Clinical Policy: Age Limit for Tazarotene (Tazorac)
Reference Number: CP.PMN.75
Effective Date: 11.01.16
Last Review Date: 11.19
Line of Business: Medicaid

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

Description
This policy applies to requests for tazarotene cream 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.

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. Diagnosis of plaque psoriasis with body surface area involvement of ≤ 20%;
      2. Prescribed by or in consultation with a dermatologist;
      3. 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):
     o Pregnancy
     o 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

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tazarotene</td>
<td>Plaque psoriasis</td>
<td>Apply gel or cream, 0.05% with strength increased to 0.1% if tolerated and medically indicated, qPM to psoriatic lesions, using</td>
<td>2 mg/cm²/day</td>
</tr>
</tbody>
</table>
**Drug Name** | **Indication** | **Dosing Regimen** | **Maximum Dose**
--- | --- | --- | ---
Tazarotene (Tazorac) cream and gel 0.1% | Acne | Apply a thin film (2 mg/cm²) of gel or cream 0.1% qPM, to the skin where acne lesions appear. | 2 mg/cm²/day

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

**VI. Product Availability**
- Cream (30 g and 60 g tubes): 0.05%, 0.1%
- Gel (30 g and 100 g tubes): 0.05%, 0.1%

**VII. References**

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

**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
This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**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.