

<b>Clinical Policy Title:</b>	tazarotene
<b>Policy Number:</b>	RxA.688
<b>Drug(s) Applied:</b>	Tazorac®
<b>Original Policy Date:</b>	07/30/2021
<b>Last Review Date:</b>	09/14/2021
<b>Line of Business Policy Applies to:</b>	All lines of business

## Background

Tazarotene (Tazorac®) is a retinoid. Tazorac® is available as cream and gel.

- Cream 0.05% and 0.1% is indicated for the topical treatment of plaque psoriasis and 0.1% is indicated for the topical treatment of acne vulgaris.
- Gel 0.05% and 0.1% is indicated for the topical treatment of plaque psoriasis of up to 20% body surface area involvement and 0.1% is indicated for the topical treatment of mild to moderate facial acne vulgaris.

### Limitations of Use

- The safety of Tazorac® gel use on more than 20% body surface area has not been established.

## Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tazarotene (Tazorac® cream and gel [0.05% and 0.1%])	Plaque psoriasis	Apply once daily, in the evening, to psoriatic lesions*, using enough (2 mg/cm <sup>2</sup> ) to cover only the lesion with a thin film.	2 mg/cm <sup>2</sup> /day
tazarotene (Tazorac® cream and gel [0.1%])	Acne vulgaris	Cleanse the face gently. After the skin is dry, apply a thin film (2 mg/cm <sup>2</sup> ) once daily, in the evening, to the skin where acne lesions appear.	2 mg/cm <sup>2</sup> /day

\*Do not cover more than 20% of body surface area with gel formulation.

## Dosage Forms

- Cream: 0.05% and 0.1% tazarotene in 30 gm and 60 gm tube.
- Gel: 0.05% and 0.1% tazarotene in 30 gm and 100 gm tube.

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

## I. Initial Approval Criteria

### A. Plaque psoriasis (must see all):

1. Diagnosis of plaque psoriasis;
2. Request meets one of the following (i or ii):
  - i. If request is for Tazorac® Cream:
    - a. Age ≥ 18 years;
  - ii. If request is for Tazorac® Gel, request meets (a or b):
    - a. Body surface area involvement of plaque psoriasis is ≤ 20%;
    - b. Age ≥ 12 years;
3. Failure of at least one topical corticosteroid (e.g., clobetasol, mometasone, triamcinolone) unless contraindicated or clinically significant adverse effects are experienced;
4. Request does not exceed 30 gm, 60 gm or 100 gm (1 tube) per month.

#### Approval Duration

**Commercial:** 12 Months

**Medicaid:** 12 Months

### B. Acne vulgaris (must see all):

1. Diagnosis of acne vulgaris;
2. Request is for Tazorac® 0.1% and meets one of the following (i or ii):
  - i. If request is for Tazorac® Cream:
    - a. Age ≥ 12 years;
  - ii. If request is for Tazorac® Gel, request meets (a and b):
    - a. Age ≥ 12 years;
    - b. Mild to moderate facial acne vulgaris;
3. Failure of two preferred retinoid agents (e.g. topical adapalene, topical adapalene, generic adapalene-benzoyl peroxide, generic tazarotene, etc.) unless contraindicated or clinically significant adverse effects are experienced;
4. Request does not exceed 30 gm, 60 gm or 100 gm (1 tube) per month.

#### Approval Duration

**Commercial:** 12 Months

**Medicaid:** 12 Months

## II. Continued Therapy Approval

### A. All Indications in Section I (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, dose does not exceed 30 gm, 60 gm or 100 gm (1 tube) per month.

#### Approval Duration

**Commercial:** 12 Months

**Medicaid:** 12 Months

## III. Appendices

### APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

### APPENDIX B: Therapeutic Alternatives

- Not applicable.

**APPENDIX C: Contraindications/Boxed Warnings**

- Contraindication(s):
  - Pregnancy;
  - Hypersensitivity.
- Boxed Warning(s):
  - None reported.

**APPENDIX D: General Information**

- Embryofetal Toxicity: Tazorac® contains tazarotene, which is a teratogen. Tazorac® is contraindicated in pregnancy. Females of childbearing potential should have a negative pregnancy test within 2 weeks prior to initiating treatment and use an effective method of contraception during treatment.
- Local Irritation: Excessive pruritus, burning, skin redness or peeling can occur. If these reactions occur, discontinue until the integrity of the skin has been restored, or consider reducing dosing frequency or in the case of psoriasis, consider switching to the lower concentration. Tazorac® should not be used on eczematous skin, as it may cause severe irritation.
- Photosensitivity and Risk for Sunburn: Avoid exposure to sunlight, sunlamps, and weather extremes. Wear sunscreen daily. Tazorac® should be administered with caution if the patient is also taking drugs known to be photosensitizers.

**References**

1. Tazorac® Cream Prescribing Information. Exton, PA: Almirall, LLC. August 2019. Available at: <https://www.tazorachcp.com/static/tazorac-cream-pi-445200720d2daf13d1a2f11f8c1dd414.pdf>. Accessed on July 30, 2021.
2. Tazorac® Gel Prescribing Information. Exton, PA: Almirall, LLC. August 2019. Available at: <https://www.tazorachcp.com/static/tazorac-gel-pi-da48ef66363cb3cefdac569c00119eb0.pdf>. Accessed on July 30, 2021.
3. Clinical Pharmacology. Tampa, FL: Gold Standard; 2019. Available at [www.clinicalpharmacology.com](http://www.clinicalpharmacology.com). Accessed on July 30, 2021.
4. Zaenglein AL, Pathy AL, Schlosser BJ et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016 May;74(5):945-73.e33. doi: 10.1016/j.jaad.2015.12.037. Available at [https://www.jaad.org/article/S0190-9622\(15\)02614-6/fulltext](https://www.jaad.org/article/S0190-9622(15)02614-6/fulltext). Accessed on July 30, 2021.
5. Tazarotene-Tazorac® Lexi-Drug. Lexicomp. Accessed with subscription at: <http://online.lexi.com>. Accessed on July 30, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	07/30/2021	09/14/2021