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Topical Tazarotene 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. 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 formulary exceptions for the following topical tazarotene products:

- Arazlo™ (tazarotene 0.045% lotion)
• Fabior® (tazarotene 0.1% foam)
• Tazorac® (tazarotene 0.05% cream, 0.05% gel, 0.1% cream, and 0.1% gel)
• tazarotene 0.1% 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:

Non-Covered Product	Criteria
<p>Arazlo (tazarotene 0.045% lotion)</p>	<p>Arazlo (tazarotene 0.045% lotion) is considered medically necessary when the individual meets ONE of the following:</p> <ol style="list-style-type: none"> 1. Acne Vulgaris. Documentation of failure, contraindication, or intolerance to ALL of the following: <ol style="list-style-type: none"> A. tazarotene 0.1% cream or 0.1% gel B. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization] C. tretinoin cream, gel, or micro gel [may require prior authorization] 2. Plaque Psoriasis. Documentation of failure, contraindication, or intolerance to ALL of the following: <ol style="list-style-type: none"> A. tazarotene 0.05% gel, 0.1% gel, or 0.1% cream B. calcipotriene cream, foam, ointment, or solution C. prescription topical corticosteroid 3. Treatment of Other <u>Non-Cosmetic Conditions</u> (for example, for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). Documentation of failure, contraindication, or intolerance to ALL of the following: <ol style="list-style-type: none"> A. tazarotene 0.05% gel, 0.1% gel, or 0.1% cream B. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization] C. tretinoin cream, gel, or micro gel [may require prior authorization]
<p>Fabior (tazarotene 0.1% foam)</p>	<p>Fabior (tazarotene 0.1% foam) is considered medically necessary when the individual meets ONE of the following:</p> <ol style="list-style-type: none"> 1. Acne Vulgaris. Documentation of failure, contraindication, or intolerance to ALL of the following: <ol style="list-style-type: none"> A. tazarotene 0.1% cream or 0.1% gel B. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization] C. tretinoin cream, gel, or micro gel [may require prior authorization] 2. Plaque Psoriasis. Documentation of failure, contraindication, or intolerance to ALL of the following: <ol style="list-style-type: none"> A. tazarotene 0.05% gel, 0.1% gel, or 0.1% cream B. calcipotriene cream, foam, ointment, or solution C. prescription topical corticosteroid 3. Treatment of Other <u>Non-Cosmetic Conditions</u> (for example, for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). Documentation of failure, contraindication, or intolerance to ALL of the following: <ol style="list-style-type: none"> A. tazarotene 0.05% gel, 0.1% gel, or 0.1% cream B. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization] C. tretinoin cream, gel, or micro gel [may require prior authorization]
<p>tazarotene 0.1% foam</p>	<p>Tazarotene 0.1% foam is considered medically necessary when the individual meets ONE of the following:</p> <ol style="list-style-type: none"> 1. Acne Vulgaris. Documentation of failure, contraindication, or intolerance to ALL of the following: <ol style="list-style-type: none"> A. tazarotene 0.1% cream or 0.1% gel

Non-Covered Product	Criteria
	<p>B. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization]</p> <p>C. tretinoin cream, gel, or micro gel [may require prior authorization]</p> <p>2. Plaque Psoriasis. Documentation of failure, contraindication, or intolerance to ALL of the following:</p> <p>A. tazarotene 0.05% gel, 0.1% gel, or 0.1% cream</p> <p>B. calcipotriene cream, foam, ointment, or solution</p> <p>C. prescription topical corticosteroid</p> <p>3. Treatment of Other <u>Non-Cosmetic Conditions</u> (for example, for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). Documentation of failure, contraindication, or intolerance to ALL of the following:</p> <p>A. tazarotene 0.05% gel, 0.1% gel, or 0.1% cream</p> <p>B. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization]</p> <p>C. tretinoin cream, gel, or micro gel [may require prior authorization]</p>
<p>Tazorac 0.05% cream (tazarotene 0.05% cream)</p>	<p>Tazorac 0.05% cream is considered medically necessary when the individual meets ONE of the following:</p> <p>1. Acne Vulgaris. Documentation of failure, contraindication, or intolerance to ALL of the following:</p> <p>A. tazarotene 0.1% cream or 0.1% gel</p> <p>B. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization]</p> <p>C. tretinoin cream, gel, or micro gel [may require prior authorization]</p> <p>2. Plaque Psoriasis. Documentation of failure, contraindication, or intolerance to ALL of the following:</p> <p>A. tazarotene 0.05% gel, 0.1% gel, or 0.1% cream</p> <p>B. calcipotriene cream, foam, ointment, or solution</p> <p>C. prescription topical corticosteroid</p> <p>3. Treatment of Other <u>Non-Cosmetic Conditions</u> (for example, for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). Documentation of failure, contraindication, or intolerance to ALL of the following:</p> <p>A. tazarotene 0.05% gel, 0.1% gel, or 0.1% cream</p> <p>B. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization]</p> <p>C. tretinoin cream, gel, or micro gel [may require prior authorization]</p>
<p>Tazorac 0.1% cream (tazarotene 0.1% cream)</p>	<p>Tazorac 0.1% cream is considered medically necessary when the individual meets ONE of the following:</p> <p>1. Acne Vulgaris. Documentation of failure, contraindication, or intolerance to ALL of the following:</p> <p>A. Trial of <u>tazarotene 0.1% cream</u> (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. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization]</p> <p>C. tretinoin cream, gel, or micro gel [may require prior authorization]</p>

