
5.90.057

Section:	Prescription Drugs	Effective Date:	April 1, 2024
Subsection:	Topical Products	Original Policy Date:	August 26, 2022
Subject:	Zoryve	Page:	1 of 6

Last Review Date: March 8, 2024

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 indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.
2. 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).

Related policies

Tazarotene, Vtama

Policy

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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))

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

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- ii. Topical corticosteroid
- iii. Topical calcineurin inhibitor (see Appendix 1)
- b. Documented baseline evaluation of the condition using Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 4
(e.g., <https://ars.els-cdn.com/content/image/1-s2.0-S0022202X1632262X-gr1.jpg>)

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))

Foam

Age 9 years of age or older

Diagnosis

Patient must have the following:

- 1. Seborrheic dermatitis
 - a. Documented improvement using Worst Itch-Numeric Rating Scale (WI-NRS)
(e.g., <https://ars.els-cdn.com/content/image/1-s2.0-S0022202X1632262X-gr1.jpg>)

Policy Guidelines

Pre – PA Allowance

None

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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, 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

1. Zoryve cream [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; October 2023.
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

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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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

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Appendix 1

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