



5.90.057

Section: Prescription Drugs

Effective Date: January 1, 2026

Subsection: Topical Products

Original Policy Date: August 26, 2022

Subject: Zoryve

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Last Review Date: December 12, 2025

Zoryve

Description

Zoryve (roflumilast) cream, foam

Background

Zoryve (roflumilast) is an inhibitor of phosphodiesterase 4 (PDE4). Inhibition of PDE4 leads to accumulation of intracellular cyclic AMP. The specific mechanism by which Zoryve exerts its therapeutic action is not well defined (1-2).

Regulatory Status

FDA-approved indications: (1-2)

1. Zoryve cream is a phosphodiesterase 4 inhibitor:

- a. Zoryve cream, 0.3%, is indicated for the topical treatment of plaque psoriasis (PsO), including intertriginous areas, in patients 6 years of age and older.
- b. Zoryve cream, 0.15%, is indicated for the topical treatment of mild to moderate atopic dermatitis (AD) in adult and pediatric patients 6 years of age and older.
- c. Zoryve cream, 0.05%, is indicated for the topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.

2. Zoryve foam is a phosphodiesterase 4 inhibitor indicated for the treatment of:

- a. Seborrheic dermatitis in adult and pediatric patients 9 years of age and older.
- b. Plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older.

The safety and effectiveness of Zoryve 0.05% cream in pediatric patients less than 2 years of

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age and older than 5 years of age for atopic dermatitis have not been established. The safety and effectiveness of Zoryve 0.3% and 0.15% cream in pediatric patients less than 6 years of age for plaque psoriasis and atopic dermatitis have not been established. The safety and effectiveness of Zoryve foam in pediatric patients less than 9 years of age for seborrheic dermatitis have not been established. The safety and effectiveness of Zoryve foam in pediatric patients less than 12 years of age for plaque psoriasis of the scalp and body have not been established (1-2).

Related policies

Tazarotene, Vtama

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Zoryve may be considered **medically necessary** if the conditions indicated below are met.

Zoryve may be considered **investigational** for all other indications.

Prior-Approval Requirements

Zoryve 0.05% Cream

Age 2-5 years of age

Diagnosis

Patient must have the following:

1. Mild to moderate atopic dermatitis (AD)
 - a. Inadequate treatment response, intolerance, or contraindication to **ONE** medication in **EACH** of the following categories:
 - i. Topical calcineurin inhibitor (see Appendix 1)
 - ii. A topical corticosteroid (see Appendix 2)
 - b. Documented baseline evaluation of the condition using **ONE** of the following scoring tools:
 - i. Investigator's Static Global Assessment (ISGA) score

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- (e.g., https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf)
- ii. Eczema Area and Severity Index (EASI)
(e.g., <https://dermnetnz.org/topics/easi-score/>)
 - iii. Patient-Oriented Eczema Measure (POEM)
(e.g., <https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png>)
 - iv. Scoring Atopic Dermatitis (SCORAD) index
(e.g., <https://dermnetnz.org/topics/scorad/>)
- c. **NO** dual therapy with another Topical Prior Authorization (PA) medication for AD (see Appendix 3)
-

Zoryve 0.3% and 0.15% Cream

Age 6 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Plaque psoriasis (PsO)
 - a. Inadequate treatment response, intolerance, or contraindication to **BOTH** of the following:
 - i. Topical corticosteroid
 - ii. Topical vitamin D analog (e.g., calcipotriene, calcitriol, etc.)
 - b. Documented baseline evaluation of the condition using the Physician's Global Assessment (PGA)
(e.g., [https://www.jaad.org/article/S0190-9622\(15\)01740-5/fulltext#gr1](https://www.jaad.org/article/S0190-9622(15)01740-5/fulltext#gr1))
2. Mild to moderate atopic dermatitis (AD)
 - a. 18 years of age or older
 - i. Inadequate treatment response, intolerance, or contraindication to **ONE** medication in **EACH** of the following categories:
 1. Topical calcineurin inhibitor (see Appendix 1)
 2. **ONE** topical corticosteroid (see Appendix 2)
 - a. **High** potency topical corticosteroid
 - b. Patients with lesions on face, neck, or skin folds
ONLY: low to medium potency topical corticosteroid
 - b. 6 to 17 years of age

