

Initial Prior Authorization with Quantity Limit Zoryve

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Zoryve	roflumilast	cream
Zoryve	roflumilast	foam

Indications

FDA-approved Indications

Zoryve Cream

Plaque Psoriasis

Zoryve cream, 0.3%, is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older.

Atopic Dermatitis

Zoryve cream, 0.15%, is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.

Zoryve Foam

Seborrheic Dermatitis

Zoryve topical foam, 0.3%, is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

Plaque Psoriasis

Zoryve topical foam, 0.3%, is indicated for the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older.

Coverage Criteria

Atopic Dermatitis

Authorization may be granted when the requested drug is being prescribed for the topical treatment of mild to moderate atopic dermatitis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) CREAM 0.15%.
- The patient is 6 years of age or older.
- The patient has experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor OR a medium or higher potency topical corticosteroid.
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month.

Plaque Psoriasis

Authorization may be granted when the requested drug is being prescribed for the topical treatment of plaque psoriasis when ONE of the following criteria are met:

- The request is for Zoryve (roflumilast) CREAM 0.3% and the patient meets ALL of the following criteria:
 - The patient is 6 years of age or older.
 - The patient meets ONE of the following:
 - The patient has experienced an inadequate treatment response, intolerance, or contraindication to a topical steroid.
 - The requested drug will be used on sensitive skin areas (e.g., face, genitals or skin folds).
 - If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month.
- The request is for Zoryve (roflumilast) FOAM and the patient meets ALL of the following criteria:
 - The patient is 12 years of age or older.
 - The requested drug will be used on the scalp or body.
 - The patient meets ONE of the following:
 - The patient has experienced an inadequate treatment response, intolerance, or contraindication to a topical steroid.
 - The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds).
 - If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month.

Seborrheic Dermatitis

Authorization may be granted when the requested drug is being prescribed for the topical treatment of seborrheic dermatitis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) FOAM.
- The patient is 9 years of age or older.
- The patient meets ONE of the following:
 - The patient is less than 16 years of age.
 - The patient has experienced an inadequate treatment response, intolerance, or contraindication to a topical ketoconazole (i.e., 2% shampoo, 2% cream, 2% foam, 2% gel) OR a topical ciclopirox (i.e., 0.77% gel, 1% shampoo) product.
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month.

Continuation of Therapy

Atopic Dermatitis

Authorization may be granted when the requested drug is being prescribed for the topical treatment of mild to moderate atopic dermatitis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) CREAM 0.15%.
- The patient is 6 years of age or older.
- The patient has achieved or maintained a positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)].
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month.

Plaque Psoriasis

Authorization may be granted when the requested drug is being prescribed for the topical treatment of plaque psoriasis when ONE of the following criteria is met:

- The request is for Zoryve (roflumilast) CREAM 0.3% and the patient meets ALL of the following criteria:
 - The patient is 6 years of age or older.
 - The patient has achieved or maintained a positive clinical response to the requested drug (e.g., clear, or almost clear outcome, patient satisfaction, etc.).
 - If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month.
- The request is for Zoryve (roflumilast) FOAM and the patient meets ALL of the following criteria:
 - The patient is 12 years of age or older.

- The patient has achieved or maintained a positive clinical response to the requested drug (e.g., clear, or almost clear outcome, patient satisfaction, etc.).
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month.

Seborrheic Dermatitis

Authorization may be granted when the requested drug is being prescribed for the topical treatment of seborrheic dermatitis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) FOAM.
- The patient is 9 years of age or older.
- The patient has achieved or maintained a positive clinical response to the requested drug (e.g., clear, or almost clear outcome, improvement from baseline, etc.).
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month.

Quantity Limits Apply

60 grams per 25 days or 180 grams per 75 days

For body surface areas requiring more than 60 grams per month: 120 grams per 25 days or 360 grams per 75 days.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 5537-C: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

References

1. Zoryve Cream [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; July 2024.
2. Zoryve Foam [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; May 2025.
3. Ciclopirox gel [package insert]. Minneapolis, MN: Padagis US LLC; March 2022.
4. Ciclopirox shampoo [package insert]. Parsippany, NY: Teva Pharmaceuticals; October 2023.
5. Ketoconazole cream [package insert]. Durham, NC: Encube Ethicals, Inc.; December 2023.
6. Ketoconazole foam [package insert]. Florham Park, NJ: Xiromed, LLC.; April 2020.
7. Ketoconazole shampoo [package insert]. South Plainfield, NJ: Cosette Pharmaceuticals, Inc.; February 2025.
8. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed June 3, 2025.

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10. 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 Acad Dermatol*. 2021; 84(2):432-470.
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12. Eichenfield L, Tom W, Berger T, et al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol*. 2014;71 (1):116-132.
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15. Desai S, McCormick E, Friedman A, An Up-to-Date Approach to the Management of Seborrheic Dermatitis. *J Drugs Dermatol*. 2022;21(12):1373-1374.
16. Clark GW, Pope SM, Jaboori KA. Diagnosis and Treatment of Seborrheic Dermatitis. *Am Fam Physician*. 2015;91(3):185-190.