Effective Date: 04/01/2022
Reviewed: 01/2022, 6/2023, 3/2024 Scope: Medicaid

OPZELURA (ruxolitinib) cream

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Atopic Dermatitis

Opzelura is a janus kinase (JAK) inhibitor indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (AD) in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Nonsegmental Vitiligo*

Opzelura is indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

***The use of Opzelura for the treatment of Nonsegmental Vitiligo is an excluded benefit and is not covered for cosmetic purposes.

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

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
   1. Chart notes or medical records showing affected areas and affected body surface area
   2. Chart notes or medical record documentation and claims history of prerequisite therapies including dosage, duration, and response to therapy. If therapy is not advisable, documentation of why therapy is not advisable.

B. Continuation requests: Documentation (e.g., chart notes) that the member has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

III. CRITERIA FOR INITIAL APPROVAL

Atopic Dermatitis (AD)

Authorization of 12 months may be granted for treatment of mild to moderate AD when all of the following criteria are met:

A. Member is 12 years of age or older
B. Medication is prescribed by, or in consultation with, a dermatologist or allergist/immunologist
C. Member has a diagnosis of mild to moderate AD with affected body surface area (BSA) of 3% to 20%
D. Member is not immunocompromised

E. Member experienced an inadequate treatment response to at least one moderate- to very high-potency topical corticosteroid for at least 2 consecutive weeks. Contraindications, adverse effects and/or intolerance must be documented.
F. Member experienced an inadequate treatment response to at least one topical calcineurin inhibitor (e.g., tacrolimus ointment, pimecrolimus cream) for 6 consecutive weeks or Eucrisa for 4 consecutive weeks. Contraindications, adverse effects and/or intolerance must be documented.
G. Opzelura will not be used concomitantly with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members requesting continuation of therapy when the member is experiencing clinical improvement in signs and symptoms of AD (e.g., improvement in pruritus, clear or almost clear skin), and when Opzelura will not be used concomitantly with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine.

V. QUANTITY LIMIT

Opzelura has a quantity limit of 60 grams per 30 days.

VI. REFERENCES

1. Opzelura [package insert]. Wilmington, DE: Incyte Corporation; September 2023.
2. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ (cited: December 29, 2021).