Clinical Policy: Tazarotene (Arazlo, Fabior, Tazorac)
Reference Number: CP.PMN.244
Effective Date: 09.01.20
Last Review Date: 08.20
Line of Business: Commercial, HIM, Medicaid

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

Description
Tazarotene lotion (Arazlo™), foam (Fabior®), cream and gel (Tazorac®) are retinoids.

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 is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.
Fabior foam is indicated for the topical treatment of acne vulgaris in patients 12 years of age or 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 Arazlo, Fabior, and Tazorac are 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. Request does not exceed 1 tube per month.
      Approval duration: 12 months
   
   B. Acne Vulgaris (must meet all):
      1. Diagnosis of acne vulgaris;
      2. For Arazlo and Fabior requests only, member meets all of the following (a, b, and c):
a. Member meets one of the following (i or ii):
   i. For Arazlo: age ≥ 9 years;
   ii. For Fabior: age ≥ 12 years;

b. Documentation supports inability to use generic formulary topical tazarotene;

c. Failure of generic formulary topical tretinoin and adapalene, unless clinically significant adverse effects are experienced or both are contraindicated;

3. Request does not exceed 1 tube (Arazlo, Tazorac) or 1 can (Fabior) 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.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and 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 request does not exceed 1 tube (Arazlo, Tazorac) or 1 can (Fabior) 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.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and 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.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and 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

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 (Tazorac) cream and gel 0.05% and 0.1%</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 enough (2 mg/cm²) to cover only the lesion with a thin film. <em>Do not cover more than 20% of body surface area with the gel formulation.</em></td>
<td>2 mg/cm²/day</td>
</tr>
<tr>
<td>Tazarotene (Tazorac) cream and gel 0.1%</td>
<td>Acne</td>
<td>Apply a thin film (2 mg/cm²) of gel or cream 0.1% qPM, to the skin where acne lesions appear.</td>
<td>2 mg/cm²/day</td>
</tr>
<tr>
<td>Tazarotene (Arazlo) lotion 0.045%</td>
<td>Acne</td>
<td>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.</td>
<td>Once daily application</td>
</tr>
<tr>
<td>Tazarotene (Fabior) foam 0.1%</td>
<td>Acne</td>
<td>Apply a thin layer to the entire affected areas of the face and/or upper trunk once daily in the evening.</td>
<td>Once daily application</td>
</tr>
</tbody>
</table>

VI. Product Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tazarotene (Tazorac)</td>
<td>Cream (30 g and 60 g tube): 0.05%, 0.1%</td>
</tr>
<tr>
<td></td>
<td>Gel (30 g and 100 g tube): 0.05%, 0.1%</td>
</tr>
<tr>
<td>Tazarotene (Arazlo)</td>
<td>Lotion (45 g tube): 0.045%</td>
</tr>
<tr>
<td>Tazarotene (Fabior)</td>
<td>Foam (50 g and 100 g can): 0.1%</td>
</tr>
</tbody>
</table>

VII. References


Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Policy created. Retire CP.PMN.75 Age Limit for Tazarotene (Tazorac, Arazlo); Fabior was added to the policy, in order to allow for SDC-requested redirection to generic preferred products for the treatment of acne vulgaris without limiting the redirection only to members &lt; 21 years of age.</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>05.28.20</td>
<td>08.20</td>
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</table>

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.

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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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