Effective Date: 04/01/2022
Reviewed: 01/2022, 6/2023, 3/2024, 2/2025, 11/2025 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 2 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. 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 2 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%. Documentation of affected areas and affected BSA is provided.
D. Member is not immunocompromised.
E. Opzelura will not be used with occlusive dressings.
F. Documentation that the member experienced an inadequate treatment response to at least one medium to super- high potency topical corticosteroid for at least 2 consecutive weeks. Contraindications, adverse effects and/or intolerance must be documented.
G. Documentation that member experienced an inadequate treatment response to one of the following 3 formulary topical drugs: tacrolimus ointment for 6 consecutive weeks, pimecrolimus cream for 6 consecutive weeks or Eucrisa (crisaborole) ointment for 4 consecutive weeks. Contraindications, adverse effects and/or intolerance must be documented.
H. Documentation that member experienced an inadequate treatment response to Zoryve cream 0.05% or 0.15% for 4 weeks or Vtama cream 1% for 8 weeks. Contraindications, adverse effects and/or intolerance must be documented.

I. Opzelura will not be used concomitantly with Eucrisa (crisaborole) ointment, Vtama (tapinoraf) cream, Zoryve (roflumilast) cream, Anzupgo (delgocitinib) cream, any therapeutic biologic drug, any targeted synthetic drug, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members requesting continuation of therapy when the following criteria are met:

A. Documentation that member has achieved or maintained a positive clinical response evidenced by low disease activity (i.e., clear or almost clear skin), or clinical improvement in signs and symptoms of AD (e.g., improvement in pruritus, redness)
B. Opzelura will not be used concomitantly with Eucrisa (crisaborole) ointment, Vtama (tapinoraf) cream, Zoryve (roflumilast) cream, Anzupgo (delgocitinib) cream, any therapeutic biologic drug, any targeted synthetic drug, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine.

IV. QUANTITY LIMIT

Opzelura 1.5% has a quantity limit of 60 grams per 30 days.

V. REFERENCES

1. Opzelura [package insert]. Wilmington, DE: Incyte Corporation; September 2025.
2. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ (cited: October 20, 2025).