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Topical Azelaic Acid Products

Table of Contents

Overview 1
Medical Necessity Criteria 1
Reauthorization Criteria 3
Authorization Duration 3
Conditions Not Covered..... 3
Background..... 3
References 4

Related Coverage Resources

- Topical Acne – Non-Retinoid Products - (IP0166)
Topical Adapalene Products – (IP0181)
Topical Clascoterone – (IP0173)
Topical Rosacea Products – (IP0003)
Topical Tazarotene Products – (IP0174)
Topical Tretinoin Products (IP0167)
Topical Trifarotene – (IP0180)

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. 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 azelaic acid products:

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

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

Medical Necessity Criteria

Coverage varies across plans and requires the use of preferred products. Refer to the customer’s benefit plan document for coverage details.

The products in the table below are considered medically necessary when the following are met:

Employer Group Non-Covered Products and the Preferred Covered Alternatives:

Non-Covered Product	Criteria
Azelex (azelaic acid 20% topical cream)	<p>Individual meets ONE of the following (1 <u>or</u> 2):</p> <ol style="list-style-type: none"> 1. Acne Vulgaris. There is documentation the individual has had an inadequate response, contraindication, or is intolerant 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) 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 2. Rosacea. There is documentation the individual has had an inadequate response, contraindication, or is intolerant to BOTH of the following (A <u>and</u> B): <ol style="list-style-type: none"> A. azelaic acid 15% gel B. TWO other topical rosacea products from the following list: <ol 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%
Finacea foam (azelaic acid 15% topical foam)	<p>Individual meets ONE of the following (1 <u>or</u> 2):</p> <ol style="list-style-type: none"> 1. Acne Vulgaris. There is documentation the individual has had an inadequate response, contraindication, or is intolerant 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) 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 2. Rosacea. There is documentation the individual has had an inadequate response, contraindication, or is intolerant to BOTH of the following (A <u>and</u> B): <ol style="list-style-type: none"> A. azelaic acid 15% gel B. TWO other topical rosacea products from the following list: <ol 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%
Finacea gel (azelaic acid 15% topical gel)	<p>Individual meets ONE of the following (1 <u>or</u> 2):</p> <ol style="list-style-type: none"> 1. Acne Vulgaris. There is documentation of BOTH of the following (A <u>and</u> B): <ol style="list-style-type: none"> A. The individual 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 B. The individual has had an inadequate response, contraindication, or is intolerant to TWO other prescription topical acne products from the following list:

Non-Covered Product	Criteria
	<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. There is documentation of BOTH of the following (A <u>and</u> B):</p> <ul style="list-style-type: none"> A. The individual 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 B. The individual has had an inadequate response, contraindication, or is intolerant to 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%

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 azelaic acid 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 is up to 12 months.
Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW

Azelaic acid cream (Azelex) is indicated for the topical treatment of mild to moderate inflammatory acne vulgaris and for the treatment of inflammatory pustules and papules of mild to moderate acne rosacea. Azelaic acid foam and gel (Finacea) are indicated for the treatment of inflammatory lesions of mild to moderate rosacea.⁴⁻⁵

Guidelines

Acne treatment guidelines do not prefer any of the specific brand name agents over their 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. Azelaic acid is considered second-line treatment or as an adjunctive therapy in the treatment of acne.²

The American Acne & Rosacea Society (AARS) updated guidelines on the management of rosacea in 2019.^{6,7} A gentle skin care and photo-protection 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 2020).^{8,9} 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.⁹

References

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