RATIONALE FOR INCLUSION IN PA PROGRAM

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).
TAZORAC/ FABIOR/ TAZAROTENE POWDER
(tazarotene)

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