MEDICAL MUTUAL®

Drug Policy

Policy:	**Topical Acne – Topical Products** **Preferred Step Therapy Policy**	**Annual Review Date: 08/22/2024** **Last Revised Date: 08/22/2024**

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, minocycline 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 preferred product prior to the use of a non-preferred product. If the step therapy rule is not met for a preferred product 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).

*Note: Aczone 7.5% gel and Onexton with DAW9 (indicating that substitution is allowed by the prescriber but the Plan requests brand) will also count as a preferred medication.

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

Preferred Products:

- Generic prescription topical acne products containing:
  - Adapalene
  - Benzoyl peroxide
  - Clindamycin products other than generic Clindagel
  - Dapsone
  - Erythromycin

- Sodium sulfacetamide
- Sodium sulfacetamide/Sulfur-containing products.

Non-preferred Products:

- Brand name prescription topical acne products containing:
  - Adapalene (Differin)
  - Azelaic acid (Azelex)
  - Benzoyl peroxide (e.g., Inova Easy Pad)
  - Clindamycin
  - Dapsone (Aczone*)
  - Erythromycin (e.g., Erygel)
  - Generic adapalene swabs
  - Generic Clindagel
  - Minocycline (Amzeeq)
  - Sodium sulfacetamide
  - Sulfacetamide/sulfur (e.g., Avar-e, Avar-e LS)
  - Trifarotene (Aklief)
  - Combinations of these products (e.g., Aktipak, Twyneo, Veltin, Onexton*)

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred product, approve a non-preferred product.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 years (730 days)
B) *Extended Approval:* 2 years (730 days)

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred products. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred products. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred products. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred products after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred product for 90 days within a 130-day look-back period

AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR

2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred product for 90 days AND that the patient has been receiving the requested non-preferred product via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred product) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2023. Available at: http://fco.factsandcomparisons.com/lco/action/home. Accessed on August 31, 2023. Search terms: benzoyl peroxide, clindamycin, minocycline, sulfacetamide/sulfur, Twyneo.
2. Clinical Pharmacology © 2023. Available at https://www.clinicalkey.com/pharmacology/. Accessed on August 31, 2023. 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.