Drug Coverage Policy

Effective Date.....4/1/2025
Coverage Policy Number.....IP0180
Policy Title..... Aklief

Topical Retinoids – Aklief

- Aklief® (trifarotene cream – Galderma)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

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

Medical Necessity Criteria

Aklief is considered medically necessary when the following is met:

FDA-Approved Indication

1. **Acne Vulgaris.** Approve for 1 year if the patient meets **BOTH** of the following (A and B):

A. Patient is ≥ 9 years of age.
B. Preferred product criteria are met for the product(s) as listed in the below table(s).

Employer Plans:

Product	Criteria
Aklief (trifarotene cream)	Patient has tried, and according to the prescriber, experienced inadequate efficacy, or significant intolerance with **ALL** the following (A, B, and C): A. A topical adapalene product; AND Note: Examples of topical adapalene products include Differin and adapalene. B. A topical tazarotene product; AND Note: Example of topical tazarotene products include Tazorac, tazarotene, Arazlo, Fabior. C. A topical tretinoin product. Note: Examples of topical tretinoin products include Retin-A, Retin-A Micro, tretinoin, Altreno, Atralin, Avita.

Individual and Family Plans:

Product	Criteria
Aklief (trifarotene cream)	Patient has tried, and according to the prescriber, experienced inadequate efficacy, or significant intolerance with **ALL** the following (A, B, and C): A. A topical adapalene product; AND Note: Examples of topical adapalene products include Differin and adapalene. B. A topical tazarotene product; AND Note: Example of topical tazarotene products include Tazorac, tazarotene, Arazlo, Fabior. C. A topical tretinoin product. Note: Examples of topical tretinoin products include Retin-A, Retin-A Micro, tretinoin, Altreno, Atralin, Avita.

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.

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

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Aklief® cream [prescribing information]. Fort Worth, TX: Galderma; October 2023.

2. Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2024;90(5): 1006.e1-1006.e30.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	IFP added to the policy. **Updated** preferred product requirements.	8/01/2024
Annual Revision	**Employer Plans, Individual and Family Plans Preferred Product Table.** **Updated from** "Patient has tried a topical adapalene product, a topical tazarotene product, AND a topical tretinoin product" **to** "Patient has tried, and according to the prescriber, experienced inadequate efficacy, or significant intolerance with ALL the following (A, B, and C): A. A topical adapalene product; AND Note: Examples of topical adapalene products include Differin and adapalene. B. A topical tazarotene product; AND Note: Example of topical tazarotene products include Tazorac, tazarotene, Arazlo, Fabior. C. A topical tretinoin product. Note: Examples of topical tretinoin products include Retin-A, Retin-A Micro, tretinoin, Altreno, Atralin, Avita."	4/1/2025

The policy effective date is in force until updated or retired.

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