UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1372-5
Program	Prior Authorization/Notification
Medication	Opzelura® (ruxolitinib)
P&T Approval Date	11/2021, 4/2022, 9/2022, 9/2023, 12/2024
Effective Date	3/1/2025

1. Background:

Opzelura (ruxolitinib) is a Janus kinase (JAK) inhibitor indicated for the topical short term and non-continuous chronic treatment of mild to moderate atopic dermatitis 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. Opzelura is also indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

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

2. Coverage Criteria[a]:

A. Atopic Dermatitis

1. **Initial Authorization**

a. **Opzelura** will be approved based on **all** of the following criteria:

(1) Diagnosis of mild to moderate atopic dermatitis

-AND-

(2) History of failure, contraindication, or intolerance to topical therapies (e.g., topical corticosteroids, topical calcineurin inhibitors)

-AND-

(3) Patient is **not** receiving Opzelura in combination with another biologic medication [e.g., Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)] or JAK inhibitor [e.g., Jakafi (ruxolitinib), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

-AND-

(4) Patient is **not** receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Opzelura** will be approved based **all** of the following criteria:

(1) Documentation of positive clinical response to therapy

-AND-

(2) Patient is **not** receiving Opzelura in combination with another biologic medication [e.g., Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)] or JAK inhibitor [e.g., Jakafi (ruxolitinib), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

-AND-

(3) Patient is **not** receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)

Authorization will be issued for 12 months.

B. Nonsegmental Vitiligo

1. **Initial Authorization**

a. **Opzelura** will be approved based on **all** of the following criteria:

(1) Diagnosis of nonsegmental vitiligo

-AND-

(2) Patient is **not** receiving Opzelura in combination with another biologic medication [e.g., Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)] or JAK inhibitor [e.g., Jakafi (ruxolitinib), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

-AND-

(3) Patient is **not** receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Opzelura** will be approved based **all** of the following criteria:

(1) Documentation of positive clinical response to therapy

-AND-

(2) Patient is **not** receiving Opzelura in combination with another biologic medication [e.g., Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)] or JAK inhibitor [e.g., Jakafi (ruxolitinib), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

-AND-

(3) Patient is **not** receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Opzelura [package insert]. Wilmington, DE: Incyte Corporation; August 2024.

Program	Prior Authorization/Notification - Opzelura (ruxolitinib)
Change Control	
11/2021	New program.
4/2022	Changed initial authorization duration from 8 weeks to 12 months.
9/2022	Added coverage criteria for nonsegmental vitiligo. Updated background, examples, and reference. Added state mandate footnote.
9/2023	Annual review with no change to clinical criteria. Updated reference.
12/2024	Annual review. Removed age requirement criteria. Updated vitiligo initial authorization to 12 months. Updated reference.