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- i. Inadequate treatment response, intolerance, or contraindication to **ONE** medication in **EACH** of the following categories:
 1. Topical calcineurin inhibitor (see Appendix 1)
 2. A topical corticosteroid (see Appendix 2)
- c. Documented baseline evaluation of the condition using **ONE** of the following scoring tools:
 - i. Investigator's Static Global Assessment (ISGA) score
(e.g., https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf)
 - ii. Eczema Area and Severity Index (EASI)
(e.g., <https://dermnetnz.org/topics/easi-score/>)
 - iii. Patient-Oriented Eczema Measure (POEM)
(e.g., <https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png>)
 - iv. Scoring Atopic Dermatitis (SCORAD) index
(e.g., <https://dermnetnz.org/topics/scorad/>)
- d. **NO** dual therapy with another Topical Prior Authorization (PA) medication for AD (see Appendix 3)

Zoryve Foam

Diagnoses

Patient must have **ONE** of the following:

1. Seborrheic dermatitis
 - a. 9 years of age or older
 - b. Inadequate treatment response, intolerance, or contraindication to **TWO** of the following:
 - i. Topical antifungal
 - ii. Topical corticosteroid
 - iii. Topical calcineurin inhibitor (see Appendix 1)
- c. Documented baseline evaluation of the condition using the Investigator Global Assessment of Disease (IGA)
(e.g.,
https://classic.clinicaltrials.gov/ProvidedDocs/28/NCT04973228/Prot_000.pdf#page=41)

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2. Plaque psoriasis (PsO) of the scalp and body
 - a. 12 years of age or older
 - b. Inadequate treatment response, intolerance, or contraindication to **BOTH** of the following:
 - i. Topical corticosteroid
 - ii. Topical vitamin D analog (e.g., calcipotriene, calcitriol, etc.)
 - c. Documented baseline evaluation of the condition using the Physician's Global Assessment (PGA)
(e.g., [https://www.jaad.org/article/S0190-9622\(15\)01740-5/fulltext#gr1](https://www.jaad.org/article/S0190-9622(15)01740-5/fulltext#gr1))

Prior – Approval *Renewal* Requirements

Zoryve 0.05% Cream

Age 2-5 years of age

Diagnosis

Patient must have the following:

1. Atopic dermatitis (AD)
 - a. Documented improvement using **ONE** of the following scores:
 - i. ISGA – decrease from baseline by at least 2 points
(e.g., https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf)
 - ii. EASI – decrease from baseline by at least 75%
(e.g., <https://dermnetnz.org/topics/easi-score/>)
 - iii. POEM – decrease from baseline by at least 3 points
(e.g., <https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png>)
 - iv. SCORAD – decrease from baseline by at least 50%
(e.g., <https://dermnetnz.org/topics/scorad/>)
 - b. **NO** dual therapy with another Topical Prior Authorization (PA) medication for AD (see Appendix 3)

Zoryve 0.3% and 0.15% Cream

Age 6 years of age or older

Diagnoses

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Patient must have **ONE** of the following:

1. Plaque psoriasis (PsO)
 - a. Documented improvement using the Physician's Global Assessment (PGA)
(e.g., [https://www.jaad.org/article/S0190-9622\(15\)01740-5/fulltext#gr1](https://www.jaad.org/article/S0190-9622(15)01740-5/fulltext#gr1))
 2. Atopic dermatitis (AD)
 - a. Documented improvement using **ONE** of the following scores:
 - i. ISGA – decrease from baseline by at least 2 points
(e.g., https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf)
 - ii. EASI – decrease from baseline by at least 75%
(e.g., <https://dermnetnz.org/topics/easi-score/>)
 - iii. POEM – decrease from baseline by at least 3 points
(e.g., <https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png>)
 - iv. SCORAD – decrease from baseline by at least 50%
(e.g., <https://dermnetnz.org/topics/scorad/>)
 - b. **NO** dual therapy with another Topical Prior Authorization (PA) medication for AD (see Appendix 3)
-

Zoryve Foam

Diagnoses

Patient must have **ONE** of the following:

1. Seborrheic dermatitis
 - a. 9 years of age or older
 - b. Documented improvement using the Investigator Global Assessment of Disease (IGA)
(e.g., https://classic.clinicaltrials.gov/ProvidedDocs/28/NCT04973228/Prot_000.pdf#page=41)
2. Plaque psoriasis (PsO) of the scalp and body
 - a. 12 years of age or older
 - b. Documented improvement using the Physician's Global Assessment (PGA)
(e.g., [https://www.jaad.org/article/S0190-9622\(15\)01740-5/fulltext#gr1](https://www.jaad.org/article/S0190-9622(15)01740-5/fulltext#gr1))

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Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Quantity

Dosage Form	Quantity
Cream	3 tubes per 90 days OR
Foam	3 cans per 90 days

Duration 12 months

Prior – Approval Renewal Limits

Same as above

Rationale

Summary

Zoryve (roflumilast) is an inhibitor of phosphodiesterase 4 (PDE4). Zoryve cream is indicated for use in patients with plaque psoriasis or atopic dermatitis, while Zoryve foam is indicated for use in patients with seborrheic dermatitis or plaque psoriasis (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Zoryve while maintaining optimal therapeutic outcomes.

