Tazarotene

**Description**

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

**Background**

Tazarotene is a retinoid medication that is made from vitamin A in treating both non-inflammatory and inflammatory types of acne, including blackheads, whiteheads, papules, pustules, and nodules and in the treatment of plaque psoriasis (1).

Tazarotene, when used for mitigation of facial fine wrinkling, is a non-covered cosmetic indication.

**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).
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 (4).

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 (1-3).

The safety and efficacy of tazarotene have not been established in pediatric patients under the age of 12 years (1-3).

Related policies
Tretinoins

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 in patients for the treatment of acne vulgaris, plaque psoriasis, acne conglobata or patients who are at high risk (ie. immunocompromised, post organ transplant) with one of the following skin conditions: actinic keratosis, basal and squamous cell carcinoma.

Tazarotene may be considered investigational for all other indications.

Prior-Approval Requirements

Age  Age less than 35 – no restriction

Diagnoses

Patient must have ONE of the following:

1. Acne vulgaris
   a. Comodones
   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 have had a negative pregnancy test within the last 2 weeks **AND** will be advised to use effective contraception during treatment

### Prior – Approval **Renewal Requirements**

**Age**  
Age less than 35 – no restriction

**Diagnoses**

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

1. Acne vulgaris
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**

**Duration** 12 months

**Rationale**

**Summary**
Tazarotene products are indicated for the topical treatment of patients with acne vulgaris, plaque psoriasis, acne conglobata and patients who are at high risk (ie. 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. The safety and efficacy of tazarotene have not been established in pediatric patients under the age of 12 years (1-3).

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

**References**
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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.