

STEP THERAPY POLICY

POLICY: Topical Acne Products Step Therapy Policy

Note: This is not an all-inclusive list.

Brand	Generic	Manufacturer	
Adapalene Products		Manufacturei	
Differin®	adapalene 0.1% gel	Galderma, generic	
Differin®	adapalene 0.1% gel adapalene 0.3% gel; adapalene 0.3% gel	Galderma, generic	
Dilletill	pump	Gaidei Illa, gelleric	
Differin®	adapalene 0.1% cream	Galderma, generic	
Differin®	adapalene 0.1% lotion	Galderma Generic only	
	adapalene 0.1% swab		
Azelaic Acid Product			
Azelex [®]	azelaic acid 20% cream	Allergan	
Benzoyl Peroxide-co	ontaining Products		
Inova [®] Easy Pad [®]	benzoyl peroxide 4% pad; benzoyl peroxide 8% pad	Inocutis	
Clindamycin-contain			
Cleocin® T	clindamycin phosphate 1% topical solution	Pfizer, generic	
Cleocin® T	clindamycin phosphate 1% gel	Pfizer, generic	
Cleocin® T	clindamycin phosphate 1% lotion	Pfizer, generic	
Clindagel®	clindamycin phosphate 1% gel	Bausch Health	
Evoclin®	clindamycin phosphate 1% foam	Mylan, generic	
Dapsone Products	cimadiffyciii phosphace 170 fodiii	Mylan, generic	
Aczone®	dapsone 5% gel	Allergan, generic	
Aczone®	dapsone 7.5% gel	Allergan, generic	
Minocycline Product		Allergan, generic	
Amzeeg [™]	minocycline 4% foam	Journey Medical	
Sulfacetaminde-conf	taining Product	Journey Medical	
Klaron®	sulfacetamide sodium 10% lotion	Bausch Health, generic	
	ir-containing Products	Dausch Health, generic	
Avar-e®	sodium sulfacetamide/sulfur 10%/5%	Mission	
Avai C	emollient cream	111331011	
Avar-e® LS	sodium sulfacetamide/sulfur 10%/2%	Mission	
7.tva. c 25	emollient cream	1 11331011	
Plexion	sodium sulfacetamide/sulfur 9.8%/4.8%	Brava	
. iexioii	cream	D. a.v.a	
Plexion	sodium sulfacetamide/sulfur 9.8%/4.8%	Brava	
	lotion		
Trifarotene Product	,		
Aklief [®]	trifarotene 0.005% cream	Galderma	
Other Combination F			
Acanya®	clindamycin phosphate/benzoyl peroxide	Bausch Health, generic	
•	1.2%/2.5% gel	, 3	
BenzaClin [®]	clindamycin phosphate/benzoyl peroxide	Bausch Health, generic	
	1%/5% gel	, ,	
Benzamycin®	benzoyl peroxide /erythromycin 5%/3% gel	Bausch Health, generic	
Cabtreo [™]	clindamycin/adapalene/benzoyl peroxide 1.2%/0.15%/3.1% gel	Bausch Health	
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 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	Medimetriks, generic	
	1.2%/5% gel		
Onexton [™]	clindamycin phosphate/benzoyl peroxide	Bausch Health, generic	
	1.2%/3.75%		
Twyneo®	tretinoin/benzoyl peroxide 0.1%/3% cream	Galderma	
Veltin™	clindamycin phosphate/tretinoin	Almirall	
	1.2%/0.025% gel		
Ziana®	clindamycin phosphate/tretinoin 1.2%0.025%	Bausch Health, generic	
	gel		

REVIEW DATE: 03/05/2025

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

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} A multimodal approach is recommended and therapy should include therapies combining multiple mechanisms of actions.³ Topical antibiotics are not recommended as monotherapy and should be used in combination with benzoyl peroxide or topical retinoids. Unlike topical antibiotics, benzoyl peroxide, a topical antimicrobial, 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.

- **Step 1:** sodium sulfacetamide/sulfur 10%/5% emollient cream, generic prescription topical adapalene-, benzoyl peroxide-, clindamycin products (other than generic Clindagel and clindamycin phosphate 1% foam), dapsone-, erythromycin-, or sodium sulfacetamide-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., Erygel), sulfacetamide (e.g., Klaron), sulfacetamide/sulfur (e.g., Avar-e, Avar-e LS), or combinations containing these active ingredients (e.g., Acanya, Benzamycin, Cabtreo, Epiduo [brand], Twyneo, Ziana, Veltin), generic adapalene swabs, generic Clindagel, generic clindamycin phosphate 1% foam, generic sodium sulfacetamide-sulfur 9.8-4.8% lotion, generic sodium sulfacetamide-sulfur 9.8-4.8% lotion, generic sodium sulfacetamide-sulfur 10-5 foam, generic sulfacetamide-sulfur 10-2% cream, generic sulfacetamide-sulfur 10-5% lotion

Topical Acne Products 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 Step 1 Product, approve a Step 2 Product.

REFERENCES

- 1. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2025. Available at: http://fco.factsandcomparisons.com/lco/action/home. Accessed on February 20, 2025. Search terms: benzoyl peroxide, clindamycin, minocycline, sulfacetamide/sulfur, Twyneo.
- 2. Clinical Pharmacology © 2025. Available at https://www.clinicalkey.com/pharmacology/. Accessed on February 20, 2025. Search terms: benzoyl peroxide and sulfur/sulfacetamide.
- 3. 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.	09/06/2023
Selected Revision	Clindamycin phosphate/benzoyl peroxide 1.2%/3.75% (generic for Onexton): Added to Step 1 under Clindamycin products other than generic Clindagel.	10/11/2023
Selected Revision	Cabtreo: Added to Step 2 under combinations containing these active ingredients. The Note under criteria one for the exception allowing Epidou Forte to be counted as a Step 1 product has been removed. Epidou Forte will only fall under Step 2. This change is effective 1/1/2024.	12/20/2023
Annual Revision	No criteria changes.	09/04/2024
Selected Revision	Policy name: Changed from Topical Acne – Topical Products Step Therapy Policy to Topical Acne Products Step Therapy Policy. Clindamycin phosphate 1% foam: Removed from Step 1 under Clindamycin products other than generic Clindagel and added to Step 2.	01/08/2025
Annual Revision	Generic sodium sulfacetamide-sulfur 9.8-4.8% cream, generic sodium sulfacetamide-sulfur 9.8-4.8% lotion, generic sodium sulfacetamide-sulfur 10-5 foam, generic sulfacetamide-sulfur 10-2% cream, generic sulfacetamide-sulfur 10-5% lotion: Moved to Step 2. Sodium sulfacetamide/sulfur 10%/5% emollient cream: Remained in Step 1	03/5/2025

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