



Commercial/Healthcare Exchange PA Criteria Effective: December 9th 2021

Prior Authorization: Opzelura™

Products Affected: Opzelura™ (ruxolitinib 1.5% cream)

Medication Description: Opzelura, a Janus kinase (JAK) inhibitor, is indicated for the topical short-term and non-continuous treatment of mild to moderate atopic dermatitis in patients ≥ 12 years of age whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.¹

Covered Uses:

1. Topical short-term and non-continuous treatment of mild to moderate atopic dermatitis
2. Vitiligo

Exclusion Criteria:

1. Concurrent use with a biologic or with other JAK inhibitors
2. Concurrent use with other potent Immunosuppressants such as:
 - a. Azathioprine
 - b. Cyclosporine
3. Patients with active hepatitis B or hepatitis C
4. The treatment of plaque psoriasis
5. The treatment of alopecia

Required Medical Information:

1. Diagnosis
2. Past medications tried and failed
3. Current medications

Age Restriction: Patients 12 years and older

Prescriber Restriction: The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

Coverage Duration:

1. Atopic Dermatitis: 8 weeks
2. Vitiligo: 6 months

Other Criteria:

Initial Approval Criteria

1. **Atopic Dermatitis:** Approve for 8 weeks if the patient meets all of the following (A, B, C, D, E, and F):

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- A. Patient is ≥ 12 years of age; **AND**
- B. Patient has mild to moderate atopic dermatitis, according to the prescriber; **AND**
- C. Patient has atopic dermatitis involvement estimated to affect $\leq 20\%$ of the body surface area; **AND**
- D. Patient meets ONE of the following (i or ii):
 - i. Patient meets ALL of the following criteria (a, b, and c):
 - a. Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; **AND**
Note: Concomitant use of a topical corticosteroid in with a topical calcineurin inhibitor would meet the requirement.
 - b. This topical corticosteroid was applied daily for at least 28 consecutive days; **AND**
 - c. Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber;
OR
 - ii. Patient is treating atopic dermatitis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia; **AND**
- E. Patients meets ALL of the following (i, ii, and iii):
 - i. Patient has tried at least one topical calcineurin inhibitor; **AND**
Note: Examples of topical calcineurin inhibitors include tacrolimus ointment (Protopic[®], generic) and pimecrolimus cream (Elidel[®], generic). Concomitant use of a topical calcineurin inhibitor with a topical corticosteroid would meet the requirement.
 - ii. This topical calcineurin inhibitor was applied daily for at least 28 consecutive days; **AND**
 - iii. Inadequate efficacy was demonstrated with this topical calcineurin inhibitor, according to the prescriber; **AND**
- F. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

2. **Vitiligo.** Approve for 6 months if the patient meets all of the following (A, B, C, D, E, and F):

- A. Patient is ≥ 12 years of age; **AND**
- B. Patient has nonsegmental vitiligo; **AND**
- C. Patient has vitiligo involvement estimated to affect $\leq 10\%$ of the body surface area; **AND**
- D. Patient meets ONE of the following (i or ii):
 - i. Patient meets ALL of the following criteria (a, b, and c):
 - a. Patient has tried at least one high-, and/or super-high-potency prescription topical corticosteroid; **AND**
Note: Concomitant use of a topical corticosteroid in with a topical calcineurin inhibitor would meet the requirement.
 - b. The duration of this topical corticosteroid therapy was at least 12 weeks; **AND**
Note: Intermittent or continuous use of a topical corticosteroid for at least 12 weeks would meet the requirement.
 - c. Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber;
OR
 - ii. Patient is treating vitiligo affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia;
AND
- E. Patients meets ALL of the following (i, ii, and iii):
 - i. Patient has tried at least one topical calcineurin inhibitor; **AND**
Note: Examples of topical calcineurin inhibitors include tacrolimus ointment (Protopic, generic) and pimecrolimus cream (Elidel, generic). Concomitant use of a topical calcineurin inhibitor with a topical corticosteroid would meet the requirement.
 - ii. This topical calcineurin inhibitor was applied daily for at least 12 weeks; **AND**
 - iii. Inadequate efficacy was demonstrated with this topical calcineurin inhibitor, according to the prescriber; **AND**
- F. The medication is prescribed by or in consultation with a dermatologist.

References:



1. Opzelura® cream [prescribing information]. Wilmington, DE: Incyte Pharmaceuticals; September 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	12/9/2021
2	Update	Added Vitiligo under Covered Uses and Other Criteria, removed vitiligo from exclusion criteria, added coverage duration for vitiligo	Covered Uses, Other Criteria, Exclusion criteria, Coverage Duration	12/20/2022

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