LOUISIANA BLUE

Topical Retinoids

Policy # 00342
Original Effective Date: 02/20/2013
Current Effective Date: 04/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Topical Tretinoins and Tretinoin Combination Products

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider topical tretinoin products (including, but not limited to Retin-A®‡, Retin-A Micro®‡, Avita®‡, Tretin X®‡, Atralin®‡ gel, Altreno™‡ lotion, tretinoin powders, and other generic topical tretinoin products) and topical tretinoin/clindamycin combination products (including, but not limited to Ziana®‡or Veltin®‡) to be **eligible for coverage**** when one of the below patient selection criteria is met:

Patient Selection Criteria

Coverage eligibility will be considered in patients greater than 30 years of age for topical tretinoin products or for topical tretinoin/clindamycin combination products when one of the following criteria is met:

- Requested drug is a topical tretinoin product or a topical tretinoin/clindamycin combination product, and the patient has a diagnosis of acne vulgaris; OR
- Requested drug is a topical tretinoin product, and the patient has a diagnosis of: acne rosacea, cystic acne, actinic [solar] keratosis (precancerous lesions), ichthyosis, diabetic foot ulcers, mucositis, warts, keloids, lichen planus, lichen scleroses, pseudofolliculitis, oral leukoplakia, molluscum contagiosum, or Darier's disease (keratosis follicularis); OR
- Requested drug is a topical tretinoin product, and the patient has a diagnosis of: skin cancers, dermatitis, folliculitis, keratosis pilaris, sebaceous hyperplasia, sebaceous cyst, milia, eczema, or confluent and reticulated papillomatosis, AND the patient has tried at least one other therapy for the current diagnosis.
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of topical tretinoin products for use in skin cancers, dermatitis, folliculitis, keratosis pilaris, sebaceous hyperplasia, sebaceous cyst, milia, eczema, or confluent and reticulated papillomatosis, without first trying at least one other therapy for the diagnosis, to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers, with the exception of cosmetic indications, the use of topical tretinoin/clindamycin combination products in the absence of an acne vulgaris diagnosis to be **investigational.***

Based on review of available data, the Company considers, with the exception of cosmetic indications, the use of topical tretinoin products in the absence of an acne vulgaris diagnosis OR in the absence of a non-cosmetic indication, included in the above patient selection criteria, to be **investigational.***

When Services Are Not Covered

The use of topical tretinoins or topical tretinoin/clindamycin combination products as treatment of wrinkles or other cosmetic conditions are a contract exclusion and is therefore **not covered.****

Aklief® (trifarotene cream)

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Aklief®‡ (trifarotene cream) to be **eligible for coverage**** when the below patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for Aklief (trifarotene cream) when the following criteria are met:

- Patient has a diagnosis of acne vulgaris; AND
- Patient is 9 years of age or older; AND
- Aklief will be used in combination with a moisturizer; AND
- Patient has tried and failed (e.g. intolerance or inadequate response) at least ONE topical product containing tretinoin unless there is clinical evidence or patient history that suggests the use of topical tretinoin-containing products will be ineffective or cause an adverse reaction to the patient. Examples of topical tretinoin-containing products include tretinoin cream, tretinoin gel, generic avita 0.025%, Altreno lotion, and clindamycin-tretinoin gel 1.2-0.025%; AND
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has tried and failed (e.g. intolerance or inadequate response) at least ONE topical product containing adapalene or tazarotene unless there is clinical evidence or patient history that suggests the use of topical adapalene or tazarotene-containing products will be ineffective or cause an adverse reaction to the patient. Examples of topical adapalene or tazarotene-containing products include adapalene 0.1% cream, adapalene 0.3% gel, tazarotene 0.1% cream, and Tazorac®‡ 0.05% cream.
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Aklief (trifarotene cream) when the patient has not tried and failed at least one topical product containing tretinoin and at least one topical product containing adapalene or tazarotene, to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Aklief in the absence of an acne vulgaris diagnosis, in patients younger than 9 years of age, or without concomitant use of a moisturizer to be **investigational.***

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Fabior® (tazarotene foam)

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Fabior®‡ (tazarotene foam) and its authorized generic to be **eligible for coverage**** when the below patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for Fabior (tazarotene foam) and its authorized generic when the following criteria are met:

- Patient has a diagnosis of acne vulgaris; AND
- Patient is 12 years of age or older.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Fabior or its authorized generic in the absence of an acne vulgaris diagnosis or in patients younger than 12 years of age to be **investigational.***

Arazlo™ (tazarotene)

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Arazlo™‡ (tazarotene) to be **eligible for coverage**** when the below patient selection criteria are met:

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Patient Selection Criteria

Coverage eligibility will be considered for Arazlo (tazarotene) when the following criteria are met:

