

## **PRIOR AUTHORIZATION POLICY**

**POLICY:** Topical Retinoids – Tazarotene Products Prior Authorization Policy

Arazlo<sup>™</sup> (tazarotene 0.045% lotion – Bausch Health)

• Fabior® (tazarotene 0.1% foam – Mayne Pharma, generic)

Tazorac<sup>®</sup> (tazarotene 0.05% cream, 0.05% gel, 0.1% cream, and 0.1% gel – Allergan, generics to 0.1% cream, 0.05% gel, and 0.1% gel only)

**REVIEW DATE:** 08/14/2024

#### 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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

# CIGNA NATIONAL FORMULARY COVERAGE:

### **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:<sup>2</sup>

- **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.**<sup>3,4</sup>

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

Page 1 of 3 - Cigna National Formulary Coverage - Policy: Topical Retinoids - Tazarotene Products Prior Authorization Policy

congenital ichthyoses.<sup>5-13</sup> Topical tazarotene products have also been used to treat cosmetic skin conditions such as wrinkles, premature aging, and treatment of photoaged or photo-damaged skin.

### **POLICY STATEMENT**

Prior Authorization is recommended for prescription benefit coverage of topical tazarotene products. All approvals are provided for the duration noted below.

Prior authorization and prescription benefit coverage are not recommended for cosmetic uses.

- Arazlo™ (tazarotene 0.045% lotion Bausch Health)
- Fabior® (tazarotene 0.1% foam Mayne Pharma, generic)
- Tazorac<sup>®</sup> (tazarotene 0.05% cream, 0.05% gel, 0.1% cream, and 0.1% gel Allergan, generics to 0.1% cream, 0.05% gel, and 0.1% gel only)

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

## **FDA-Approved Indications**

- **1. Acne Vulgaris.** Approve for 1 year.
- **2. Plaque Psoriasis.** Approve for 1 year.

### **Other Uses with Supportive Evidence**

**3. Treatment of Other Non-Cosmetic Conditions.** Approve for 1 year.

<u>Note</u>: Examples of other non-cosmetic conditions include: acne keloidalis nuchae, basal cell carcinoma, comedonal acne, cystic acne, cutaneous T-cell lymphoma, ichthyosis (e.g., congenital, lamellar, vulgaris, X-linked), keratoderma blennorrhagicum, keratosis (e.g., keratosis follicularis [Darier's disease], keratosis pilaris), mycosis fungoides, nail psoriasis, oral lichen planus, and warts.

### **CONDITIONS NOT COVERED**

- Arazlo™ (tazarotene 0.045% lotion Bausch Health)
- Fabior® (tazarotene 0.1% foam Mayne Pharma, generic)
- Tazorac<sup>®</sup> (tazarotene 0.05% cream, 0.05% gel, 0.1% cream, and 0.1% gel Allergan, generics to 0.1% cream, 0.05% gel, and 0.1% gel only)

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available): 1. Cosmetic Conditions. Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical pharmacy benefit.

Note (this is not an all-inclusive list): 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.

#### REFERENCES

- 1. Tazorac® gel 0.05%, 0.1% [prescribing information]. Irvine, CA: Allergan; April 2018.
- 2. Tazorac® cream 0.05%, 0.1% [prescribing information]. Irvine, CA: Allergan; August 2019.
- 3. Arazlo™ lotion [prescribing information]. Bridgewater, NJ: Bausch Health US; August 2023.
- 4. Fabior® foam 0.1% [prescribing information]. Greenville, NC: Mayne Pharma; February 2023.
- 5. DRUGDEX® System. Thomson Reuters (Healthcare) Inc. Available at: https://www.micromedexsolutions.com/micromedex2/librarian/.. Accessed on August 12, 2024. Search term: tazarotene.
- 6. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2024. Available at: https://fco.factsandcomparisons.com/lco/action/home. Accessed on August 12, 2024. Search term: tazarotene.
- 7. Acne Keloidalis Nuchae. Available at: https://www.skinsight.com/skin-conditions/adult/acne-keloidalis-nuchae. Accessed on August 12, 2024.
- 8. Tanghetti E, Dhawan S, Green L, et al. Clinical evidence for the role of a topical anti-inflammatory agent in comedonal acne: findings from a randomized study of dapsone gel 5% in combination with tazarotene cream 0.1% in patients with acne vulgaris. *Drugs Dermatol*. 2011;10:783-792.
- 9. Morin CB, Roberge D, Turchin I, et al. Tazarotene 0.1% cream as monotherapy for early-stage cutaneous T-cell lymphoma. *J Cutan Med Surg*. 2016;20:244-248.
- 10. Del Rosso J. Treatment of keratosis pilaris with topical tazarotene cream. Pediatrics. 2005;52:P74.
- 11. Wennberg E, Richards PQ, Bain PA, et al. Topical treatments for early-stage mycosis fungoides using grading recommendations assessment, development and evaluation (GRADE) criteria: a systematic review. *JAAD Int*. 2021;3:26-41.
- 12. Petruzzi M, De Benedittis M, Grassi R, et al. Oral lichen planus: a preliminary clinical study on treatment with tazarotene. *Oral Dis.* 2002;8:291-295.
- 13. Petruzzi M, Lucchese A, Lajolo C, et al. Topical retinoids in oral lichen planus treatment: an overview. *Dermatol.* 2013;226:61-67.
- 14. Pasch N. Nail psoriasis: a review of treatment options. Drugs. 2016;76(6):675-705.
- 15. Rosen T. A multimodality approach to recalcitrant warts. Available at https://assets.bmctoday.net/practicaldermatology/pdfs/PD0812\_SF\_Warts.pdf.. Accessed on August 12, 2024.

### **HISTORY**

Type of	Summary of Changes	Review
Revision		Date
Annual	No criteria changes.	08/02/2023
Revision		
Annual	No criteria changes.	08/02/2023
Revision		

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2024 The Cigna Group.