Pharmacy Medical Necessity Guidelines: Zoryve (roflumilast) cream

Effective: December 1, 2025

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Zoryve (roflumilast) cream is a phosphodiesterase 4 (PDE4) inhibitor that is indicated for:

For Zoryve 0.3% cream, topical treatment of plaque psoriasis, including intertriginous areas, in patients that are 6 years of age and older.

For Zoryve 0.15% cream, topical treatment of mild to moderate atopic dermatitis in patients that are 6 years of age or older.

For Zoryve 0.05% cream, topical treatment of mild to moderate atopic dermatitis in patients that are 2 to 5 years of age.

COVERAGE GUIDELINES

The plan may authorize coverage of **Zoryve (roflumilast) cream** for Members when the following criteria are met:

Initial Authorization Criteria

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Member is 6 years of age or older

AND

3. Zoryve is prescribed by or in consultation with a dermatologist

AND

4. Documentation of **ONE** of the following:
    a. Documentation that the member has had an inadequate response or adverse reaction to TWO or contraindication to ALL medium to very high potency topical corticosteroids (e.g., betamethasone dipropionate 0.05% lotion/cream, triamcinolone 0.5% cream/ointment, betamethasone dipropionate augmented 0.05% gel/lotion/ointment)

OR

    b. Documentation that the member is not a candidate for treatment with medium to high potency corticosteroid therapy (e.g., eyelid dermatitis, facial dermatitis, or dermatitis associated with genital area eruptions)

AND

5. Documentation that the member has had an inadequate response or adverse reaction to ONE or contraindication to **ALL** of the following:
    a. Topical vitamin D analog (e.g., calcipotriene 0.005% cream, calcitriol 3 mcg/g ointment)

OR

    b. Topical tazarotene (e.g., tazarotene 0.1% cream, tazarotene 0.05% gel)

6. Request is for Zoryve 0.3% cream

Atopic Dermatitis

1. Documented diagnosis of mild to moderate atopic dermatitis

AND

2. Zoryve is prescribed by or in consultation with a dermatologist, allergist, or immunologist

AND

3. Documentation that the Member has had an inadequate response or adverse reaction to ONE topical corticosteroid or contraindication to ALL topical corticosteroids

AND

4. Documentation that the Member has had an inadequate response or adverse reaction to ONE topical calcineurin inhibitor or contraindication to ALL topical calcineurin inhibitors

AND

5. **ONE** of the following:
    a. **BOTH** of the following:
        i. Member is 6 years of age or older
        ii. Request is for Zoryve 0.15% cream
    b. **BOTH** of the following:
        i. Member is 2 to 5 years of age
        ii. Request is for Zoryve 0.05% cream

Reauthorization Criteria

1. Documentation of improvement with Zoryve therapy

LIMITATIONS

1. Initial and reauthorization approvals will be granted for 12 months.

CODES

None

REFERENCES

1. Zoryve (roflumilast) cream [prescribing information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc; October 2025.
2. Eichenfield, Lawrence F. et al. Guidelines of care for the management of atopic dermatitis. Journal of the American Academy of Dermatology, Volume 71, Issue 1, 116 – 132, July 2014.

APPROVAL HISTORY

February 14, 2023: Reviewed by Pharmacy & Therapeutics Committee.
Subsequent endorsement date(s) and changes made:

1. January 9, 2024: Effective February 1, 2024, updated MNG title to include "cream" in the name. Updated the approvable member age to 6 years old as a result of updated package labeling. Updated the RxUM fax number.
2. March 11, 2025: No changes
3. December 9, 2025: Effective December 1, 2025, added Zoryve 0.15% and 0.05% cream to the MNG which are indicated for atopic dermatitis. Clarified that Zoryve 0.3% cream is indicated for plaque psoriasis in the Overview section. Updated initial criteria to clarify that the plaque psoriasis criteria is applicable for Zoryve 0.3% cream requests.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services