



STEP THERAPY POLICY

- POLICY:** Topical Medications for Inflammatory Rosacea Step Therapy Policy
- Epsolay[®] (benzoyl peroxide 5% cream – Galderma)
 - Finacea[®] foam (azelaic acid aerosol 15% – LEO Pharma)
 - Finacea[®] gel (azelaic acid 15% – Bayer Healthcare, generic)
 - MetroCream[®] (metronidazole cream 0.75% – Galderma, generic)
 - MetroGel[®] (metronidazole gel 1% – Galderma, generic)
 - MetroLotion[®] (metronidazole lotion 0.75% – Galderma, generic)
 - Noritate[®] (metronidazole cream 1% – Bausch Health)
 - Rosadan[®] Kits (metronidazole 0.75% gel or 0.75% cream and Rehyla[™] Wash – MediMetrics)
 - Soolantra[®] (ivermectin cream 1% – Galderma, generic)
 - Zilxi[™] (minocycline foam 1.5% – Foamix)

REVIEW DATE: 02/16/2022; selected revision 06/29/2022

OVERVIEW

Topical metronidazole, topical azelaic acid, topical ivermectin, Epsolay, and Zilxi are all indicated for the treatment of **inflammatory lesions of rosacea**.^{1-12,16} 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]).¹⁻⁸ Noritate is also indicated for the treatment of erythema of rosacea.⁴ Topical azelaic acid 15% is available as a gel (Finacea gel, generic) and a foam (Finacea foam).^{9,10} Topical ivermectin (Soolantra, generic) and Epsolay are only available as a cream and Zilxi is only available as a foam.^{11,12,16}

Guidelines/Recommendations

The American Acne & Rosacea Society (AARS) updated guidelines on the management of rosacea in 2019 (neither Epsolay nor Zilxi is addressed in the guidelines).¹³ 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 (updated in 2019).^{14,15} The panel notes first-line therapies for patients with mild or moderate inflammatory papules/pustules are topical azelaic acid, topical ivermectin, topical metronidazole, and oral doxycycline. Recommended therapies for patients with severe inflammatory papules/pustules are topical ivermectin, oral doxycycline, and oral isotretinoin.

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

Step 2: Epsolay, 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.

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.

2. No other exceptions are recommended.

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. Rosadan[®] cream [prescribing information]. Fairfield, NJ: Medimetriks; September 2019.
 6. Rosadan[®] gel [prescribing information]. Fairfield, NJ: Medimetriks; August 2019.
 7. Rosadan[®] gel kit. Available at: <http://www.medimetriks.com/prescription-brands/rosadan-cream-kit-rosadan-gel>. Accessed on February 9, 2022.
 8. Rosadan[®] cream kit [prescribing information]. Available at: <http://www.medimetriks.com/prescription-brands/rosadan-cream-kit-rosadan-gel>. February 9, 2022.
 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, Tangheiti 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 Dermatol*. 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.
 16. Epsolay[®] cream [prescribing information]. Fort Worth, TX; Galderma; April 2022.
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HISTORY

| Type of Revision | Summary of Changes | Review Date |
|-------------------|---|-------------|
| Annual Revision | <ul style="list-style-type: none"> • Policy name changed from “Topical Products for Inflammatory Rosacea Step Therapy” to “Topical Medications for Inflammatory Rosacea Step Therapy”. • No criteria changes. | 02/10/2021 |
| Update | <p>06/18/2021, Soolantra: A note was added that 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.</p> | -- |
| Annual Revision | No criteria changes. | 02/16/2022 |
| Selected Revision | Epsolay (benzoyl peroxide 5% cream): Epsolay was added to Step 2. | 06/29/2022 |