Drug and Biologic Coverage Policy

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Coverage Policy Number IP0180

Topical Trifarotene

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Overview

This policy supports medical necessity review for trifarotene 0.005% topical cream (**Aklief®**).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Non-Covered Product	Criteria
Aklief (trifarotene 0.005% cream)	**Aklief is considered medically necessary when the individual meets the following criteria:** **Acne Vulgaris.** Documentation of **BOTH** of the following: A. Age 9 years or older

Non-Covered Product	Criteria
	B. Failure, contraindication, or intolerance to **ALL** of the following: i. tazarotene 0.1% cream/gel ii. adapalene 0.1% cream/lotion/solution or 0.3% gel [may require prior authorization] iii. tretinoin cream (0.025%, 0.05% or 0.1%), gel (0.01%, 0.025% or 0.05%) or micro gel (0.04% or 0.1%) [may require prior authorization]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of trifarotene (Aklief) is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 12 months.
Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Any other use is considered not medically necessary.

Background

OVERVIEW
Aklief, a topical retinoid, is **indicated for the topical treatment of acne vulgaris in patients ≥ 9 years of age**.[1]

Guidelines
The American Academy of Dermatology guidelines for the management of acne (2016) note topical therapies, either as monotherapy or in combination with other topical agents or oral agents, as the treatment of choice for initial control and maintenance therapy of acne.[2] Topical retinoids are the cornerstone of acne management due to their comedolytic and anti-inflammatory properties.

References

1. Aklief® cream [prescribing information]. Fort Worth, TX: Galderma; October, 2019.
2. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016;74:945-73.