

Clinical Policy Title:	tazarotene
Policy Number:	RxA.627
Drug(s) Applied:	Arazlo™
Original Policy Date:	05/21/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Tazarotene 0.045% is a topical lotion with the brand name Arazlo. Arazlo is approved for the topical treatment of acne vulgaris in patients nine years of age and older. This is the first tazarotene acne treatment available as a lotion.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tazarotene (Arazlo™)	Acne vulgaris	Apply a thin layer of Arazlo to the affected areas once daily. Avoid the eyes, mouth, paranasal creases, and mucous membranes.	Once daily dosing

Dosage Forms

- 0.045% topical lotion

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Acne Vulgaris (must meet all):

1. Diagnosis of acne vulgaris;
2. Age \geq 9 years;
3. Failure of two preferred topical retinoid agents (e.g., topical adapalene, topical tretinoin, generic adapalene-benzoyl peroxide, generic tazarotene, etc.) ,) unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 45 g container per month (1 tube per month);

Approval Duration:

Commercial: 12 months

Medicaid: 12 months

II. Continued Therapy Approval

A. Acne Vulgaris (must meet all):

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 tube per month;

Approval Duration

Commercial: 12 months

Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Topical Retinoids		
adapalene (Differin®)	Lotion, Cream: 0.1%; Gel, gel with pump: 0.1%, 0.3%; Apply topically once daily	Not applicable
tretinoin (Retin-A®, Retin-A Micro®)	Cream: 0.025%, 0.05%, 0.1%; Gel: 0.01%, 0.025%, 0.05%; Microsphere Gel, gel with pump: 0.04%, 0.1% Apply topically once daily	Not applicable
Adapalene-benzoyl peroxide (Epiduo, Epiduo Forte)	Gel with pump: 0.1-2.5%, 0.3%-2.5%; Apply a thin film topically to affected area of face or trunk once daily;	Not applicable
Tazarotene (Tazorac)	Gel/jelly, cream: 0.1%, 0.05%; After cleansing the face, apply 0.1% cream topically every evening	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):
 - Arazlo is contraindicated in pregnancy
- Boxed Warning(s):
 - Not applicable

APPENDIX D: General Information

Topical retinoids are used for the treatment of both noninflammatory and inflammatory acne and are recommended for the initial management in most patients with moderate-to-severe acne. Topical tretinoin, Adapalene and tazarotene are other effective topical products.

Arazlo is the first tazarotene acne treatment available as lotion form. It helps with moderate and severe acne in those who struggle to stay on tazarotene treatment due to tolerability issues like dry skin, skin irritation. Arazlo is for use on skin only. It cannot be used in eyes, mouth, the corners of your nose, or vagina. Patients must not be pregnant before starting treatment with Arazlo or become pregnant during treatment. It may cause birth defects if used during pregnancy.

References

1. Arazlo (Tazarotene)0.045% topical lotion, prescribing information (per FDA). Bridgewater, NJ; Bausch Health US, LLC; December, 2019. Available at: <https://www.arazlo.com/> Accessed January, 19 2021.
2. Arazlo. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI; 2020, March 17. Accessed with subscription at: <http://www.micromedexsolutions.com>. Accessed January, 19 2021.
3. 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. Available at <https://www.aad.org/member/clinical-quality/guidelines/acne>. Accessed January, 19 2021.

Review/Revision History	_VK	P&T Approval Date
Policy established.	05/04/2020	05/21/2020
Policy was reviewed: 1) Continuation therapy criteria II.A.1. rephrased to “Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy 2) Appendix B: Therapeutic Alternatives QD,BID,TID changed to once daily,twice a day and three times a day respectively 3) Therapeutic alternative verbiage changed to “Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements” 4) References were updated 5) Updated initial approval criteria based on the clinical guidelines and the availability of preferred agents within same drug class	01/19/2021	03/09/2021

6) Updated therapeutic alternatives table to include other topical retinoids.		
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