

STEP THERAPY POLICY

POLICY: Topical Acne – Topical Products Step Therapy Policy

Adapalene products:

- Differin® (adapalene 0.1% gel – Galderma, generics)
- Differin® (adapalene 0.3% gel; adapalene 0.3% gel pump – Galderma, generics)
- Differin® (adapalene 0.1% cream – Galderma, generics)
- Differin® (adapalene 0.1% lotion – Galderma)
- Plixda™ (adapalene 0.1% topical solution – Galderma, generics)

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, generics)
- Cleocin T® (clindamycin phosphate 1% gel – Pfizer, generics)
- Cleocin T (clindamycin phosphoate 1% lotion – Pfizer, generics)
- Clindagel® (clindamycin phosphate 1% gel – Valeant/Bausch)
- Evoclin® (clindamycin phosphate 1% foam – Mylan, generics)

Dapsone (topical only) products:

- Aczone® (dapsone 5% gel – Allergan, generics)
- Aczone® (dapsone 7.5% gel – Allergan)

Minocycline products:

- Amzeeq™ (minocycline 4% foam, Foamix Pharmaceuticals)

Sulfacetamide-containing products:

- Klaron® (sulfacetamide sodium 10% lotion – Valeant/Bausch, generics)

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; sodium sulfacetamide/sulfur 9.8%/4.8% lotion – Brava)

Other combination products:

- Acanya® (clindamycin phosphate/benzoyl peroxide 1.2%/2.5% gel – Valeant, generics)
- Aktipak™ (benzoyl peroxide gel/erythromycin gel 5%/3% – Cutanea Life Sciences)
- BenzaClin® (clindamycin phosphate/benzoyl peroxide 1%/5% gel – Valeant/Bausch, generics)
- Benzamycin® (benzoyl peroxide gel/erythromycin gel 5%/3% – Valeant, generics)
- Duac® (clindamycin phosphate/benzoyl peroxide 1.2%/5% gel – Stiefel, generics)

- Epiduo® (adapalene/benzoyl peroxide 0.1%/2.5% gel [gel pump] – Galderma, generics)
- Epiduo® Forte (adapalene/benzoyl peroxide 0.3%/2.5% gel [gel pump] – Galderma)
- Inova® 4/1 Easy Pad (benzoyl peroxide/salicylic acid 4%/1% pad – Innotec)
- Inova® 8/2 Easy Pad (benzoyl peroxide/salicylic acid 8%/2% pad – Innotec)
- Neucac® (clindamycin/benzoyl peroxide 1.2%/5% gel – Medimetrix, generics)
- NuOx® (benzoyl peroxide/sulfur 6%/3% gel – Gentex Pharma)
- Onexton™ (clindamycin/benzoyl peroxide 1.2%/3.75% – Valeant)
- Veltin™ (clindamycin phosphate/tretinoin 1.2%/0.025% gel – Valeant/Bausch)
- Ziana® (clindamycin phosphate/tretinoin 1.2%/0.025% gel – Valeant/Bausch, generics)

REVIEW DATE: 12/02/2020

OVERVIEW

All of these products are indicated for use in the management of **acne vulgaris**.^{1,2} Benzoyl peroxide-containing products are generally indicated for the treatment or prevention of mild to moderate acne vulgaris.^{1,2} Azelex (azelaic acid cream) is indicated for the topical treatment of mild to moderate inflammatory acne vulgaris and for the treatment of inflammatory pustules and papules of mild to moderate acne rosacea. Amzeeq (minocycline foam) is indicated for the topical treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and pediatric patients ≥ 9 years of age. Topical clindamycin, erythromycin, and Aczone (dapsone gel) are indicated for the treatment of 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. Acne treatment guidelines do not prefer any of the specific brand name agents over their similar products available as generics for the treatment of acne.³

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 oil skin (although newer aqueous gels may also be suitable for sensitive skin).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. Azelaic acid is considered second-line treatment or as an adjunctive therapy in the treatment of acne.²

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.

Automation: A patient with a history 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: Aczone, Amzeeq, Azelex, Differin, Plixda, or brand name topical acne products containing benzoyl peroxide (e.g., Inova Easy Pad), sulfacetamide (e.g., Klaron), sulfacetamide/sulfur (e.g., Avar-e, Avar-e LS), clindamycin (e.g., Cleocin T, Evoclin) or combinations containing these active ingredients (e.g., Acanya, Aktipak, Benzamycin Epiduo [brand], Inova Easy Pad, Ziana, Veltin).

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

REFERENCES

1. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2020. Available at: <http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&qs>. Accessed on November 24, 2020. Search terms: benzoyl peroxide, clindamycin, minocycline, sulfacetamide/sulfur.
2. Clinical Pharmacology © 2020. Available at <http://www.clinicalpharmacology-ip.com/Default.aspx>. Accessed on November 24, 2020. 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.