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Coverage P	olicy/Guideline				
Name:	Zoryve (roflumi	last) cream and foam	Page:	1 of 5	
Effective Date: 7/23/2025			Last Revie	w Date: 6/2025	
Applies to:	⊠Illinois	□New Jersey		Maryland	
	□Florida Kids	□Pennsylvania K	ids 🖂	Virginia	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Zoryve cream and foam under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

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.

Applicable Drug List:

Zoryve (roflumilast) 0.3% cream Zoryve (roflumilast) 0.15% cream Zoryve (foflumilast) 0.3% foam

Policy/Guideline:

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.

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- 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.

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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:
 - o 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 plague 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.

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- 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.

Approval Duration and Quantity Restrictions:

Initial Approval: 3 months

Renewal Approval: 12 months

Quantity Level Limit: 60 grams per 30 days; for body surface areas requiring more than 60gm per month: 120gm per 30 days

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.

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- 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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