

Generic Name: roflumilast

Preferred: N/A

Therapeutic Class or Brand Name: N/A

Non-preferred: N/A

Applicable Drugs: Zoryve (roflumilast)

Date of Origin: 1/1/2025

Date Last Reviewed / Revised: 1/17/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

- I. Documented diagnosis of one of the following conditions A through C AND must meet ALL criteria listed under applicable diagnosis.
 - A. Atopic Dermatitis
 - i. Mild to moderate atopic dermatitis with an Eczema Area and Severity Index (EASI) score of at least 5
 - ii. Documentation that the patient has Body Surface Area (BSA) involvement of 3% to 20%.
 - iii. Documented treatment failure or contraindication to two topical corticosteroids as appropriate for disease severity 1 or 2:
 1. Mild disease: low or lower-mid potency topical corticosteroids (eg, betamethasone valerate 0.1% cream or lotion, desonide 0.05% cream or ointment, or hydrocortisone 0.1% cream, etc).
 2. Moderate disease: medium or high potency topical corticosteroids (eg, fluocinolone 0.025% ointment, triamcinolone 0.1% cream or ointment, betamethasone dipropionate 0.05% cream, etc).
 - iv. Documented treatment failure or contraindication to one topical calcineurin inhibitor (eg, pimecrolimus, tacrolimus).
 - B. Psoriasis
 - i. Documentation that the patient has Body Surface Area (BSA) involvement of 2% to 20%
 - ii. Documented treatment failure with three or more of the following topical therapies for a duration of at least 4 weeks:
 1. Corticosteroids (eg, betamethasone, clobetasol, desonide)
 2. Vitamin D analogs (eg, calcitriol, calcipotriene)
 3. Tazarotene
 4. Calcineurin inhibitors (eg, tacrolimus, pimecrolimus)
 5. Coal Tar
 6. Anthralin

C. Seborrheic dermatitis

- i. Documented treatment failure with one agents from each of the following topical therapies for a duration of at least 4 weeks:
 1. Topical corticosteroids (eg, betamethasone, hydrocortisone)
 2. Topical, shampoo, or systemic antifungals (eg, ketoconazole, ciclopirox, itraconazole)
 3. Topical calcineurin inhibitors (eg, tacrolimus, pimecrolimus)
- II. Prescribed by or in consultation with a dermatologist.
- III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines. See Appendix, Table 1.
- IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Concomitant diagnosis of nonplaque psoriasis (eg, guttate, erythrodermic/exfoliative, palmoplantar-only involvement, or pustular psoriasis)
- Concomitant use with a Targeted Immune Modulator
- Moderate to severe liver impairment (Child-Pugh B or C)

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- One 60-gram tube per 30 days

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 1 year

APPENDIX

Table 1. Topical Roflumilast Formulations and Indications

Roflumilast Formulation	Indication	Age
Cream, 0.15%	Mild to moderate atopic dermatitis	≥ 6 years

Cream, 0.3%	Plaque psoriasis	≥ 6 years
Foam, 0.3%	Seborrheic dermatitis	≥ 9 years

REFERENCES

1. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023;89(1):e1-e20. doi:10.1016/j.jaad.2022.12.029
2. AAAAI/ACAAI JTF Atopic Dermatitis Guideline Panel, Chu DK, Schneider L, 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*. Published online December 18, 2023. doi:10.1016/j.anai.2023.11.009
3. Elmetts 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 Acad Dermatol*. 2021;84(2):432-470. doi:10.1016/j.jaad.2020.07.087
4. Zoryve. Prescribing information. Arcutis Biotherapeutics, Inc: 2024. Accessed January 12, 2025. <https://www.arcutis.com/wp-content/uploads/USPI-roflumilast-cream.pdf>
5. Zoryve. Prescribing information. Arcutis Biotherapeutics, Inc; 2023. Accessed January 12, 2025. <https://www.arcutis.com/wp-content/uploads/zoryve-foam-pi-hcp.pdf>

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.