STEP THERAPY POLICY

POLICY: Topical Products – Zoryve Foam Step Therapy Policy
- Zoryve® Foam (roflumilast 0.3% topical foam – Arcutis)

REVIEW DATE: 02/19/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 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.

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

Topical Products – Zoryve Foam Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

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.

REFERENCES

1. Jackson JM, Alexis A, Zirwas M, et al. Unmet needs for patients with seborrheic dermatitis. *J Am Acad Dermatol*. 2024;90(3):597-604.
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 3, 2025. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	02/14/2024
Annual Revision	No criteria changes.	02/19/2025