- Patient has a diagnosis of acne vulgaris; AND
- Patient is greater than or equal to 9 years of age; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) at least ONE topical product containing tazarotene (e.g., tazarotene 0.1% cream or Tazorac 0.05% cream) unless there is clinical evidence or patient history that suggests the use of topical tazarotene will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has tried and failed (e.g., intolerance or inadequate response) at least ONE topical product containing tretinoin or adapalene (e.g., tretinoin cream, tretinoin gel, generic avita 0.025%, Altreno lotion, clindamycin/tretinoin gel 1.2/0.025%, adapalene 0.1% cream, or adapalene 0.3% gel) unless there is clinical evidence or patient history that suggests the use of topical tretinoin or adapalene will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Arazlo (tazarotene) when the patient has not tried and failed at least one topical product containing tazarotene and at least one topical product containing tretinoin or adapalene, to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Arazlo (tazarotene) in the absence of an acne vulgaris diagnosis or in patients younger than 9 years of age to be **investigational.***

Background/Overview

Topical retinoids are a cornerstone of management of acne vulgaris due to their comedolytic and anti-inflammatory properties and include adapalene, tazarotene, tretinoin, and trifarotene. Numerous brand and generic topical tretinoins are available for the treatment of acne vulgaris. Combination products containing clindamycin phosphate and tretinoin gel (e.g., Ziana and Veltin) are indicated for the topical treatment of acne vulgaris in patients aged ≥ 12 years. Fabior and Arazlo (tazarotene) are also indicated for the topical treatment of acne vulgaris with Fabior and its authorized generic being indicated in patients ages ≥12 years and Arazlo indicated in patients ages ≥9 years.

Additionally, there are many generic adapalene and tazarotene products available. Aklief (trifarotene cream) is the first trifarotene product to be approved by the Food and Drug Administration (FDA) and is indicated for the treatment of acne vulgaris in combination with a moisturizer in patients aged ≥9 years. In general, the topical retinoids are similar in efficacy and the efficacy of individual agents increases with higher concentrations.

Topical tretinoins have been used to treat numerous other medical skin conditions in addition to acne vulgaris. Some indications have minimal published clinical data and thus appear experimental.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy take into consideration clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient. Additionally, a review of available data indicates that there is no advantage to the use of one retinoid product over another. Based on this review, in the absence of the above mentioned caveat, there is no advantage of using a brand name topical retinoid over the available generic topical retinoids. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

The use of topical tretinoin products should be limited to the treatment of medical conditions. Cosmetic application of these products is not considered a covered benefit. Additionally, the combination of clindamycin plus tretinoin products (e.g., Ziana, Veltin), Aklief, Arazlo, and Fabior are only approved by the FDA for the treatment of acne vulgaris. Patient selection criteria are based on information collected in a review of the available data.

References

1. Express Scripts. Topical Tretinoin Products Prior Authorization Policy. 9/2018.
2. DRUGDEX®‡ System. Thomson Reuters (Healthcare) Inc. Available at: http://www.thomsonhc.com. Accessed on 6/4/2013. Search terms: tretinoin.
3. Aklief [package insert]. Galderma Laboratories, L.P. Fort Worth, TX. October 2019.
4. Aklief Drug Evaluation. Express Scripts. Updated October 2019.
5. Fabior [package insert]. Mayne Pharma. Greenville, NC. June 2018.
6. Arazlo [package insert]. Bausch Health. Bridgewater, NJ. December 2019.

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Policy History

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02/07/2013	Medical Policy Committee review
02/20/2013	Medical Policy Implementation Committee approval. New policy.
02/06/2014	Medical Policy Committee review
02/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/05/2015	Medical Policy Committee review
02/18/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/04/2016	Medical Policy Committee review
02/17/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2017	Medical Policy Committee review
02/15/2017	Medical Policy Implementation Committee approval. No change to coverage.
02/01/2018	Medical Policy Committee review
02/21/2018	Medical Policy Implementation Committee approval. No change to coverage.
04/04/2019	Medical Policy Committee review
04/24/2019	Medical Policy Implementation Committee approval. Added new product Altreno lotion. No change to coverage.
02/06/2020	Medical Policy Committee review
02/12/2020	Medical Policy Implementation Committee approval. Title change to include all topical retinoids. Added new section for new product, Aklief, with relevant criteria.
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. Added new section for new product, Fabior, with relevant criteria
01/07/2021	Medical Policy Committee review
01/13/2021	Medical Policy Implementation Committee approval. Added new section for new product, Arazlo, with relevant criteria.
03/03/2022	Medical Policy Committee review
03/09/2022	Medical Policy Implementation Committee approval. Added new Fabior authorized generic to criteria and background information.
03/02/2023	Medical Policy Committee review
03/08/2023	Medical Policy Implementation Committee approval. No change to coverage.
03/07/2024	Medical Policy Committee review
03/13/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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03/06/2025 Medical Policy Committee review
03/12/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 03/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.