosacea

Authorization may be granted for the requested drug when the patient has a diagnosis of rosacea.

Continuation of Therapy

Rosacea

Authorization may be granted for the requested drug when the patient has a diagnosis of rosacea when the following criteria is met:

 The patient has experienced a reduction in symptoms of rosacea from baseline (e.g., inflammatory papules or pustules, facial erythema).

Duration of Approval (DOA)

- 1486-A:
 - Emrosi: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months
 - Finacea, Mirvaso, Noritate, Rhofade, Soolantra: Initial therapy DOA: 4 months;
 Continuation of therapy DOA: 36 months

References

- 1. Emrosi [package insert]. Scottsdale, AZ: Journey Medical Corporation; November 2024.
- 2. Finacea Gel [package insert]. Madison, NJ: LEO Pharma Inc.; November 2021.
- 3. Finacea Foam [package insert]. Madison, NJ: LEO Pharma Inc.; December 2020.
- 4. Mirvaso [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; December 2022.
- 5. Noritate [package insert]. Bridgewater, NJ: Bausch Health US, LLC; June 2020.
- Rhofade [package insert]. Charleston, SC: EPI Health, LLC; November 2019.
- 7. Soolantra [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; October 2022.
- 8. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed June 12, 2024.
- 9. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 06/12/2024).