Effective Date **6/1/2024**
Coverage Policy Number **IP0003**

Topical Rosacea Products

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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.

Overview

This policy supports medical necessity review for the following topical rosacea products:

- **MetroCream®** (metronidazole 0.75% cream)
- **MetroGel®** (metronidazole 1% gel)
- **MetroLotion®** (metronidazole 0.75% lotion)
- **Noritate®** (metronidazole 1% cream)
- **Zilxi™** (minocycline 1.5% foam)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

For Employer Group Plans:

Product	Criteria
MetroCream 0.75% Cream (metronidazole)	**MetroCream 0.75% Cream** is considered medically necessary when there is documentation of **BOTH** of the following: A. The individual has tried **metronidazole 0.75% cream** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. The individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following: i. azelaic acid 15% gel ii. ivermectin 1% cream iii. sodium sulfacetamide 10%/sulfur 5%
MetroGel 1% Gel (metronidazole)	**MetroGel 1% Gel** is considered medically necessary when there is documentation of **BOTH** of the following: A. The individual has tried **metronidazole 1% gel** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. The individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following: i. azelaic acid 15% gel ii. ivermectin 1% cream iii. sodium sulfacetamide 10%/sulfur 5%
MetroLotion 0.75% Lotion (metronidazole)	**MetroLotion 0.75% Lotion** is considered medically necessary when there is documentation of **BOTH** of the following: A. The individual has tried **metronidazole 0.75% lotion** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. The individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following: i. azelaic acid 15% gel ii. ivermectin 1% cream iii. sodium sulfacetamide 10%/sulfur 5%
Noritate 1% Cream (metronidazole)	**Noritate 1% Cream** is considered medically necessary when there is documentation the individual has had an inadequate response, contraindication, or is intolerant to **BOTH** of the following: A. metronidazole 0.75% cream, gel, lotion or 1% gel B. **TWO** of the following: i. azelaic acid 15% gel ii. ivermectin 1% cream iii. sodium sulfacetamide 10%/sulfur 5%
Zilxi 1.5% Topical Foam (minocycline)	**Zilxi 1.5% Topical Foam** is considered medically necessary when there is documentation the individual has had an inadequate response, contraindication, or is intolerant to **THREE** of the following:

Product	Criteria
	i. azelaic acid 15% gel ii. ivermectin 1% cream iii. metronidazole 0.75% cream, gel, lotion or 1% gel iv. sodium sulfacetamide 10%/sulfur 5%

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Topical rosacea products are considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Background

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 Rehyla™ 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.

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.

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6. Epsolay cream [prescribing information]. Fort Worth, TX; Galderma; April 2022
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11. Soolantra cream [prescribing information]. Fort Worth, TX: Galderma; July 2018.
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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.