Non-Covered Product	Criteria
	<p>2. Plaque Psoriasis. Documentation of failure, contraindication, or intolerance to ALL of the following:</p> <ul style="list-style-type: none"> A. Trial of tazarotene 0.1% 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. calcipotriene cream, foam, ointment, or solution C. prescription topical corticosteroid <p>3. Treatment of Other Non-Cosmetic Conditions (for example, for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). Documentation of failure, contraindication, or intolerance to ALL of the following:</p> <ul style="list-style-type: none"> A. Trial of tazarotene 0.1% 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. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization] C. tretinoin cream, gel, or micro gel [may require prior authorization]
<p>Tazorac gel (tazarotene 0.05% gel <u>and</u> 0.1% gel)</p>	<p>Tazorac gel is considered medically necessary when the individual meets ONE of the following:</p> <p>1. Acne Vulgaris. Documentation of failure, contraindication, or intolerance to ALL of the following:</p> <ul style="list-style-type: none"> A. Trial of tazarotene 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. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization] C. tretinoin cream, gel, or micro gel [may require prior authorization] <p>2. Plaque Psoriasis. Documentation of failure, contraindication, or intolerance to ALL of the following:</p> <ul style="list-style-type: none"> A. Trial of tazarotene 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. calcipotriene cream, foam, ointment, or solution C. prescription topical corticosteroid <p>3. Treatment of Other Non-Cosmetic Conditions (for example, for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). Documentation of failure, contraindication, or intolerance to ALL of the following:</p> <ul style="list-style-type: none"> A. Trial of tazarotene 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. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization] C. tretinoin cream, gel, or micro gel [may require prior authorization]

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

Continuation of topical tazarotene products is considered medically necessary when the above medical necessity 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

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Cosmetic Conditions: Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical pharmacy benefit. Examples of cosmetic conditions include actinic purpura, age spots (also called liver spots, solar lentigines, sun spots), melasma/cholasma, milia, mottled hyperpigmentation, mottled hypopigmentation, photo-aged or photo-damaged skin, pokiloderma (of Civatte), premature aging, scarring, sebaceous hyperplasia, seborrheic keratosis, skin laxity, skin roughness, solar elastosis, solar purpura, stretch marks, and wrinkles.

Background

OVERVIEW

Tazorac gel is indicated for the following uses:¹

- **Plaque psoriasis**, in patients with up to 20% body surface area involvement (0.05% and 0.1% strengths).
- **Facial acne vulgaris**, in patients with mild to moderate severity (0.1% strength only).

Tazorac cream is indicated for the following uses:²

- **Plaque psoriasis** (0.05% and 0.1% strengths).
- **Acne vulgaris** (0.1% strength only).

Both Arazlo lotion and Fabior foam are indicated for the topical treatment of **acne vulgaris**.^{3,4}

In addition to acne vulgaris and plaque psoriasis, topical tazarotene products have been used to treat other medical skin conditions, such as basal cell carcinoma and congenital ichthyoses.⁵⁻¹³ Topical tazarotene products have also been used to treat cosmetic skin conditions such as wrinkles, premature aging, and treatment of photo-aged or photo-damaged skin.

References

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