Clinical Policy: Tazarotene (Arazlo, Fabior, Tazorac)
Reference Number: CP.PMN.244
Effective Date: 09.01.20
Last Review Date: 11.20
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)
Tazarotene is indicated for the topical treatment of:
- Plaque psoriasis *(Tazorac cream and gel 0.05% and 0.1%)*
- Acne vulgaris:
  - That is mild to moderate *(Tazorac cream and gel 0.1%)*
  - In patients 9 years of age and older *(Arazlo lotion)*
  - In patients 12 years of age or older *(Fabior foam)*

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. 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*
   This table provides a listing of preferred alternative therapy recommended in the approval 
   criteria. The drugs listed here may not be a formulary agent for all relevant lines of business 
   and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>tretinoin (Retin-A®)</td>
<td>0.025% gel, 0.05% cream, 0.1% cream: Apply once daily</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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</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. *Do not cover more than 20% of body surface area with the gel formulation.</td>
<td>2 mg/cm²/day</td>
</tr>
<tr>
<td>Tazarotene (Tazorac) cream and gel</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. Avoid the eyes, lips, and mucous membranes.</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

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>05.28.20</td>
<td>08.20</td>
</tr>
<tr>
<td>4Q 2020 annual review: removed requirement for dermatologist for plaque psoriasis indication; references reviewed and updated.</td>
<td>08.06.20</td>
<td>11.20</td>
</tr>
</tbody>
</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
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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
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connection with diagnosis and treatment decisions.

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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
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