Pharmacy Medical Necessity Guidelines: Opzelura™ (ruxolitinib)

Effective: February 1, 2026

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

Opzelura (ruxolitinib) is a Janus Kinase (JAK) inhibitor indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 2 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Use of Opzelura (ruxolitinib) in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.

COVERAGE GUIDELINES

The plan may authorize coverage of Opzelura (ruxolitinib) for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of atopic dermatitis

AND

2. Patient is 2 years of age or older

AND

3. Prescribed by or in consultation with a dermatologist, allergist, or immunologist

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to two drugs within the topical corticosteroid or topical calcineurin inhibitor classes
    b. Contraindication to both topical corticosteroids and topical calcineurin inhibitors

AND

5. Documented inadequate response, adverse reaction, or contraindication to Eucrisa

Reauthorization Criteria

1. Documented diagnosis of atopic dermatitis

AND

2. Patient is 2 years of age or older

AND

3. Prescribed by or in consultation with a dermatologist, allergist, or immunologist

AND

4. Documentation the patient has experienced a therapeutic response as defined by **one (1)** of the following:
    a. Reduction in body surface area involvement relative to pretreatment baseline
    b. Improvement in atopic dermatitis symptoms as evidenced by marked improvements in symptoms such as pruritus, xerosis, crusting, or lichenification

LIMITATIONS

- The plan will not authorize coverage of Opzelura for the treatment of vitiligo.
- Initial approval of Opzelura will be authorized for six (6) months. Reauthorization of Opzelura will be in 12-month intervals.
- Members new to the plan stable on Opzelura should be reviewed against Reauthorization Criteria.

CODES

None

REFERENCES

1. Kim BS, Howell MD, Sun K, et al. Treatment of atopic dermatitis with ruxolitinib cream (JAK1/JAK2 inhibitor) or triamcinolone cream. J Allergy Clin Immunol. 2020 Feb;145(2):572-82.

2. Kim BS, Sun K, Papp K, et al. Effects of ruxolitinib cream on pruritus and quality of life in atopic dermatitis: Results from a phase 2, randomized, dose-ranging vehicle- and active-controlled study. J American Academy of Dermatology. 2020 June;82(6):1305-13.
3. Opzelura (ruxolitinib) [prescribing information]. Wilmington, DE: Incyte Corporation; September 2025.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement dates(s) and changes made:

- December 12, 2023: Added provider specialty requirements. Added Reauthorization criteria (eff 3/1/24).
- November 12, 2024: No changes (eff 11/12/24).
- December 9, 2025: updated age requirement to 2 years of age or older for atopic dermatitis based on updated package labeling (eff 2/1/26).

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.