

STEP THERAPY POLICY

POLICY: Topical Products – Zoryve Foam Step Therapy Policy

- Zoryve™ Foam (roflumilast 0.3% topical foam – Arcutis)

REVIEW DATE: 02/14/2024

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.

GUIDELINES

There are no formal treatment guidelines for the management of seborrheic dermatitis. The current standard of care for seborrheic dermatitis is to use multiple agents (usually an antifungal and/or anti-inflammatory). The American Academy of Dermatology cite topical antifungal agents as typical first-line therapy.¹ Low potency topical corticosteroids may be considered as first-line or second-line therapy; however, use is limited to short durations due to the potential for adverse effects. Additionally, recommendations provided by the Clinical, Cosmetic, and Investigational Dermatology (CCID) [2022] non-preferentially recommend topical ciclopirox or topical ketoconazole for scalp and non-scalp seborrheic dermatitis; formulation is guided by patient preference.²

POLICY STATEMENT

This program has been developed to encourage the use of one 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.

Automation: A patient with a 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

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

Step 2: Zoryve 0.3% foam

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.
4. No other exceptions are recommended.

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: Medimetrix; 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.