Drug Coverage Policy

Effective Date.....9/15/2026
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 where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

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

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of Aklief. All approvals are provided for the duration noted below.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information.

Prescription benefit coverage is excluded for cosmetic use.

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; AND
   - **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 **[documentation required]**; AND Note: Examples of topical adapalene products include Differin and adapalene. **B.** A topical tazarotene product **[documentation required]**; AND Note: Example of topical tazarotene products include Tazorac, tazarotene, Arazlo, Fabior. **C.** A topical tretinoin product **[documentation required]**. 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 **[documentation required]**; AND Note: Examples of topical adapalene products include Differin and adapalene. **B.** A topical tazarotene product **[documentation required]**; AND

Product	Criteria
	Note: Example of topical tazarotene products include Tazorac, tazarotene, Arazlo, Fabior. **C.** A topical tretinoin product **[documentation required]**. Note: Examples of topical tretinoin products include Retin-A, Retin-A Micro, tretinoin, Altreno, Atralin, Avita.

Conditions Not Covered

Aklief for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Cosmetic Use.** Cosmetic use is excluded from coverage in a typical pharmacy benefit. Note (this is not an all-inclusive list): Examples of cosmetic conditions include actinic purpura, age spots (also called liver spots, solar lentigines, sunspots), melasma/chloasma, milia, mottled hyperpigmentation, mottled hypopigmentation, photo-aged or photo-damaged skin, pokiloderma (of Civatte), premature aging, scarring, sebaceous hyperplasia, seborrheic keratosis, skin laxity, skin roughness, solar elastosis, solar purpura, stretch marks, and wrinkles.

References

1. Aklief® cream [prescribing information]. Fort Worth, TX: Galderma; September 2024.

Revision Details

Summary of Changes	Review Date	Effective Date
IFP added to the policy. **Updated** preferred product requirements.	5/23/2024	8/01/2024
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.	1/30/2025	4/1/2025

Note: Examples of topical tretinoin products include Retin-A, Retin-A Micro, tretinoin, Altreno, Atralin, Avita."		
Policy Statement: The following was added "Prescription benefit coverage is excluded for cosmetic uses." **Conditions Not Recommended for Approval**: Treatment of cosmetic conditions was added. **Added [documentation required] to** preferred product tables for Employer Plans and Individual and Family Plans.	10/23/2025	12/1/2025
No criteria changes.	9/3/2026	9/15/2026

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

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2026 The Cigna Group.