



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 Rehya™ Wash – MediMetriks)
 - Soolantra® (ivermectin cream 1% – Galderma, generic)
 - Zilxi™ (minocycline foam 1.5% – Foamix)

REVIEW DATE: 03/06/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Topical metronidazole, topical azelaic acid, topical ivermectin, Epsolay, and Zilxi are all indicated for the treatment of **inflammatory lesions of rosacea**.¹⁻¹² 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 Rehya™ wash [moisturizing wash]).^{1-5,7,8} 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.^{6,11,12}

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.

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

Topical Medications for Inflammatory Rosacea product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

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.

REFERENCES

1. MetroCream® [prescribing information]. Fort Worth, TX: Galderma; January 2017.
2. MetroGel® [prescribing information]. Fort Worth, TX: Galderma; November 2023.
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.; 2024. Available at: <https://fco.factsandcomparisons.com/lco/action/home>. Accessed on February 29, 2024. Search terms: azelaic acid, ivermectin, metronidazole, minocycline.
6. Epsolay® cream [prescribing information]. Fort Worth, TX; Galderma; April 2023
7. Rosadan® gel kit. Available at: <https://pharmacy.services.conduent.com/mohealthnet/September%202012%20Drug/Rosadan%20Ogel-kit.pdf>. Accessed on February 29, 2024.
8. Rosadan® cream kit [prescribing information]. Available at: <https://www.drugs.com/pro/rosadan-cream.html#s-34069-5>. February 29, 2024.
9. Finacea® gel [prescribing information]. Whippany, NJ: Bayer Healthcare; August 2016.
10. Finacea® foam [prescribing information]. Madison, NJ: LEO Pharma; December 2020.
11. Soolantra® cream [prescribing information]. Fort Worth, TX: Galderma; October 2022.
12. Zilxi™ topical foam {1.5%} [prescribing information]. Bridgewater, NJ: Foamix; September 2022.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/01/2023
Annual Revision	No criteria changes.	03/06/2024

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