



STEP THERAPY POLICY

- POLICY:** Topical Acne – Kits Step Therapy Policy
- Clindacin® ETZ 1% Kit (clindamycin phosphate 1% pledget and Acuwash® cleanser – Medimetriks)
 - Clindacin® PAC Kit (clindamycin phosphate 1% pledget and Acuwash® cleanser – Medimetriks)
 - Clindavix Kit (clindamycin phosphate topical solution 1% and Dynashield [dimethicone 1.8%, zinc oxide 2%] – Perrigo [obsolete 08/01/2022])

REVIEW DATE: 12/18/2024

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 NATIONAL FORMULARY COVERAGE:

OVERVIEW

Many topical products are available for the **treatment of acne vulgaris**.^{1,2} Benzoyl peroxide-containing products are generally indicated for the treatment and prevention of mild to moderate acne vulgaris. Sulfacetamide sodium and sulfur are antimicrobial and antiseptic agents, respectively, and are available in a variety of strengths and formulations. They help to remove keratin and to dry the skin. These products (sulfacetamide/sulfur) are additionally used for acne rosacea and seborrheic dermatitis. Topical clindamycin products are indicated for the treatment of acne vulgaris.³⁻⁵ Both Clindacin ETZ kit and Clindacin PAC kit include topical clindamycin pledgets and a bottle of Acuwash® moisturizing daily cleanser.^{3,4} Clindavix kit includes clindamycin topical solution and a tube of Dynashield (dimethicone, zinc oxide), which is a general skin protectant.⁵ Acne treatment guidelines do not prefer any of the brand name products over similar generic products.⁶

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product (one prescription topical acne product and one prescription acne cleanser) prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Step 1: Prescription topical acne products: brand or generic topical adapalene, azelaic acid, benzoyl peroxide, clindamycin, dapsone, sulfacetamide or sulfacetamide/sulfur-containing products (see Appendix A for examples); AND
Prescription topical acne cleansers: brand or generic topical benzoyl peroxide- or sulfacetamide/sulfur-containing products (see Appendix A for examples)

Step 2: Acne kits (Clindacin ETZ, Clindacin PAC, Clindavix Kit)

Topical Acne – Kits Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient has tried one prescription topical acne product (Step 1) AND one prescription acne cleanser (Step 1), approve a Step 2 Product.

REFERENCES

1. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2024. Available at: <https://fco.factsandcomparisons.com/lco/action/home>. Accessed on December 12, 2024. Search terms: benzoyl peroxide, clindamycin, sulfacetamide/sulfur.
2. Clinical Pharmacology © 2024. Available at <https://www.clinicalkey.com/pharmacology/>. Accessed on December 12, 2024. Search Terms: sulfur and sulfacetamide, clindamycin, benzoyl peroxide.
3. Clindacin® ETZ [prescribing information]. Fairfield, NJ: Medimetriks; September 2022.
4. Clindacin® PAC [prescribing information]. Fairfield, NJ: Medimetriks; November 2022.
5. Clindavix [prescribing information]. Allegan, MI: Perrigo; May 2018.
6. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/20/2023
Annual Revision	No criteria changes.	12/18/2024

Appendix A

Examples (not a complete list)

Prescription Topical Acne Products (not cleansers).

Generic name	Trade names (examples)
Adapalene	Differin®
Azelaic Acid	Azelex®
Benzoyl peroxide	Inova® Easy Pad®
Benzoyl peroxide/clindamycin	Acanya®, BenzaClin®
Benzoyl peroxide/erythromycin	Benzamycin®
Benzoyl peroxide/salicylic acid	Inova® 4/1 Easy Pad, Inova® 8/2 Easy Pad
Clindamycin phosphate	Cleocin T®, Evoclin®
Clindamycin/tretinoin	Veltin™, Ziana®
Dapsone	Aczone®
Sulfacetamide	Klaron®
Sulfacetamide/sulfur	Avar-e®™, Avar-e® LS

Refer to *Topical Acne – Topical Product Step Therapy Policy* for more examples.

Prescription Acne Cleansers.

Generic name	Trade names (examples)
Benzoyl peroxide	Pacnex® 7% wash, Pacnex® HP, Pacnex® LP
Sulfacetamide/sulfur	Avar™, Avar™ LS, Plexion®, Sumadan™, Sumaxin® CP, Sumaxin®, Sumaxin TS

Refer to *Topical Acne – Cleansers Step Therapy Policy* for more examples.

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