STEP THERAPY POLICY

Topical Acne – Topical Products Step Therapy Policy Policy:

Brand	Generic	Manufacturer
Adapalene Products		
Differin®	adapalene 0.1% gel	Galderma, generic
Differin [®]	adapalene 0.3% gel; adapalene 0.3% gel pump	Galderma, generic
Differin®	adapalene 0.1% cream	Galderma, generic
Differin®	adapalene 0.1% lotion	Galderma
	adapalene 0.1% swab	generic
Azelaic Acid Products		
Azelex®	azelaic acid 20% cream	Allergan
Benzoyl Peroxide-containing Products		
Inova® Easy Pad®	benzoyl peroxide 4% pad; benzoyl peroxide 8% pad	Inocutis
Clindamycin-containing Products		
Cleocin® T	clindamycin phosphate 1% topical solution	Pfizer, generic
Cleocin® T	clindamycin phosphate 1% gel	Pfizer, generic
Cleocin® T	clindamycin phosphoate 1% lotion	Pfizer, generic
Clindagel®	clindamycin phosphate 1% gel	Bausch Health
Evoclin®	clindamycin phosphate 1% foam	Mylan, generic
Dapsone Products		
Aczone®	dapsone 5% gel	Allergan, generic
Aczone®	dapsone 7.5% gel	Allergan, generic
Minocycline Product		
Amzeeq™	minocycline 4% foam	Journey Medical Corporation
Sulfacetaminde-containing Product		
Klaron®	sulfacetamide sodium 10% lotion	Bausch Health, generic
Sulfacetamide/Sulfur-containing Products		
Avar-e®	sodium sulfacetamide/sulfur 10%/5% emollient cream	Mission Pharma
Avar-e® LS	sodium sulfacetamide/sulfur 10%/2% emollient cream	Mission Pharma
Plexion	sodium sulfacetamide/sulfur 9.8%/4.8% cream	Brava
Plexion	sodium sulfacetamide/sulfur 9.8%/4.8% lotion	Brava
Trifarotene Product		
Aklief [®]	Trifarotene 0.005% cream	Galderma
Other Combination Products		
Acanya®	clindamycin phosphate/benzoyl peroxide 1.2%/2.5% gel	Bausch Health, generic
BenzaClin®	clindamycin phosphate/benzoyl peroxide 1%/5% gel	Bausch Health, generic
Benzamycin®	benzoyl peroxide gel/erythromycin gel 5%/3%	Bausch Health, generic
Epiduo [®]	adapalene/benzoyl peroxide 0.1%/2.5% gel (gel pump)	Galderma, generic
Epiduo® Forte	adapalene/benzoyl peroxide 0.3%/2.5% gel (gel pump)	Galderma (60 g gel pump is
_p	maniferance community fractions are to the fact from the	brand only)
Inova® 4/1 Easy Pad	benzoyl peroxide/salicylic acid 4%/1% pad	Innocutis
Inova® 8/2 Easy Pad	benzoyl peroxide/salicylic acid 8%/2% pad	Innocutis
Neuac [®]	Clindamycin phosphate/benzoyl peroxide 1.2%/5% gel	Medimetriks, generic
Onexton TM	Clindamycin phosphate/benzoyl peroxide 1.2%/3.75%	Bausch Health
Twyneo®	Tretinoin/benzoyl peroxide 0.1%/3% cream	Galderma
Veltin™	clindamycin phosphate/tretinoin 1.2%/0.025% gel	Almirall
Ziana [®]	clindamycin phosphate/tretinoin 1.2%0.025% gel	Bausch Health, generic
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Note: This is not an all-inclusive list.

REVIEW DATE: 08/31/2022

OVERVIEW

All of these products are indicated for use in the management of **acne vulgaris**.^{1,2} Some of the benzoyl peroxide-containing products are available over-the-counter (OTC) and these products are generally indicated for the treatment or prevention of mild to moderate acne vulgaris. Sulfacetamide sodium and sulfur are used together to treat acne vulgaris; sulfacetamide is an antimicrobial and sulfur is an antimicrobial and a keratolytic agent that causes a peeling and drying effect. In addition to being indicated for the treatment of acne, sulfacetamide/sulfur products are used for acne rosacea and seborrheic dermatitis. Please refer to the product labeling for specific details.

The topical products for treatment of acne are available in multiple formulations.^{1,2} Creams and lotions may be best for dry or sensitive skin and gels or foams may be best for more oily skin (although newer aqueous gels may also be suitable for sensitive skin).³

Acne treatment guidelines do not prefer any of the specific brand name agents over similar products available as generics for the treatment of acne.³ Acne management should focus on preventing formation of microcomedones and minimizing the potential for visible acne lesions.^{1,2} The combination of a topical retinoid and benzoyl peroxide remains the preferred approach for almost all patients with acne. Unlike other topical antibiotics, benzoyl peroxide has not been associated with the development of antibiotic resistance.

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.

Note: For the purpose of this policy, a topical acne product is defined as a gel, cream, lotion, solution/pledget, pad, foam, or ointment.

<u>Automation</u>: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

- **Step 1:** Generic prescription topical adapalene-, benzoyl peroxide-, clindamycin-, dapsone-, erythromycin-, sodium sulfacetamide-, or sodium sulfacetamide/sulfur-containing products
- Step 2: Brand name prescription topical acne products: Aklief, Amzeeq, Azelex, or brand name topical acne products containing adapalene (e.g., Differin), benzoyl peroxide (e.g., Inova Easy Pad), clindamycin (e.g., Cleocin T, Evoclin), dapsone (e.g., Aczone), erythromycin (e.g., Aknemycin), sulfacetamide (e.g., Klaron), sulfacetamide/sulfur (e.g., Avar-e, Avar-e LS), or combinations containing these active ingredients (e.g., Acanya, Benzamycin, Epiduo [brand], Twyneo, Ziana, Veltin), generic adapalene swabs

CRITERIA

- 1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

 Note: Epiduo Forte with DAW 9 (indicating that substitution is allowed by the prescriber but the Plan requests brand) will also count as a Step 1 Product.
- 2. No other exceptions are recommended.

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REFERENCES

- Facts and Comparisons[®] Online. Wolters Kluwer Health, Inc.; 2022. Available at: http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&qs. Accessed on August 26, 2022. Search terms: benzoyl peroxide, clindamycin, minocycline, sulfacetamide/sulfur, Twyneo.
- 2. Clinical Pharmacology © 2022. Available at http://www.clinicalpharmacology-ip.com/Default.aspx. Accessed on August 26, 2022 Search terms: benzoyl peroxide and sulfur/sulfacetamide.
- 3. 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.