

Clinical Policy: Tazarotene (Tazorac)

Reference Number: PA.CP.PMN.75

Effective Date: 01/18

Last Review Date: 04/19

Coding Implications
Revision Log

Description

This policy applies to tazarotene cream and gel (Tazorac[®]) with 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.

Policy/Criteria

Provider <u>must</u> submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness [®] 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 $\leq 20\%$;
 - 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 – Refer to PA.CP.PMN.53 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):

- Currently receiving medication via Pennsylvania Health and Wellness benefit or member has met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
- 2. Member is responding positively to therapy;
- 3. If request is for a dose increase, new dose does not exceed 1 tube per month.

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Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

- 1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
- 2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months

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 policy – PA.CP.PMN.53 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

Drug Name	Indication	Dosing Regimen	Maximum Dose
Tazarotene (Tazorac) cream and gel	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/cm²) to cover only the lesion with a thin film.	2 mg/cm ² /day
		*Do not cover more than 20% of body surface area with the gel formulation.	
Tazarotene (Tazorac)	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

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Drug Name	Indication	Dosing Regimen	Maximum Dose
cream and gel			

VI. Product Availability

Cream: 0.05% and 0.1% Gel: 0.05% and 0.1%

VII. References

- 1. Tazorac Gel Prescribing Information. Irvin, CA: Allergan, Inc., May 2014. Available at https://www.allergan.com/assets/pdf/tazorac_gel_pi . Accessed August 7, 2018
- 2. Tazorac Cream Prescribing Information. Irvin, CA: Allergan, Inc., July 2017. Available at https://www.allergan.com/assets/pdf/tazorac_cream_pi . Accessed August 7, 2018.
- 3. Clinical Pharmacology. Tampa, FL: Gold Standard; 2016. Available at www.clinicalpharmacology.com. Accessed August 7, 2018.
- 4. 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	Approval Date
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.	08/18	
2Q 2019 annual review removed specialist requirement for acne vulgaris; references reviewed and updated.	04/19	