OVERVIEW
Acne is a chronic inflammatory condition that affects approximately 40 to 50 million individuals; more than 85% of teenagers are affected with acne. The impact of acne on emotional well-being can be critical and is often associated with depression, anxiety, social withdrawal, and above average unemployment rates.

Many topical products are available for the treatment of acne vulgaris. Benzoyl peroxide-containing products are generally indicated for the treatment or prevention of mild-to-moderate acne vulgaris. 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. Topical clindamycin, erythromycin and Aczone (dapsone gel) are indicated for the treatment of acne vulgaris. Sulfacetamide sodium and sulfur are antimicrobial and antiseptic agents, respectively which aid in the removal of keratin and drying of the skin. In addition to being indicated for the treatment of acne, sulfacetamide/sulfur products are used for acne rosacea and seborrheic dermatitis. Guidelines do not prefer any of the specific name brand agents over their similar products available as generics for the treatment of acne.

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

Automation: Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.

Step 1: Generic prescription topical adapalene-, benzoyl peroxide-, clindamycin-, erythromycin-, adapalene/benzoyl peroxide 0.1%/2.5, sodium sulfacetamide-, or sodium sulfacetamide/sulfur-containing products.

Step 2: Brand name prescription topical acne products: Aczone, Azelex, Differin, or brand name topical acne products containing benzoyl peroxide (e.g., Inova Easy Pad, Benzefoam), sulfacetamide (e.g., Klaron, Ovace Plus), sulfacetamide/sulfur (e.g., Avar-E, Avar LS, Clarifoam EF), clindamycin (e.g., Cleocin T, Evoclin) or combinations of these products (e.g., Acanya, Benzamycin PAK, Epiduo, Aktipak, Inova, Ziana, Veltin).

CRITERIA
1. If the patient has tried a Step 1 product, approve a Step 2 product.

2. No other exceptions are recommended.
References


For reference, drugs affected:

**Note:** This is not an all-inclusive list.

**Benzoyl peroxide-containing products:**

*Foam*
- BenzEfoam™ (benzoyl peroxide 5.3% foam – Onset, generics)
- BenzEfoam Ultra (short contact benzoyl peroxide 9.8% foam – Onset)

*Pads*
- Inova® Easy Pad® (benzoyl peroxide 4% and 8% pad – Inocutis)

**Sulfacetamide-containing products:**
- Klaron® (sulfacetamide sodium 10% suspension – Dermik/Aventis)
- Ovace® Plus Cream (sulfacetamide sodium 10% cream – Mission Pharmacal)
- Ovace® Plus Lotion (sulfacetamide sodium 10% lotion – Mission Pharmacal)

**Sulfacetamide/sulfur-containing products:**

*Creams*
- Avar-E™ (sodium sulfacetamide/sulfur 10%/5% cream – Kylemore)
- Avar™ LS (sodium sulfacetamide/sulfur 10%/2% cream – Kylemore)
- Plexion (sodium sulfacetamide/sulfur 10%/5% cream and lotion – Valeant)

*Foam*
- Clarifoam® EF (sulfacetamide/sulfur 10%/5% emollient foam – Onset)

**Clindamycin-containing products**

*Topical Solution*
- Cleocin® T (clindamycin phosphate 1% topical solution – Pfizer, generics)

*Gel*
- Cleocin T® (clindamycin phosphate 1% gel – Pfizer, generics)
- Clindagel® (clindamycin phosphate 1% gel – Galderma)

*Foam*
- Evoclin® (clindamycin phosphate 1% foam – Stiefel, generics)

*Lotion*
- Cleocin T (clindamycin phosphate 1% lotion – Pfizer, generics)
Azelaic Acid
- Azelex® (azelaic acid 20% cream – Allergan)

Dapsone (topical only)
- Aczone® (dapsone 5% gel – Allergan)
- Aczone® (dapsone 7.5% gel – Allergan)

Adapalene
- Differin® (adapalene 0.1% gel, generics)
- Differin® (adapalene 0.3% gel, 0.3% gel pump, generics)
- Differin® (adapalene 0.1% cream, generics)
- Differin® (adapalene 0.1% lotion – Galderma)

Other Combinations
- Acanya® (clindamycin phosphate/benzoyl peroxide 1.2%/2.5% gel – Dow)
- Aktipak (erythromycin and benzoyl peroxide gel, 3%/5%)
- BenzaClin® (clindamycin phosphate/benzoyl peroxide 1%/5% gel – Sanofi Aventis, generics)
- Benzamycin® Pak (benzoyl peroxide/erythromycin 5%/3% gel – Valeant)
- Benzamycin® (benzoyl peroxide gel/erythromycin powder 5%/3% – Valeant, generics)
- Duac® (clindamycin phosphate/benzoyl peroxide 1%/5% gel – Stiefel, generics)
- Epiduo® (adapalene/benzoyl peroxide 0.1%/2.5% gel [gel pump] – Galderma)
- 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 – Centrix)
- Inova® 8/2 Easy Pad (benzoyl peroxide/salicylic acid 8%/2% pad – Centrix)
- Onexton™ (clindamycin/benzoyl peroxide 1.2%/3.75% – Valeant)
- Neuac® (clindamycin/benzoyl peroxide 1.2%/5% gel – Medimetriks, generics)
- NuOx® (benzoyl peroxide/sulfur 6%/3% gel – Gentex Pharma)
- Veltin™ (clindamycin phosphate/tretinoin 1.2%/0.025% gel – Stiefel)
- Ziana (clindamycin phosphate/tretinoin 1.2%/0.025% gel – Medicis, generics)