Clinical Policy Title:	trifarotene
Policy Number:	RxA.625
Drug(s) Applied:	Aklief®
Original Policy Date:	05/21/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Aklief® is a selective retinoic acid receptor (RAR) topical retinoid cream formulation that is suitable for use on the face and trunk. It is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
trifarotene (Aklief®)	Acne vulgaris	Apply a thin layer of Aklief® Cream to the affected areas of the face and/or trunk once a day, in the evening, on clean and dry skin. Avoid contact with the eyes, lips, paranasal creases, and mucous membranes	Once daily dosing

Dosage Forms

- 0.005% topical cream

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 ≥ 9 years;
3. Prescribed by or in consultation with a dermatologist;
4. 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;
5. Dose does not exceed 45 grams (1 tube) per month.

Approval Duration

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

A. Acne Vulgaris (must meet all):

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 45 grams (1 tube) per month.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
RAR: Retinoic Acid Receptor
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	Maximum Dose
Topical Retinoids		
adapalene (Differin®)	Lotion, Cream: 0.1%; Gel: 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: 0.04%, 0.1% Apply topically once daily	Not applicable
Topical Antibiotics		
benzoyl peroxide erythromycin (Benzamycin®)	Gel: 5% benzoyl peroxide/3% erythromycin Apply topically once to twice daily	Not applicable
clindamycin (Cleocin T®, Clindagel®, Clindamax®)	Solution, Gel, Lotion 1%: Apply topically twice daily Foam 1%: Apply topically once daily	Not applicable
benzoyl peroxide/ clindamycin phosphate (Neuac®, BenzaClin®)	Neuac®: 1.2% clindamycin/5% benzoyl peroxide: Apply topically once daily BenzaClin®: 1% clindamycin/5% benzoyl peroxide: Apply topically twice daily	Not applicable

erythromycin (Erygel®)	Solution: 2%; Gel: 2% Apply topically twice daily	Not applicable
sulfacetamide/sulfur	Various strengths Apply topically once to three times 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):
  - None reported.

- Boxed Warning(s):
  - None reported.

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.

Aklief® is the first new retinoid product to receive FDA approval for the treatment of acne. It is an agonist of RAR, with specific activity at the gamma subtype of RAR, which may be associated with Aklief®'s effects on acne vulgaris. Aklief® appears to be a safe and effective topical retinoid acne treatment option that reduces inflammatory lesions on the face, back, chest, and shoulders.

References

1. Aklief® (trifarotene) 0.005% topical cream, prescribing information (per FDA). Fort Worth, TX; Galderma Laboratories, L.P.; October, 2019. Accessed February 04, 2021.
2. Aklief® Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI; 2020, March 17. Accessed with subscription at: http://www.micromedexsolutions.com. Accessed February 04, 2021.
3. 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 February 04, 2021.

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. 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..."	02/18/2021	03/09/2021

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.		