

PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

FINACEA
(azelaic acid)

MIRVASO
(brimonidine)

NORITATE
(metronidazole)

RHOFADE
(oxymetazoline)

SOOLANTRA
(ivermectin)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

Ref # BOG 4915-A
Ref # 1486-A

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Finacea Gel

Finacea (azelaic acid) 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 (azelaic acid) is indicated for topical treatment of the inflammatory papules and pustules of mild to moderate rosacea.

Mirvaso

Mirvaso (brimonidine) is an alpha adrenergic agonist indicated for the topical treatment of persistent (non-transient) erythema of rosacea in adults 18 years of age or older.

Noritate

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

Rhofade

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

Soolantra

Soolantra (ivermectin) is indicated for the treatment of inflammatory lesions of rosacea.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of rosacea

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Finacea (azelaic acid) is indicated for topical treatment of the inflammatory papules and pustules of mild to moderate rosacea. Mirvaso (brimonidine) is indicated for the topical treatment of persistent (non-transient) facial erythema of rosacea in adults 18 years of age or older. Noritate is indicated for the topical treatment of inflammatory lesions and erythema of rosacea. Rhofade (oxymetazoline) is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults. Soolantra (ivermectin) is indicated for the treatment of inflammatory lesions of rosacea.¹⁻⁶

REFERENCES

1. Finacea Gel [package insert]. Madison, NJ: LEO Pharma Inc.; May 2021.
2. Finacea Foam [package insert]. Madison, NJ: LEO Pharma Inc.; December 2020.
3. Mirvaso [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; June 2018.
4. Noritate [package insert]. Bridgewater, NJ: Bausch Health US, LLC; June 2020.
5. Rhofade [package insert]. Charleston, SC: EPI Health, LLC; November 2019.
6. Soolantra [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; July 2018.
7. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed July 1, 2021.
8. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed July 1, 2021.

Written by: UM Development (SF)

Date Written: 06/2016

Revised: 09/2016 (added target drugs); MS) 02/2017(added Rhofade), (SF) 06/2017 (no clinical changes), (ME) 06/2018 (no clinical changes), 06/2019 (no clinical changes), 07/2020 (no clinical changes); (PM) 08/2021 (no clinical changes), 09/2021 (added BOG 4915-A)

Reviewed: Medical Affairs (LMS) 06/2016, (JG) 02/2017, (CHART) 07/30/20, 08/05/21, 09/16/21

External Review: 09/2016, 02/2016, 04/2017, 10/2017, 10/2018, 10/2019, 10/2020, 10/2021

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of rosacea?	Yes	No
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Mapping Instructions (1486-A and BOG 4915-A)

	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Approve, 36 months (Note for Ref # BOG 4915-A only: If the request is for Soolantra approve Brand name Soolantra)	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have rosacea. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]