

Topical Acne Kits

Policy # 00344

Original Effective Date: 02/20/2013

Current Effective Date: 03/10/2025

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.

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 acne kits (including, but not limited to Clindacin[®] ETZ 1% Kit [clindamycin phosphate 1% pledget and Acuwash[®] cleanser] and Clindacin[®] PAC Kit [clindamycin phosphate 1% pledget and Acuwash[®] cleanser]) to be **eligible for coverage**** when one of the below patient selection criteria is met:

Patient Selection Criteria

Coverage eligibility will be considered for topical acne kits when one of the following criteria is met:

- The patient has tried one prescription topical acne product (brand or generic versions of topical adapalene, azelaic acid, benzoyl peroxide, clindamycin, dapsone, or sulfacetamide/sulfur containing products) AND one prescription topical acne cleanser (brand or generic topical benzoyl peroxide or sulfacetamide/sulfur containing products); OR
- There is clinical evidence or patient history that suggests separate brand or generic topical acne products and topical acne cleansers will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of topical acne kits when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary.****

Background/Overview

Topical acne products and topical acne cleansers are used in the treatment of acne. Benzoyl peroxide containing products are generally indicated for the treatment or prevention of mild to moderate acne vulgaris. Adapalene products are indicated for the treatment of acne. Azelaic acid is indicated for the topical treatment of mild to moderate inflammatory acne vulgaris and for the treatment of inflammatory pustules and papules of mild to moderate acne rosacea. Topical clindamycin and

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dapsone gel are indicated for the treatment of acne vulgaris. Sulfacetamide sodium and sulfur are antimicrobial and antiseptic agents, respectively which aid in the removal of keratin and drying of the skin. Sometimes, combinations of products are packaged together in convenience kits.

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 regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests separate brand or generic topical acne products and topical acne cleansers will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above-mentioned caveat, there is no advantage of using a topical acne kit over a combination of the available brand or generic topical acne products and cleansers.

References

1. Express Scripts. Topical Acne Kit Step Therapy Policy. 12/2024
2. James WD. Acne. N Engl J Med. 2005;352(14):1463-1472.
3. Clinical Pharmacology© 2010. Available at <http://www.clinicalpharmacology-ip.com/Default.aspx>. Search Terms: sulfur and sulfacetamide, clindamycin, benzoyl peroxide, Brevoxyl, Neobenz, Rosula.Thiboutot D, Gollnick, Vincenzo B, et al on behalf of the Global Alliance to Improve Outcomes in Acne. New insights into the management of acne: An update from the Global Alliance to Improve Outcomes in Acne Group. J Am Acad Dermatol. 2009;60:S1-50).
4. Clindacin PAC [package insert]. Medimetriks Pharmaceuticals, Inc. Fairfield, NJ. November 2023.
5. Clindacin ETZ [package insert]. Medimetriks Pharmaceuticals, Inc. Fairfield, NJ. December 2024.

Policy History

Original Effective Date: 02/20/2013

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02/07/2013 Medical Policy Committee review

02/20/2013 Medical Policy Implementation Committee approval.

02/06/2014 Medical Policy Committee review

02/19/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.



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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. Added coverage for adapalene products.
02/02/2017 Medical Policy Committee review
02/15/2017 Medical Policy Implementation Committee approval. No change to coverage.
03/02/2017 Medical Policy Committee review
03/15/2017 Medical Policy Implementation Committee approval. Removed generic erythromycin from step 1 as the brand erythromycin product is obsolete.
02/01/2018 Medical Policy Committee review
02/21/2018 Medical Policy Implementation Committee approval. No change to coverage.
02/07/2019 Medical Policy Committee review
02/20/2019 Medical Policy Implementation Committee approval. No change to coverage.
02/06/2020 Medical Policy Committee review
02/12/2020 Medical Policy Implementation Committee approval. No change to coverage.
02/04/2021 Medical Policy Committee review
02/10/2021 Medical Policy Implementation Committee approval. No change to coverage.
02/03/2022 Medical Policy Committee review
02/09/2022 Medical Policy Implementation Committee approval. No change to coverage.
02/02/2023 Medical Policy Committee review
02/08/2023 Medical Policy Implementation Committee approval. No change to coverage.
02/01/2024 Medical Policy Committee approval
02/14/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2025 Medical Policy Committee review
02/12/2025 Medical Policy Implementation Committee approval. Added new products, Clindacin ETZ 1% Kit and Clindacin PAC Kit, to the policy. Removed obsolete products Levoclen, Zacare, Cleanse and Treat pads, Duac CS and Benzaclin CareKit from the policy.

Next Scheduled Review Date: 02/2026

**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



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- 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

