

## STEP THERAPY POLICY

- POLICY:** Topical Medications for Inflammatory Rosacea Step Therapy Policy
- Finacea® foam (azelaic acid aerosol 15% – LEO Pharma)
  - Finacea® gel (azelaic acid 15% – Bayer Healthcare, generics)
  - MetroCream® (metronidazole cream 0.75% – Galderma, generics)
  - MetroGel® (metronidazole gel 1% – Galderma, generics)
  - MetroLotion® (metronidazole lotion 0.75% – Galderma, generics)
  - Noritate® (metronidazole cream 1% – Valeant)
  - Rosadan® Kits (metronidazole 0.75% gel or 0.75% cream and Rehyla™ Wash – MediMetriks)
  - Soolantra® (ivermectin cream 1% – Galderma, generics)
  - Zilxi™ (minocycline foam 1.5% – Foamix)

**REVIEW DATE:** 02/10/2021

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### OVERVIEW

Topical metronidazole, topical azelaic acid, topical ivermectin, and Zilxi are all indicated for the treatment of **inflammatory lesions of rosacea**.<sup>1-12</sup> The topical metronidazole products are available generically as 0.75% cream, gel, and lotion and 1% gel; as brand Noritate® cream; and as a kit (Rosadan® cream or gel with a Rehyla™ wash [moisturizing wash]).<sup>1-8</sup> Noritate is also indicated for the treatment of erythema of rosacea.<sup>4</sup> Topical azelaic acid 15% is available as a gel (Finacea gel, generics) and a foam (Finacea foam).<sup>9,10</sup> Topical ivermectin is only available as a cream (Soolantra, generics) and Zilxi is only available as a foam.<sup>11,12</sup>

The metronidazole 0.75% products are to be applied twice daily (BID) [morning and evening] and the 1% products are to be applied once daily (QD).<sup>1-8</sup> Azelaic acid gel 15% and Finacea foam are to be applied BID and ivermectin cream 1% and Zilxi are to be applied QD.<sup>9-12</sup>

The most common adverse events (AEs) associated with these topical products are local skin-related AEs (e.g., skin burning/stinging/tingling, skin irritation, scaling/dry skin/xerosis, and pruritus).<sup>1-12</sup>

### Guidelines/Recommendations

The American Acne & Rosacea Society (AARS) updated guidelines on the management of rosacea in 2019 (Zilxi is not addressed in the guidelines).<sup>13,14</sup> A gentle skin care and photoprotection regimen is recommended for all patients with rosacea. In patients with diffuse centrofacial erythema with papulopustular lesions, treatment options are topical metronidazole, topical azelaic acid, topical ivermectin, oral tetracyclines, topical alpha agonists, and oral isotretinoin.

The ROSacea Consensus (ROSCO) international expert panel, consisting of 17 dermatologists and three ophthalmologists, released their consensus recommendations in 2017.<sup>15</sup> The panel notes first-line therapies for patients with mild or moderate inflammatory papules/pustules are topical azelaic acid products, topical ivermectin cream, topical metronidazole products, and oral doxycycline. Recommended therapies for patients with severe inflammatory papules/pustules are ivermectin cream, oral doxycycline, and oral isotretinoin. Note the ROSCO panel updated recommendations but there were no new recommendations on treatment options.<sup>16</sup>

### POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product 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:** A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

**Step 1:** azelaic acid gel 15%, ivermectin cream 1%, metronidazole cream 0.75%, metronidazole gel 0.75%, metronidazole gel 1%, metronidazole lotion 0.75%, Rosadan cream, Rosadan gel

**Step 2:** Finacea foam, Finacea gel, MetroCream, MetroGel, MetroLotion, Noritate cream, Rosadan Cream Kit, Rosadan Gel Kit, Soolantra, Zilxi

## CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

## REFERENCES

1. MetroCream<sup>®</sup> [prescribing information]. Fort Worth, TX: Galderma; January 2017.
2. MetroGel<sup>®</sup> [prescribing information]. Fort Worth, TX: Galderma; June 2012.
3. MetroLotion<sup>®</sup> [prescribing information]. Fort Worth, TX: Galderma; February 2017.
4. Noritate<sup>®</sup> [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; June 2019.
5. Rosadan<sup>®</sup> cream [prescribing information]. Fairfield, NJ: Medimetriks Pharmaceuticals, Inc.; September 2019.
6. Rosadan<sup>®</sup> gel [prescribing information]. Fairfield, NJ: Medimetriks Pharmaceuticals, Inc.; August 2019.
7. Rosadan<sup>®</sup> gel kit. Available at: <http://www.medimetriks.com/prescription-brands/rosadan-cream-kit/rosadan-gel>. Accessed on February 7, 2020.
8. Rosadan<sup>®</sup> cream kit [prescribing information]. Available at: <http://www.medimetriks.com/prescription-brands/rosadan-cream-kit/rosadan-gel>. February 7, 2020.
9. Finacea<sup>®</sup> gel [prescribing information]. Whippany, NJ: Bayer Healthcare Pharmaceuticals; August 2016.
10. Finacea<sup>®</sup> foam [prescribing information]. Madison, NJ: LEO Pharma Inc, Seven Giralda Farms; August 2018.
11. Soolantra<sup>®</sup> cream [prescribing information]. Fort Worth, TX: Galderma Laboratories; July 2018.
12. Zilxi<sup>™</sup> topical foam {1.5%} [prescribing information]. Bridgewater, NJ: Foamix Pharmaceuticals; May 2020.
13. Del Rosso JQ, Thiboutot D, Gallo R. Consensus recommendations from the American Acne & Rosacea Society on the management of rosacea, part 5: a guide on the management of rosacea. *Cutis*. 2014;93(3):134-138.
14. 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.
15. 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.
16. 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.