References

1. Zoryve cream [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; October 2025.
2. Zoryve foam [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; May 2025.

Policy History

Date

Action

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August 2022	Addition to PA
December 2022	Annual review
September 2023	Annual editorial review. Added “topical” to the t/f vitamin D analog requirement for clarity
November 2023	Per PI update, lowered age requirement from 12 years to 6 years and older
December 2023	Annual review
January 2024	Addition of Zoryve foam to policy
March 2024	Annual review
June 2024	Annual review and reference update. Per SME, changed Worst-Itch Numeric Rating Scale for seborrheic dermatitis to Investigator Global Assessment of Disease
August 2024	Per PI update, added indication of atopic dermatitis to Zoryve cream. Added Appendix 2 and 3.
September 2024	Annual review
December 2024	Annual review. Per SME, added caveat that patients 18 or older with lesions on face, neck, or skin folds can t/f a low or medium potency topical corticosteroid
June 2025	Per PI update, added indication of plaque psoriasis of the scalp and body to Zoryve foam
September 2025	Annual review
October 2025	Per PI update, added Zoryve 0.05% cream for patients 2-5 years of age with atopic dermatitis
December 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

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Appendix 1

Relative Potency of Topical Calcineurin Inhibitors		
Drug	Dosage Form	Strength
Medium Potency		
Tacrolimus	Ointment	0.1%
Low Potency		
Tacrolimus	Ointment	0.03%
Pimecrolimus	Cream	1%

Appendix 2

Relative Potency of Selected Topical Corticosteroids		
Drug	Dosage Form	Strength
Very high Potency		
Augmented betamethasone dipropionate	Ointment, Gel	0.05%
Clobetasol propionate	Cream, Ointment	0.05%
Diflorasone diacetate	Ointment	0.05%
Flurandrenolide	Tape	4 mcg/cm ²
Halobetasol propionate	Cream, Ointment	0.05%
High Potency		
Amcinonide	Cream, Lotion, Ointment	0.1%
Augmented betamethasone dipropionate	Cream, Lotion	0.05%
Betamethasone dipropionate	Cream, Ointment	0.05%
Betamethasone valerate	Ointment	0.1%
Desoximetasone	Cream, Ointment	0.25%
	Gel	0.05%
Diflorasone diacetate	Cream, Ointment (emollient base)	0.05%
Fluocinonide	Cream, Ointment, Gel	0.05%
Halcinonide	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment	0.5%
Medium Potency		
Betamethasone dipropionate	Lotion	0.05%
Betamethasone valerate	Cream	0.1%

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Clocortolone pivalate	Cream	0.1%
Desoximetasone	Cream	0.05%
Fluocinolone acetonide	Cream, Ointment	0.025%
Flurandrenolide	Cream, Ointment, Lotion	0.05%
Fluticasone propionate	Cream	0.05%
	Ointment	0.005%
Hydrocortisone butyrate	Ointment, Solution	0.1%
Hydrocortisone valerate	Cream, Ointment	0.2%
Mometasone furoate	Cream, Ointment, Lotion	0.1%
Prednicarbate	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%
	Cream, Ointment, Lotion	0.1%
Low Potency		
Alclometasone dipropionate	Cream, Ointment	0.05%
Desonide	Cream	0.05%
Fluocinolone acetonide	Cream, Solution	0.01%
Hydrocortisone	Lotion	0.25%
	Cream, Ointment, Lotion,	0.5%
	Aerosol	
	Cream, Ointment, Lotion,	1%
	Solution	
Hydrocortisone acetate	Cream, Ointment, Lotion	2.5%
	Cream, Ointment	0.5%
	Cream, Ointment	1%

Appendix 3 – List of Topical PA Medications for Atopic Dermatitis (AD)

Generic Name	Brand Name
crisaborole	Eucrisa
roflumilast	Zoryve cream
ruxolitinib	Opzelura
tapinarof	Vtama