MEDICAL MUTUAL®

Drug Policy

Policy: **CC** **Impacted Drugs:**	**Topical Products for Rosacea** **Preferred Step Therapy Policy** • Finacea foam & gel • MetroCream • MetroGel • MetroLotion • Noritate cream • Rosadan cream & gel Kits • Soolantra	**Annual Review Date:** **03/21/2024** **Last Revised Date:** **03/21/2024**

OVERVIEW

Topical metronidazole, topical azelaic acid, topical ivermectin, Eposolay, and Zilxi are all indicated for the treatment of inflammatory lesions of rosacea. The topical metronidazole products are available generically as 0.75% cream, gel, and lotion and 1% gel; as brand Noritate® cream; and as kits (Rosadan® cream or gel with a Rehyla™ wash [moisturizing wash]). Noritate is also indicated for the treatment of erythema of rosacea. Topical azelaic acid 15% is available as a gel (Finacea gel, generic) and a foam (Finacea foam). Topical ivermectin (Soolantra, generic) and Epsolay are only available as a cream and Zilxi is only available as a foam.

POLICY STATEMENT

A step therapy program has been developed to encourage the use of a generic Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.
* Note: Soolantra (with DAW9) will also count as a Preferred drug.

Preferred Medications: generic azelaic acid gel 15%, generic ivermectin cream 1%, generic metronidazole cream 0.75%, generic metronidazole gel 0.75% and 1%, generic metronidazole lotion 0.75%, Rosadan cream, Rosadan gel

Non-preferred Medications: Finacea gel, Finacea foam, MetroCream, MetroGel, MetroLotion, Noritate cream, Rosadan Cream Kit, Rosadan Gel Kit, Soolantra

CRITERIA

1. If the patient has tried one preferred product, then authorization for a non-preferred product may be given.
Note: Soolantra with DAW 9 (indicating that substitution is allowed by the prescriber but the Plan requests brand) will also count as a Step 1 Product.

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

Step Therapy criteria exception
Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list specific diagnosis and/or specific patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the specific contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following (i or ii):
    i. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    ii. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. MetroCream® [prescribing information]. Fort Worth, TX: Galderma; January 2017.
2. MetroGel® [prescribing information]. Fort Worth, TX: Galderma; June 2012.
3. MetroLotion® [prescribing information]. Fort Worth, TX: Galderma; February 2017.
4. Noritate® [prescribing information]. Bridgewater, NJ: Bausch Health; June 2020.
5. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2023. Available at: http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&qs=. Accessed on February 24, 2023. Search terms: azelaic acid, ivermectin, metronidazole, minocycline.
6. Epsolay® cream [prescribing information]. Fort Worth, TX; Galderma; April 2022
7. Rosadan® gel kit. Available at: https://pharmacy.services.conduent.com/mohealthnet/September%202012%20Drug/Rosadan%20gel-kit.pdf. Accessed on February 24, 2023.
8. Rosadan® cream kit [prescribing information]. Available at: https://www.drugs.com/pro/rosadan-cream.html#s-34069-5. February 24, 2023.
9. Finacea® gel [prescribing information]. Whippany, NJ: Bayer Healthcare; August 2016.
10. Finacea® foam [prescribing information]. Madison, NJ: LEO Pharma; August 2018.
11. Soolantra® cream [prescribing information]. Fort Worth, TX: Galderma; July 2018.
12. Zilxi™ topical foam {1.5%} [prescribing information]. Bridgewater, NJ: Foamix; May 2020.
13. Del Rosso JQ, Tanghetti E, Webster G, et al. Update on the management of rosacea from the American Acne & Rosacea Society (AARS). *J Clin Aesthet Dermatol*. 2019;12:17-24.
14. Schaller M, Almeida LMC, Bewley A, et al. Rosacea treatment update: recommendations from the global ROSacea COnsensus (ROSCO) panel. *Br J Derm*. 2017;176:465-471.
15. Scaller M, Almeida LMC, Beley A, et al. Recommendations for rosacea diagnosis, classification and management: update from the global ROSacea COnsensus 2019 panel. *Br J Dermatol*. 2020;182(5):1269-1276.