

Drug Policy

Policy: CC Impacted Drugs:	<p style="text-align: center;">Topical Acne – Kits</p> <p style="text-align: center;">Preferred Step Therapy Policy</p> <p>Note: This is not an all-inclusive list</p> <ul style="list-style-type: none"> • Clindacin ETZ • Clindacin PAC • Clindavix Kit 	Annual Review Date: 03/16/2023 Last Revised Date: 03/16/2023
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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.

POLICY STATEMENT

A step therapy program has been developed to encourage the use of a generic Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 12 months in duration.

Automation: Patients with a history of one prescription topical acne product (Step 1) and one prescription acne cleanser (Step 1) within the 130-day look-back period are excluded from step therapy.

Preferred Medications: Prescription topical acne products (brand or generic topical adapalene, azelaic acid, benzoyl peroxide, clindamycin, dapson, 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]).

Non-preferred Medications: Acne kits (e.g., Clindacin ETZ, Clindacin PAC, Clindavix Kit)

CRITERIA

1. If the patient has tried one prescription (brand or generic) preferred topical acne product (Step 1) AND one prescription (brand or generic) preferred acne cleanser (Step 1), then authorization for a non-preferred acne kit (Step 2) may be given.

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Initial Approval/ Extended Approval.

A) *Initial Approval:* 365 days (1 year)

B) *Extended Approval:* 365 days (1 year)

Step Therapy Exception Criteria

In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

- A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics **[documentation required]; OR**
- B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent **[documentation required]; OR**
- C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
 - 1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
 - 2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as **[documentation required]**. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

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performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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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

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