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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	March 10, 2003
Subject:	Tazarotene	**Page:**	1 of 6

Last Review Date: September 6, 2024

Tazarotene

Description

Tazorac (tazarotene), Arazlo (tazarotene), Fabior (tazarotene), tazarotene powder

Background
Tazarotene is a retinoid medication derived from vitamin A used to treat both non-inflammatory and inflammatory types of acne, including blackheads, whiteheads, papules, pustules, and nodules and in the treatment of plaque psoriasis (1-4).

Tazarotene may also be used for cosmetic purposes such as treatment for wrinkles, fine lines and solar or photo aging. These indications are excluded from plan coverage.

Regulatory Status
FDA-approved indications:

Tazorac cream, 0.05% and 0.1% are indicated for the topical treatment of patients with plaque psoriasis. Tazorac cream 0.1% is also indicated for the topical treatment of patients with acne vulgaris (1).

Tazorac gel 0.05% and 0.1% are indicated for the topical treatment of patients with stable plaque psoriasis of up to 20% body surface area involvement (2).

Tazorac gel 0.1% is also indicated for the topical treatment of patients with facial acne vulgaris of mild to moderate severity (2).

Fabior foam 0.1% is indicated for the topical treatment of acne vulgaris in patients 12 years of

age or older (3).

Arazlo lotion 0.045% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older (4).

Off-Label Use:
Tazarotene is also recommended topically to treat skin conditions in high-risk patients (i.e., immunocompromised, post organ transplant) with actinic keratosis, basal and squamous cell carcinoma (5).

Products containing tazarotene are contraindicated in pregnancy. Females of child-bearing potential should have a negative pregnancy test two weeks prior to starting therapy, which should begin during a normal menstrual period, and use effective contraception during therapy (1-4).

Related policies

Aczone, Tretinoin, Vtama, Winlevi, Zoryve

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tazarotene may be considered **medically necessary** if the conditions indicated below are met.

Tazarotene may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 35 years of age or older
No PA needed for age < 35

Diagnoses

Patient must have **ONE** of the following:

1. Acne vulgaris

a. Comedones
b. Cysts (eruptive vellus hair cyst, cystic acne)
c. Papules
d. Pustules

2. Acne conglobata

3. Plaque psoriasis

4. Patient is at high risk (i.e., immunocompromised, post organ transplant) with one of the following diagnoses:
   a. Actinic keratosis
   b. Basal cell carcinoma
   c. Squamous cell carcinoma

AND the following for **ALL** indications:

a. Female patients of reproductive potential will be advised to use effective contraception during treatment

Prior – Approval *Renewal* Requirements

Age 35 years of age or older
No PA needed for age < 35

Diagnoses

Patient must have **ONE** of the following:

1. Acne vulgaris
   a. Comedones
   b. Cysts (eruptive vellus hair cyst, cystic acne)
   c. Papules
   d. Pustules
2. Acne conglobata
3. Plaque psoriasis
   a. Improvement in lesions
4. Patient is at high risk (i.e., immunocompromised, post organ transplant) with one of the following diagnoses:
   a. Actinic keratosis
   b. Basal cell carcinoma

c. Squamous cell carcinoma

AND the following for **ALL** indications:

a. Female patients of reproductive potential are not currently pregnant **AND** will be advised to use effective contraception during treatment

Policy Guidelines

Pre – PA Allowance

Age Age less than 35 – no restriction
Age 35 or greater – no Pre-PA allowance

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Tazarotene is a retinoid medication derived from vitamin A. Tazarotene products are indicated for the topical treatment of patients with acne vulgaris, plaque psoriasis, acne conglobata, and patients who are at high risk (i.e., immunocompromised, post organ transplant) with one of the following skin conditions: actinic keratosis, basal and squamous cell carcinoma. Products containing tazarotene are contraindicated in pregnancy (1-4).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of tazarotene while maintaining optimal therapeutic outcomes.

References

1. Tazorac Cream [package insert]. Irvine, CA: Allergan, Inc.; July 2017.
2. Tazorac Gel [package insert]. Irvine, CA: Allergan, Inc.; April 2018.
3. Fabior [package insert]. Greenville, NC: Mayne Pharma.; June 2018.
4. Arazlo [package insert]. Bridgewater, NJ: Bausch Health Companies Inc.; August 2023.

5. Stockfleth E, Ulrich C, Meyer T, Christophers E. Epithelial malignancies in organ transplant patients: clinical presentation and new methods of treatment. Recent Results Cancer Res. 2002; 160:251-8.

Policy History

Date	Action
November 2010	Addition of malignant and pre-malignant conditions to criteria. The use of Tazorac and other topical retinoids for the treatment of malignant and pre-malignant skin conditions is well documented in medical literature (3). Adding these diagnoses brings Tazorac in line with the current topical retinoid criteria.
December 2011	Annual review and update
December 2012	Annual review and update
September 2013	Line-addition of Tazarotene 0.1% cream, Fabior 0.1% Foam, and tazarotene powder. Reference update.
June 2014	Annual editorial review and reference update Addition of high-risk to malignant and pre-malignant conditions per SME
March 2015	Annual editorial review and reference update
September 2015	Annual editorial review and reference update
September 2016	Annual editorial review and reference update Policy number change from 5.14.02 to 5.90.02
September 2017	Annual review and reference update
September 2018	Annual editorial review and reference update
March 2019	Annual review and reference update
August 2019	Addition of requirement for female patients of reproductive potential are not pregnant and will be advised to use effective contraception per FEP
September 2019	Annual review
March 2020	Annual review
September 2020	Addition of Arazlo
December 2020	Annual review
March 2021	Annual editorial review
December 2021	Annual review
June 2022	Annual review and reference update
September 2022	Annual review
December 2022	Annual review
September 2023	Annual review. Per SME, removed negative pregnancy test requirement
June 2024	Annual review and reference update
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.