

Drug Policy

Policy:	Opzelura (ruxolitinib)	Annual Review Date: 12/19/2024 Last Revised Date: 12/19/2024
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OVERVIEW

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.

POLICY STATEMENT

This policy involves the use of Opzelura. Prior authorization is recommended for pharmacy benefit coverage of Opzelura. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Opzelura as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Opzelura be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Opzelura is recommended in those who meet the following criteria:

1. **Vitiligo.** Approve if the patient meets all 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 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.

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- 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 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.

Initial Approval/ Extended Approval.

- A) *Initial Approval:* 6 months
- B) *Extended Approval:* 6 months

2. Atopic Dermatitis

Approve if the patient meets all the following (A, B, C, D, E, and F):

- 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 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):

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- 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.

Initial Approval/ Extended Approval.

A) *Initial Approval:* 8 weeks

B) *Extended Approval:* 8 weeks

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Opzelura has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concurrent Use with a Biologic or with other JAK inhibitors.** Use of Opzelura in combination with therapeutic biologics or other JAK inhibitors is not recommended (see Appendix for examples).¹ Use of biologics or other JAK inhibitors was prohibited during the Opzelura pivotal studies.² There are no data evaluating combination use of Opzelura with these therapies; therefore, safety and efficacy of these combinations are unknown.
2. **Concurrent use with Other Potent Immunosuppressants** (e.g., azathioprine, cyclosporine). Use of Opzelura in combination with potent immunosuppressants is not recommended.¹ Use of systemic immunosuppressants was prohibited during the Opzelura pivotal studies.² There are no data evaluating combination of Opzelura with these therapies; therefore, safety and efficacy of these combinations are unknown.
3. **Alopecia.** Opzelura is not indicated for the treatment of alopecia.¹ A Phase II study involving patients with alopecia areata did not find any significant improvement in hair regrowth with Opzelura 1.5% cream compared with vehicle.⁷ Additional data are needed to establish the efficacy and safety of Opzelura in patients with alopecia.

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- 4. Plaque Psoriasis.** Opzelura is not indicated for the treatment of plaque psoriasis.¹ There are very limited Phase II data regarding the use of Opzelura in patients with plaque psoriasis.^{8,9} Additional data are needed to establish the efficacy and safety of Opzelura in patients with plaque psoriasis.
- 5.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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APPENDIX

Table 1. Examples of Other Therapeutic Biologics and Other JAK Inhibitors.

Product	Mechanism of Action
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF
Simponi®, Simponi® Aria™ (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF
Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6
Kezara® (sarilumab SC injection)	Inhibition of IL-6
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody
Kineret® (anakinra SC injection)	Inhibition of IL-1
Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23
Siliq® (brodalumab SC injection)	Inhibition of IL-17
Cosentyx® (secukinumab SC injection)	Inhibition of IL-17A
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23
Omvoh™ (mirikizumab-mrkz SC injection, mirikizumab IV injection)	Inhibition of IL-23
Skyrizi® (risankizumab-rzaa SC injection)	Inhibition of IL-23
Tremfya® (guselkumab SC injection)	Inhibition of IL-23
Entyvio® (vedolizumab IV infusion)	Integrin receptor antagonist
Otezla® (apremilast tablets)	Inhibition of PDE4
Sotyktu™ (deucravacitinib tablets)	Inhibition of TYK2
Inrebic® (fedratinib tablets)	Inhibition of JAK pathways
Jakafi® (ruxolitinib tablets)	Inhibition of JAK pathways
Leqselvi™ (deuruxolitinib tablets)	Inhibition of JAK pathways
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways
Cibinqo® (abrocitinib tablets)	Inhibition of JAK pathways
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways
Xeljanz® (tofacitinib tablets, oral solution)	Inhibition of JAK pathways
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways
Litfulo™ (ritlectinib capsules)	Inhibition of kinases
Xolair® (omalizumab SC injection)	IgE antagonist
Dupixent® (dupilumab SC injection)	IL-4 receptor antagonist
Cinqair® (reslizumab IV injection)	IL-5 antagonist
Nucala® (mepolizumab SC injection)	IL-5 antagonist
Fasenra® (benralizumab SC injection)	IL-5 receptor antagonist
Adbry® (tralokinumab-ldrm SC injection)	IL-13 antagonist
Nemluvio® (nemlizumab-ilto SC injection)	IL-31 receptor antagonist
Zeposia® (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator
Velsipity® (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator
Tezspire® (tezepelumab-ekko SC injection)	TSLP blocker

JAK – Janus kinase; SC – Subcutaneous; TNF – Tumor necrosis factor; IV – Intravenous; IL – Interleukin; PDE4 – Phosphodiesterase 4; TYK2 – Tyrosine kinase 2; IgE – Immunoglobulin E; TSLP – Thymic stromal lymphopoietin.