Protocol for Opzelura® (ruxolitinib)
January 2026

Opzelura (ruxolitinib)

Protocol applies to FDA approved biosimilars and related indications and dosages

Background:
Opzelura® is a janus kinase (JAK) inhibitor approved for the treatment of mild to moderate atopic dermatitis and nonsegmental vitiligo.

General Criteria for Initial Approval (must meet all of the following):

1. Patient is of the FDA-labeled or compendial approved age
2. The medication will not be used concomitantly with biologic immunomodulators, JAK inhibitors or potent immunosuppressants
3. The medication is prescribed by or in consultation with a specialist who has appropriate knowledge and experience
4. Patient is not immunocompromised
5. Patient does not have any contraindications to therapy
6. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Approval Criteria for Specific Diagnoses:

1. **Atopic Dermatitis** (must meet all of the following):
    a. Patient has a diagnosis of mild to moderate atopic dermatitis
    b. Opzelura will not be used on more than 20% of the patient's body surface area
    c. Patient has tried and failed topical corticosteroids for at least 2 weeks or has an intolerance or contraindication to topical steroids (for example the affected area is on the face, groin or skin folds)
    d. Patient has tried and failed topical calcineurin inhibitors (e.g., Elidel®, Protopic®) or phosphodiesterase 4 (PDE4) inhibitor (Eucrisa®) for at least 4 weeks or has an intolerance or contraindication to one of these products
    e. Topical emollients are concomitantly used in the affected areas to help prevent flares

2. **Nonsegmental Vitiligo** (must meet all of the following):
    a. Patient has a diagnosis of nonsegmental vitiligo
    b. Opzelura will not be used on more than 10% of the patient's body surface area
    c. Initial approval is limited to 24 weeks
    d. Patient has tried and failed each of the following or has a contraindication or intolerance to all:
        i. Topical corticosteroid, unless the affected area is on the face, groin or skin folds
        ii. Topical tacrolimus or topical pimecrolimus

Criteria for Continued Approval (must meet all of the following):

1. The medication will not be used concomitantly with biologic immunomodulators, JAK inhibitors or potent immunosuppressants
2. Patient is not immunocompromised
3. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex,

Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

4. Patients with atopic dermatitis must meet all of the following:
    a. Opzelura will not be used on more than 20% of the patient's body surface area
    b. Documentation of a positive clinical response from baseline is received
    c. Topical emollients are concomitantly used in the affected areas to help prevent flares
5. Patients with nonsegmental vitiligo must meet all of the following
    a. Opzelura will not be used on more than 10% of the patient's body surface area
    b. Documentation of a positive clinical response with stable disease and/or re-pigmentation compared to baseline is received

There is a black box warning for serious infections, mortality, malignancy, major adverse cardiovascular events and thrombosis. See full prescribing information for complete boxed warning.

Approval Duration and Quantity Restrictions:

- Nonsegmental Vitiligo
  Initial therapy: 7 months
  Continuation of therapy: 12 months

- Atopic Dermatitis
  Initial therapy: 3 months
  Continuation of therapy: 12 months

Quantity Level Limit:

- 60 grams per 28 days
- Vitiligo - for larger body surface area (BSA): 180 grams per 28 days.
- Atopic Dermatitis - for larger body surface area (BSA): Pediatric patients 2 to 11 years of age: 120 grams per 28 days.
- Atopic Dermatitis - for larger body surface area (BSA): Patients 12 years of age and older: 240 grams per 28 days.

References:

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