



Drug Coverage Policy

Effective Date.....5/01/2024
Coverage Policy Number.....IP0172
Policy Title.....Topical Azelaic Acid
Products

Topical Azelaic Acid Products

- Azelex® (azelaic acid 20% topical cream)
- Finacea® foam (azelaic acid aerosol 15%)
- Finacea® gel (azelaic acid 15% gel)

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 patient 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 Healthcare Coverage Policy

OVERVIEW

Topical products for the treatment of acne are available in multiple formulations.^{1,2} Creams and lotions may be best for dry or sensitive skin and gels or foams may be best for more oily skin (although newer aqueous gels may also be suitable for sensitive skin).³

Acne treatment guidelines do not prefer any of the specific brand name agents over similar products available as generics for the treatment of acne.³ Acne management should focus on preventing formation of microcomedones and minimizing the potential for visible acne lesions.^{1,2} The combination of a topical retinoid and benzoyl peroxide remains the preferred approach for almost all patients with acne. Unlike other topical antibiotics, benzoyl peroxide has not been associated with the development of antibiotic resistance.

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 centropacial 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.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table(s)**:

All products are approved for a duration of 12 months unless otherwise noted.

Employer Plans:

Product	Criteria
Azelex (azelaic acid 20% topical cream)	Azelex is considered medically necessary when the patient meets ONE of the following (1 <u>or</u> 2): <ol style="list-style-type: none"> 1. Acne Vulgaris. Failure, contraindication, or intolerance to BOTH of the following (A <u>and</u> B): <ol style="list-style-type: none"> A. azelaic acid 15% gel B. TWO other prescription topical acne products from the following list: <ol style="list-style-type: none"> i. topical antibiotics (for example, clindamycin, erythromycin)

Product	Criteria
	<ul style="list-style-type: none"> ii. tretinoin [cream (0.025%, 0.05% or 0.1%), gel (0.01%, 0.025% or 0.05%) or micro gel (0.04% or 0.1%)] [may require prior authorization] iii. adapalene 0.1% cream, 0.3% gel or 0.1% lotion [may require prior authorization] iv. tazorotene 0.1% cream v. dapsone 5% or 7.5% gel vi. sulfacetamide-containing products <p>2. Rosacea. Failure, contraindication, or intolerance to BOTH of the following (A <u>and</u> B):</p> <ul style="list-style-type: none"> A. azelaic acid 15% gel B. TWO other topical rosacea products from the following list: <ul style="list-style-type: none"> i. ivermectin 1% cream ii. metronidazole 0.75% cream, gel, lotion or 1% gel iii. sodium sulfacetamide 10%/sulfur 5%
<p>Finacea foam (azelaic acid 15% topical foam)</p>	<p>Finacea foam is considered medically necessary when the patient meets ONE of the following (1 <u>or</u> 2):</p> <p>1. Acne Vulgaris. Failure, contraindication, or intolerance to BOTH of the following (A <u>and</u> B):</p> <ul style="list-style-type: none"> A. azelaic acid 15% gel B. TWO other prescription topical acne products from the following list: <ul style="list-style-type: none"> i. topical antibiotics (for example, clindamycin, erythromycin) ii. tretinoin [cream (0.025%, 0.05% or 0.1%), gel (0.01%, 0.025% or 0.05%) or micro gel (0.04% or 0.1%)] [may require prior authorization] iii. adapalene 0.1% cream, 0.3% gel or 0.1% lotion [may require prior authorization] iv. tazorotene 0.1% cream v. dapsone 5% or 7.5% gel vi. sulfacetamide-containing products <p>2. Rosacea. Failure, contraindication, or intolerance to BOTH of the following (A <u>and</u> B):</p> <ul style="list-style-type: none"> A. azelaic acid 15% gel B. TWO other topical rosacea products from the following list: <ul style="list-style-type: none"> i. ivermectin 1% cream ii. metronidazole 0.75% cream, gel, lotion or 1% gel iii. sodium sulfacetamide 10%/sulfur 5%
<p>Finacea gel (azelaic acid 15% topical gel)</p>	<p>Finacea gel is considered medically necessary when the patient meets ONE of the following (1 <u>or</u> 2):</p> <p>1. Acne Vulgaris. BOTH of the following (A <u>and</u> B):</p>

Product	Criteria
	<p>A. The patient has tried azelaic acid 15% 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</p> <p>B. Failure, contraindication, or intolerance to TWO other prescription topical acne products from the following list:</p> <ul style="list-style-type: none"> i. topical antibiotics (for example, clindamycin, erythromycin) ii. tretinoin [cream (0.025%, 0.05% or 0.1%), gel (0.01%, 0.025% or 0.05%) or micro gel (0.04% or 0.1%)] [may require prior authorization] iii. adapalene 0.1% cream, 0.3% gel or 0.1% lotion [may require prior authorization] iv. tazorotene 0.1% cream v. dapsone 5% or 7.5% gel vi. sulfacetamide-containing products <p>2. Rosacea. BOTH of the following (A and B):</p> <p>A. The patient has tried azelaic acid 15% 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</p> <p>B. Failure, contraindication, or intolerance to TWO other topical rosacea products from the following list:</p> <ul style="list-style-type: none"> i. ivermectin 1% cream ii. metronidazole 0.75% cream, gel, lotion or 1% gel iii. 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.

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

Conditions Not Covered

Any other use is considered not medically necessary

References

1. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2023. Available at: <http://fco.factsandcomparisons.com/lco/action/home>. Accessed on August 31, 2023. Search terms: benzoyl peroxide, clindamycin, minocycline, sulfacetamide/sulfur, Twynéo.
2. Clinical Pharmacology © 2023. Available at <https://www.clinicalkey.com/pharmacology/>. Accessed on August 31, 2023. Search terms: benzoyl peroxide and sulfur/sulfacetamide.

3. Thiboutot DM, Dreno B, Abanmi A, et al. Practical management of acne for clinicians: an international consensus from the Global Alliance to Improve Outcomes in Acne. *J Am Acad Dermatol.* 2018;78:S1-S23.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No changes to criteria intent	5/1/2024

The policy effective date is in force until updated or retired.

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