



Pharmacy Drug Policy & Procedure

Policy Name:	Zoryve (roflumilast) cream	Policy #:	3155P
---------------------	-----------------------------------	------------------	--------------

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Zoryve (roflumilast) topical products.

Statement of the Policy

Health Alliance Medical Plans will approve the use of topical Zoryve (roflumilast) under the pharmacy benefit, when the following criteria have been met:

Criteria

1. Coverage Criteria for Psoriasis (0.3% cream)

- 1.1 Diagnosis of plaque psoriasis with body surface area (BSA) \leq 20%
- 1.2 Age 6 years or older
- 1.3 Prescribed by or in consultation with a dermatologist (skin doctor) or rheumatologist (doctor of the musculoskeletal system)
- 1.4 Documented failure, intolerance, or contraindication to a high potency topical steroid
- 1.5 Documented failure, intolerance, or contraindication to calcipotriene topical OR tazarotene topical

2. Coverage Criteria for Atopic Dermatitis (0.15% cream)

- 2.1 Diagnosis of mild to moderate atopic dermatitis
- 2.2 Age 6 years or older
- 2.3 Prescribed by or in consultation with a dermatologist
- 2.4 Documented failure, intolerance, or contraindication to a topical corticosteroid
- 2.5 Documented failure, intolerance, or contraindication to a topical calcineurin inhibitor (such as tacrolimus or pimecrolimus)

3. Coverage Criteria for Seborrheic Dermatitis (foam)

- 3.1 Documented diagnosis of seborrheic dermatitis present on face and/or scalp
- 3.2 Age 9 years or older
- 3.3 Prescribed by or in consultation with a dermatologist (skin doctor)
- 3.4 Documented failure, intolerance, or contraindication to a generic topical antifungal (such as ketoconazole)
- 3.5 Documented failure, intolerance, or contraindication to a generic topical anti-inflammatory (such as topical corticosteroids, topical calcineurin inhibitors)

4. Managed Dose Limit

- 4.1 60 grams (1 tube) per 30 days

5. Approval Period

- 5.1 Initial authorization: 12 months
- 5.2 Subsequent authorizations: 12 months with documented beneficial clinical response to therapy

CPT Codes

--	--

HCPCS Codes

--	--

References

1. Zoryve (roflumilast) [prescribing information]. Westlake Village, CA: Arcutis Biotherapeutics Inc; January 2024.
2. Lebwohl MG, et al. Effect of roflumilast cream vs vehicle cream on chronic plaque psoriasis: the DERMIS-1 and DERMIS-2 randomized clinical trials. *JAMA*. 2022;328(11):1073–1084.
3. Blauvelt A, Draelos ZD, Stein Gold L, et al. Roflumilast foam 0.3% for adolescent and adult patients with seborrheic dermatitis: A randomized, double-blinded, vehicle-controlled, phase 3 trial. *J Am Acad Dermatol*. 2024 Jan 20:S0190-9622(24)00107-5.
4. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD–NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Aca Derm*. 2021 Feb 1; 84(2):432-470.
5. Okokon EO, Verbeek JH, Ruotsalainen JH, et al. Topical antifungals for seborrhoeic dermatitis. *Cochrane Database Syst Rev* 2015; :CD008138.
6. Kastarinen H, Oksanen T, Okokon EO, et al. Topical anti-inflammatory agents for seborrhoeic dermatitis of the face or scalp. *Cochrane Database Syst Rev* 2014; :CD009446.
7. AAAAI/ACAAI JTF Atopic Dermatitis Guideline Panel; Chu DK, Schneider L, Asiniwasis RN, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE- and Institute of Medicine-based recommendations. *Ann Allergy Asthma Immunol*. 2024 Mar;132(3):274-312.

Created Date: 12/01/2022

Effective Date: 12/01/2022

Posted to Website: 12/07/2022

Revision Date: 12/04/2024

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.