
5.90.057

Section:	Prescription Drugs	Effective Date:	January 1, 2025
Subsection:	Topical Products	Original Policy Date:	August 26, 2022
Subject:	Zoryve	Page:	1 of 8

Last Review Date: December 13, 2024

Zoryve

Description

Zoryve (roflumilast) cream, foam*

*This medication is currently pending tier determination and may not be available at this time

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)

- Zoryve cream is a phosphodiesterase 4 inhibitor:
 - 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.
 - 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.
- Zoryve foam is a phosphodiesterase 4 inhibitor indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

The safety and effectiveness of Zoryve cream in pediatric patients less than 6 years of age have not been established. The safety and effectiveness of Zoryve foam in pediatric patients less than 9 years of age have not been established (1-2).

Section:	Prescription Drugs	Effective Date:	January 1, 2025
Subsection:	Topical Products	Original Policy Date:	August 26, 2022
Subject:	Zoryve	Page:	2 of 8

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

Cream

Age 6 years of age or older

Diagnosis

Patient must have 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

Section:	Prescription Drugs	Effective Date:	January 1, 2025
Subsection:	Topical Products	Original Policy Date:	August 26, 2022
Subject:	Zoryve	Page:	3 of 8

- b. Patients with lesions on face, neck, or skin folds
ONLY: low to medium potency topical corticosteroid
- b. 6 to 17 years of age
 - 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)

Foam

Age 9 years of age or older

Diagnosis

Patient must have the following:

- 1. Seborrheic dermatitis
 - a. Inadequate treatment response, intolerance, or contraindication to **TWO** of the following:
 - i. Topical antifungal
 - ii. Topical corticosteroid
 - iii. Topical calcineurin inhibitor (see Appendix 1)

Section:	Prescription Drugs	Effective Date:	January 1, 2025
Subsection:	Topical Products	Original Policy Date:	August 26, 2022
Subject:	Zoryve	Page:	4 of 8

- b. 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)

Prior – Approval *Renewal* Requirements

Cream

Age 6 years of age or older

Diagnosis

Patient must have 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)

Foam

Age 9 years of age or older

Diagnosis

Patient must have the following:

Section:	Prescription Drugs	Effective Date:	January 1, 2025
Subsection:	Topical Products	Original Policy Date:	August 26, 2022
Subject:	Zoryve	Page:	5 of 8

1. Seborrheic dermatitis
 - a. Documented improvement using the Investigator Global Assessment of Disease (IGA)
(e.g.,
https://classic.clinicaltrials.gov/ProvidedDocs/28/NCT04973228/Prot_000.pdf#page=41)

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 (1-2).

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

References

5.90.057

Section:	Prescription Drugs	Effective Date:	January 1, 2025
Subsection:	Topical Products	Original Policy Date:	August 26, 2022
Subject:	Zoryve	Page:	6 of 8

1. Zoryve cream [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; July 2024.
2. Zoryve foam [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; December 2023.

Policy History

Date	Action
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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.

Section: Prescription Drugs

Effective Date: January 1, 2025

Subsection: Topical Products

Original Policy Date: August 26, 2022

Subject: Zoryve

Page: 7 of 8

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	0.05%
	(emollient base)	
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%

5.90.057

Section: Prescription Drugs

Effective Date: January 1, 2025

Subsection: Topical Products

Original Policy Date: August 26, 2022

Subject: Zoryve

Page: 8 of 8

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%
<i>Low Potency</i>		
Alclometasone dipropionate	Cream, Ointment	0.05%
Desonide	Cream	0.05%
Fluocinolone acetonide	Cream, Solution	0.01%
Hydrocortisone	Lotion	0.25%
	Cream, Ointment, Lotion, Aerosol	0.5%
	Cream, Ointment, Lotion, Solution	1%
	Cream, Ointment, Lotion	2.5%
Hydrocortisone acetate	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