# Clinical Policy: Age Limit for Tazarotene (Tazorac, Arazlo)

Reference Number: CP.PMN.75
Effective Date: 11.01.16
Last Review Date: 11.19
Line of Business: Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

This policy applies to requests for tazarotene lotion (Arazlo™), cream (Tazorac®) and gel (Tazorac®) that exceed the age limit of 21 years of age.

## FDA Approved Indication(s)

Tazorac cream and gel 0.05% and 0.1% are indicated for the topical treatment of plaque psoriasis.

Tazorac cream and gel 0.1% are also indicated for the topical treatment of mild-to-moderate acne vulgaris.

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

Limitation(s) of use: The safety of Tazorac gel use on more than 20% body surface area has not been established.

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Tazorac is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Plaque Psoriasis** (must meet all)**:**

1. Request is for Tazorac cream or gel;
2. Diagnosis of plaque psoriasis with body surface area involvement of ≤ 20%;
3. Prescribed by or in consultation with a dermatologist;
4. Dose does not exceed 1 tube per month.

**Approval duration: 12 months**

**B. Acne Vulgaris** (must meet all)**:**

1. Diagnosis of acne vulgaris;
2. Dose does not exceed 1 tube per month.

**Approval duration: 12 months**

**C. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

## II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 tube per month.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*
Not applicable

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Pregnancy
  - Tazorac: Individuals who have known hypersensitivity to any of its components
- Boxed warning(s): none reported

*Appendix D: General Information*

- Prior authorization is required for members ≥ 21 years of age to prevent inappropriate use for cosmetic purposes.

## V. Dosage and Administration

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| Tazarotene (Tazorac) cream and gel 0.05% and 0.1% | Plaque psoriasis | Apply gel or cream, 0.05% with strength increased to 0.1% if tolerated and medically indicated, qPM to psoriatic lesions, using enough (2 mg/cm$^2$) to cover only the lesion with a thin film.<br><br>**Do not cover more than 20% of body surface area with the gel formulation.* | 2 mg/cm$^2$/day |
| Tazarotene (Tazorac) cream and gel 0.1% | Acne | Apply a thin film (2 mg/cm$^2$) of gel or cream 0.1% qPM, to the skin where acne lesions appear. | 2 mg/cm$^2$/day |
| Tazarotene (Arazlo) lotion 0.045% | Acne | Apply a thin layer to the affected areas once daily. Avoid the eyes, mouth, paranasal creases and mucous membranes. Not for oral, ophthalmic or intravaginal use. | |

## VI. Product Availability

| Drug Name | Availability |
|---|---|
| Tazarotene (Tazorac) | Cream (30 g and 60 g tubes): 0.05%, 0.1%<br>Gel (30 g and 100 g tubes): 0.05%, 0.1% |
| Tazarotene (Arazlo) | Lotion (45g): 0.045% |

## VII. References

1. Tazorac Gel Prescribing Information. Irvine, CA: Allergan, Inc., April 2018. Available at https://www.allergan.com/assets/pdf/tazorac_gel_pi. Accessed August 13, 2019.
2. Tazorac Cream Prescribing Information. Irvine, CA: Allergan, Inc., July 2017. Available at https://www.allergan.com/assets/pdf/tazorac_cream_pi. Accessed August 13, 2019.
3. Clinical Pharmacology. Tampa, FL: Gold Standard; 2019. Available at www.clinicalpharmacology.com. Accessed August 13, 2019.
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.
5. Arazlo lotion Prescribing Information. Bridgewater, NJ: Bausch Health, LLC., December 2019. Available at: https://www.bauschhealth.com/portals/25/pdf/pi/arazlo-pi.pdf. Accessed January 10, 2020.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created. | 09.16 | 11.16 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Updated template and updated references. | 08.01.17 | 11.17 |
| 4Q 2018 annual review: added specialist requirement; removed pregnancy as contraindication from initial approval criteria; changed dose limit from 1 package per claim to 1 tube per month; references reviewed and updated. | 08.31.18 | 11.18 |
| 2Q 2019 annual review: removed specialist requirement for acne vulgaris; references reviewed and updated. | 01.29.19 | 05.19 |
| 4Q 2019 annual review: no significant changes; references reviewed and updated. | 08.13.19 | 11.19 |
| RT4: added Arazlo to policy | 01.10.20 | |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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