

**Policy Name:** Zoryve (roflumilast)**Policy#:** 3155P**Purpose of the Policy****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) less than or equal to 20%
- 1.2 Age 6 years or older
- 1.3 Prescribed by or in consultation with a dermatologist (skin doctor) or rheumatologist (musculoskeletal doctor)
- 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 Psoriasis (foam)**

- 2.1 Diagnosis of plaque psoriasis of the scalp and body
- 2.2 Age 12 years or older
- 2.3 Prescribed by or in consultation with a dermatologist or rheumatologist
- 2.4 Documented failure, intolerance, or contraindication to a high potency topical steroid
- 2.5 Documented failure, intolerance, or contraindication to calcipotriene topical (such as tacrolimus or pimecrolimus) or tazarotene topical

**3. Coverage Criteria for Atopic Dermatitis (0.15% cream)**

- 3.1 Diagnosis of mild to moderate atopic dermatitis
- 3.2 Age 6 years or older
- 3.3 Prescribed by or in consultation with a dermatologist (skin doctor)
- 3.4 Documented failure, intolerance, or contraindication to a topical corticosteroid
- 3.5 Documented failure, intolerance, or contraindication to a topical calcineurin inhibitor (such as tacrolimus or pimecrolimus)

**4. Coverage Criteria for Seborrheic Dermatitis (foam)**

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

**5. Managed Dose Limit**

- 5.1 60 grams (1 tube) per 30 days

**6. Approval Period**

- 6.1 Initial authorization: 12 months
- 6.2 Subsequent authorizations: 12 months with documented beneficial clinical response to therapy

**References**

- 1. Zoryve cream (roflumilast) [prescribing information]. Westlake Village, CA: Arcutis Biotherapeutics Inc; July 2024.
- 2. Zoryve foam (roflumilast) [prescribing information]. Westlake Village, CA: Arcutis Biotherapeutics Inc.;

May 2025.

3. Lebwohl MG, et al. Effect of roflumilast cream vs vehicle cream on chronic plaque psoriasis: the DERMIS-I and DERMIS-2 randomized clinical trials. *JAMA*. 2022;328(11):1073-1084.
4. 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.
5. 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.
6. Okokon EO, Verbeek JH, Ruotsalainen JH, et al. Topical antifungals for seborrhoeic dermatitis. *Cochrane Database Syst Rev* 2015; :CD008138.
7. 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.
8. 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.

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