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)

REVIEW DATE: 12/14/2022

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 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.

<u>Automation</u>: A patient with a of one prescription topical acne product (Step 1) <u>and</u> one prescription acne cleanser (Step 1) within the 130-day look-back period is excluded from Step Therapy.

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)

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.
- 2. No other exceptions are recommended.

REFERENCES

- Facts and Comparisons[®] Online. Wolters Kluwer Health, Inc.; 2022. Available at: http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&qs. Accessed on December 9, 2022. Search terms: benzoyl peroxide, clindamycin, sulfacetamide/sulfur.
- 2. Clinical Pharmacology © 2022. Available at http://www.clinicalpharmacology-ip.com/Default.aspx. Accessed on December 9, 2022. Search Terms: sulfur and sulfacetamide, clindamycin, benzoyl peroxide.
- 3. Clindacin® ETZ [prescribing information]. Fairfield, NJ: Medimetriks; October 2016.
- 4. Clindacin® PAC [prescribing information]. Fairfield, NJ: Medimetriks; November 2016.
- 5. Clindavix [prescribing information]. Allegan, MI: Perrigo; May 2018.
- 6. Thiboutot DM, Dreno B, Abanmi A, et al. Practical management of acne for clinicians: an international consensus from the Global Alliance to Improve Outcomes in Acne. *J Am Acad Dermatol*. 2018;78:S1-S23.

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/15/2021
Selected Revision	Clindavix Kit: Clindavix Kit (clindamycin phosphate topical solution 1%	03/09/2022
	and Dynashield [dimethicone 1.8%, zinc oxide 2%]) was added to Step 2.	
Annual Revision	No criteria changes.	12/14/2022

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.

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