Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Opzelura (ruxolitinib) Step Therapy Program

Effective: June 9, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Opezlura (ruxolitinib) is a Janus kinase (JAK) inhibitor indicated for:

- **Atopic dermatitis**
  Topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 2 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
- **Vitiligo**
  For the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older

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

Opzelura provides an alternative to topical corticosteroids and topical calcineurin inhibitors.

Clinical Guideline Coverage Criteria

Note: Prescriptions that meet the initial step therapy requirements will adjudicate **automatically** at the point of service. If the patient does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan for patients who do not meet the step therapy criteria at the point of service.

Refer to the table below for formularies and medications subject to this policy:

Drug	Commercial and Public Plan Products
Step-1	
pimecrolimus cream	Covered as listed on formulary
tacrolimus ointment	
topical corticosteroids	
Step-2	
Opzelura	Requires prior use of drug on Step-1

Automated Step Therapy Coverage

The following stepped approach applies to coverage of Step-2 medications by the plan:

- The patient has had a trial of a one (1) Step-1 medication as evidenced by a previous paid claim under the prescription benefit administered by the plan.

Coverage Criteria for Patients not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale:

The plan may cover medications on Step-2 if the following criteria are met:

1. The patient has had a trial of a Step-1 medication as evidenced by physician's documented use

OR

2. The patient has a physician documented contraindication or intolerance to all of the Step-1 medications

Limitations

None

Codes

None

References

1. AAAAI/ACAA JTF Atopic Dermatitis Guideline Panel, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE- and Institute of Medicine-based recommendations. Ann Allergy Asthma Immunol. 2023 Dec; S1081-1206(23)01455-2.
2. Boguniewicz MD, et al. Atopic dermatitis yardstick update. Ann Allergy Asthma Immunol. 2023 June;130(6):811-20.
3. Eleftheriadou V, et al. British Association of Dermatologists guidelines for the management of people with vitiligo 2021. British Journal of Dermatology. 2021 Jun;186(1):18-29.
4. Sidbury R, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. Journal of the American Academy of Dermatology. 2023 Jul;89(1): E1-E20.
5. Taieb A, et al. Guidelines for the management of vitiligo: the European Dermatology Forum Consensus. British Journal of Dermatology. 2012 Jul;168:5-19.
6. Opzelura (ruxolitinib) [prescribing information]. Wilmington, DE: Incyte Corporation.; September 2025.

Approval And Revision History

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

Subsequent endorsement date(s) and changes made:

- January 10, 2023: Administrative update to clarify intended coverage for Opzelura when criteria is met.
- January 9, 2024: No changes
- March 12, 2024: Updated management to an automated step therapy program (effective 6/1/2024).
- June 10, 2025: No changes (eff 6/10/25)
- June 9, 2026: Administrative update to overview with Opzelura's expanded age in mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patient 2 years of age and older. Administrative update to remove CareLink from the Medical Necessity Guideline template.

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.