Clinical Policy: Tazarotene (Arazlo, Fabior, Tazorac)

Reference Number: CP.PMN.244
Effective Date: 09.01.20
Last Review Date: 11.22
Line of Business: Commercial, HIM, 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 facial and of mild to moderate severity (*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 tazarotene 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. Member must 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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 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.PA.154 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.

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
adapalene (Differin®)	**Acne Vulgaris** Lotion, Cream: 0.1%; Gel: 0.1%, 0.3% Apply topically QD	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.	2 mg/cm^2/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		**Do not cover more than 20% of body surface area with the gel formulation.*	
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
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. Avoid the eyes, lips, and mucous membranes.	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. Arazlo Prescribing Information. Bridgewater, NJ: Bausch Health US LLC, May 2021. Available at: https://pi.bauschhealth.com/globalassets/BHC/PI/arazlo-pi.pdf. Accessed August 15, 2022.Fabior Prescribing Information. Greenville, NC: Mayne Pharmaceuticals, June 2018. Available at: www.dailymed.nlm.nih.gov. Accessed August 15, 2022.
2. Tazorac Cream Prescribing Information. Irvine, CA: Allergan, Inc., August 2019. Available at https://www.tazorachcp.com/static/tazorac-cream-pi-54115b39c03f775e241400f432307541.pdf. Accessed August 15, 2022.
3. Tazorac Gel Prescribing Information. Irvine, CA: Allergan, Inc., August 2019. Available at: https://www.almirall.us/pdf/Tazorac_Gel_USPI_final_Aug2019.pdf . Accessed August 15, 2022.
4. Clinical Pharmacology. Tampa, FL: Gold Standard; 2021. Available at: www.clinicalpharmacology.com. Accessed August 15, 2022.
5. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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	05.28.20	08.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
treatment of acne vulgaris without limiting the redirection only to members < 21 years of age.		
4Q 2020 annual review: removed requirement for dermatologist for plaque psoriasis indication; references reviewed and updated.	08.06.20	11.20
4Q 2021 annual review: no significant changes; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	08.09.21	11.21
4Q 2022 annual review: no significant changes; for acne vulgaris converted "Documentation supports inability to use" to "Member must use" language; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	08.15.22	11.22

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.

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.