Clinical Policy Title:	trifarotene
Policy Number:	RxA.625
Drug(s) Applied:	Aklief®
Original Policy Date:	05/21/2020
Last Review Date:	11/30/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Acne Vulgaris (must meet all):

1. Diagnosis of acne vulgaris;
2. Trial and failure of one (1) topical anti-acne agents (e.g., topical adapalene, tretinoin, benzoyl peroxide/erythromycin, clindamycin, benzoyl peroxide/clindamycin phosphate, erythromycin, sulfacetamide/sulfur), at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Acne Vulgaris (must meet all):

1. Member is currently receiving or has been treated with the medication within the past 90 days, excluding manufacturer samples.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. Hauk L. Acne Vulgaris: Treatment Guidelines from the AAD. Am Fam Physician. 2017 Jun 1;95(11):740-741. PMID: 28671431. Available at: https://www.aad.org/member/clinical-quality/guidelines/acne. Accessed October 19, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	05/04/2020	05/21/2020
Policy was reviewed. 1. Policy title table was updated.	02/18/2021	03/09/2021

2. Background section was updated for simplification. 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Appendix B standard verbiage was updated. 5. Dosing frequency sig codes were expanded. 6. Appendix B was updated to remove brand Duac® as it was discontinued. 7. References were updated.		
Policy was reviewed. 1. Dosing Information, Maximum Dose, Aklief®: Updated maximum dosing information from once daily dosing to Not applicable for indication Acne vulgaris. 2. Dosage Forms: Updated dosage form from 0.005% topical cream to 0.005% topical cream (45-gm pump). 3. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 4. Initial Approval Criteria, I.A.4: Updated trial and failure criteria from Failure of two preferred topical anti-acne agents (e.g., topical adapalene, tretinoin, benzoyl peroxide/erythromycin, clindamycin, benzoyl peroxide/clindamycin phosphate, erythromycin, sulfacetamide/sulfur) unless contraindicated or clinically significant adverse effects are experienced to Failure of at least two (2) preferred topical anti-acne agents (e.g., topical adapalene, tretinoin, benzoyl peroxide/erythromycin, clindamycin, benzoyl peroxide/clindamycin phosphate, erythromycin, sulfacetamide/sulfur), at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced. 5. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 6. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both	12/08/2021	01/17/2022

generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only. 7. References were reviewed and updated.		
Policy was reviewed. 1. Dosing Information, Maximum dose: Updated from not applicable to one application/day. 2. Initial Approval Criteria I.A.4: Updated from trial and failure of at least two (2) preferred topical anti-acne agents to trial and failure of one (1) topical anti-acne agents. 3. Initial Approval Criteria; Commercial and Medicaid approval duration updated from 6 months to 12 months. 4. Appendix B, Drug Name: Updated to include new therapeutic alternative tazarotene (Tazorac®) 5. References were reviewed and updated.	10/19/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed. 1. Age criteria removed. 2. Dosing criteria removed. 3. Reauthorization requirement for positive response to therapy removed.	12/4/2023	11/30/2023