Clinical Policy: Tazarotene (Arazlo, Fabior, Tazorac)

Reference Number: IL.ERX.PMN.244
Effective Date: 06.01.21
Last Review Date: 11.21
Line of Business: Illinois Medicaid

Revision Log

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 topical 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 Envolve Pharmacy Solutions 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. Diagnosis of plaque psoriasis with body surface area involvement of ≤ 20%;
2. Request is for tazarotene cream or gel;
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, unless contraindicated or clinically significant adverse effects are experienced;
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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
tretinoin (Retin-A®)	**Acne Vulgaris** 0.025% gel, 0.05% cream, 0.1% cream: Apply once daily	Not applicable

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

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

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. **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.	Once daily application

Drug Name	Indication	Dosing Regimen	Maximum Dose
Tazarotene (Fabior) foam 0.1%	Acne	Apply a thin layer to the entire affected areas of the face and/or upper trunk once daily in the evening.	Once daily application

VI. Product Availability

Drug Name	Availability
Tazarotene (Tazorac)	Cream (30 g and 60 g tube): 0.05%, 0.1% (*generic available*) Gel (30 g and 100 g tube): 0.05%, 0.1%
Tazarotene (Arazlo)	Lotion (45 g tube): 0.045%
Tazarotene (Fabior)	Foam (50 g and 100 g can): 0.1%

VII. References

1. Clinical Pharmacology. Tampa, FL: Gold Standard; 2021. Available at www.clinicalpharmacology.com. Accessed August 9, 2021.
2. 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.

Prescribing Information

3. Arazlo lotion Prescribing Information. Bridgewater, NJ: Bausch Health, LLC., May 2021. Available at: www.fda.gov. Accessed August 9, 2021
4. Fabior foam Prescribing Information. Greenville, NC: Mayne Pharmaceuticals, May 2012. Available at www.fda.gov. Accessed August 9, 2021.
5. Tazorac Cream Prescribing Information. Irvine, CA: Allergan, Inc., July 2017. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021184s009lbl.pdf. Accessed August 9, 2021.
6. Tazorac Gel Prescribing Information. Irvine, CA: Allergan, Inc., April 2018. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020600s010lbl.pdf. Accessed August 9, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.15.21	05.21
4Q 2021 annual review: for PsO, added that request must be for tazarotene cream or gel and removed requirement for dermatologist prescriber; for acne, removed requirement for adapalene trial per PDL status; references reviewed and updated.	08.09.21	11.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.