MEDICAL MUTUAL®

Drug Policy

Policy:	Zoryve Foam Step Therapy	Annual Review Date: 05/22/2025
Impacted Drugs:	• Zoryve™ Foam (roflumilast 0.3% topical foam – Arcutis)	Last Revised Date: 05/22/2025

OVERVIEW

Seborrheic dermatitis is a chronic inflammatory skin disorder affecting primarily the skin of the scalp, face, chest, and intertriginous areas, causing scaling and redness of the skin.[1,2] Primary treatment options include topical antifungals and topical anti-inflammatory agents.

- Topical antifungals indicated for the treatment of **seborrheic dermatitis** caused by *Malassezia* yeast include:[3-6]
  - Ciclopirox shampoo/gel. The gel formulation is indicated for the treatment of scalp and non-scalp seborrheic dermatitis. All ciclopirox products are indicated in **patients ≥ 16 years of age**.
  - Ketoconazole shampoo/foam. The foam formulation is indicated for the treatment of scalp and non-scalp seborrheic dermatitis. All ketoconazole products are indicated in **patients ≥ 12 years of age**.
- Topical corticosteroids are, in general, indicated for the **symptomatic relief of inflammation and/or pruritus associated with various skin disorders (dermatoses).**[7] Low potency steroids are generally reserved for facial application while higher potency steroids are utilized for the body or scalp.[1,2]

Zoryve foam is indicated for the treatment of **seborrheic dermatitis in patients ≥ 9 years of age**.[8] It is a selective, highly potent phosphodiesterase-4 (PDE4) inhibitor with 25- to 300-fold greater potency than other topical PDE4 inhibitors *in vitro*.[9] The exact mechanism by which Zoryve foam exerts its therapeutic action in SD is not well defined; however, it is a non-steroidal therapy that provides anti-inflammatory benefits.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

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 topical corticosteroid, Generic topical antifungal

Topical Corticosteroids*	
• Alclometasone cream/ointment • Betamethasone dipropionate, augmented cream/ointment • Betamethasone dipropionate cream/ointment • Betamethasone valerate cream/ointment/foam • Desonide cream/gel/ointment • Desoximetasone cream/gel/ointment • Fluocinolone acetonide cream/ointment • Flurandrenolide cream/ointment • Hydrocortisone acetate cream/ointment • Hydrocortisone butyrate cream/ointment • Hydrocortisone probutate cream • Hydrocortisone valerate cream/ointment	• Clobetasol propionate cream/foam/gel/ointment/shampoo • Clocortolone pivalate cream • Diflorasone diacetate cream/ointment • Fluocinonide-E cream • Fluticasone propionate cream/ointment • Fluocinonide cream/gel/ointment • Halcinonide cream/ointment • Halobetasol propionate cream/foam/ointment • Mometasone furoate cream/ointment • Prednicarbate cream/ointment • Triamcinolone acetonide cream/ointment
Topical Antifungal	
• Ketoconazole 2% cream/foam/shampoo	• Ciclopirox 0.77% cream/gel • Ciclopirox 1% shampoo

* This list is not all-inclusive and may not include all available topical corticosteroids (strength or formulation).

Step 2: Zoryve 0.3% foam

PREFERRED STEP THERAPY CRITERIA

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

2. If the patient has tried a combination product containing a topical antifungal, approve a Step 2 product.

3. If the patient has tried a combination product containing a topical corticosteroid, approve a Step 2 product.

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

Step Therapy Exception Criteria
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 agents. If so, please list diagnosis and/or patient characteristics*; **OR**

B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent*; **OR**
C. The patient is continuing therapy with the requested non-preferred agent 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 agent 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 agent for 90 days AND that the patient has been receiving the requested non-preferred agent 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 agent) 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 an asterisk (*). 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. Jackson JM, Alexis A, Zirwas M, Taylor S. Unmet needs for patients with seborrheic dermatitis. *J Am Acad Dermatol*. 2022 Dec 17. [Online ahead of print].
2. Dall'Oglio F, Nasca MR, Gerbino G, et al. An overview of the diagnosis and management of seborrheic dermatitis. *Clinical, Cosmetic and Investigational Dermatology*. 2022:15 1537–1548.
3. Ciclopirox shampoo [prescribing information]. Parsippany, NJ: Actavis; September 2019.
4. Ciclopirox gel [prescribing information]. Mahwah, NJ: Glenmark; January 2017.
5. Ketodan® foam [prescribing information]. Fairfield, NJ: Medimetriks; September 2021.
6. Ketoconazole shampoo [prescribing information]. New York, NY: Thirty Madison: March 2022.

7. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2024. Available at: https://www.clinicalkey.com/pharmacology/resources/overviews?id=1549472. Accessed on February 8, 2024. Search terms: topical corticosteroids.
8. Zoryve® 0.3% topical foam [prescribing information]. Westlake Village, CA: Arcutis; December 2023.
9. Zirwas MJ, Draelos ZD, DuBois J, et al. Efficacy of roflumilast foam, 0.3%, in patients with seborrheic dermatitis: A double-blind, vehicle-controlled phase 2a randomized clinical trial. *JAMA Dermatol.* 2023;159(6):613-620.