UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2261-7
Program	Prior Authorization/Medical Necessity
Medication	Opzelura® (ruxolitinib)
P&T Approval Date	11/2021, 4/2022, 7/2022, 9/2022, 9/2023, 12/2024, 12/2025
Effective Date	3/1/2026

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 2 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) **One** of the following:

(a) History of failure, contraindication, or intolerance to **two** of the following therapeutic classes of topical therapies^:

i. **One** of the following:
- For mild atopic dermatitis: a topical corticosteroid [e.g., DesOwen (desonide), hydrocortisone] (any potency)
- For moderate atopic dermatitis: a topical corticosteroid of at least a medium- to high-potency (e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]

ii. One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]*

iii. Eucrisa (crisaborole)*

-OR-

(b) **Both** of the following:

i. Patient is currently on Opzelura therapy

-AND-

ii. Patient has not received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Incyte sponsored Opzelura IncyteCARES program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Opzelura[¥]

[¥] Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Incyte sponsored Opzelura IncyteCARES program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

-AND-

(3) Patient is **not** receiving Opzelura in combination with a biologic medication or JAK inhibitor [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), 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 on **all** of the following criteria:

(1) Documentation of positive clinical response to therapy

-AND-

(2) Patient is **not** receiving Opzelura in combination with a biologic medication or JAK inhibitor [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), 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) Other causes of depigmentation have been ruled out (e.g., nevus depigmentosus, pityriasis alba, idiopathic guttate hypomelanosis, tinea (pityriasis) versicolor, halo nevus, piebaldism, progressive macular hypomelanosis, lichen sclerosus, chemical leukoderma, drug-induced leukoderma, hypopigmented mycosis fungoides)

-AND-

(3) Affected areas not to exceed 10% body surface area

-AND-

(4) History of failure, contraindication, or intolerance to previous nonsegmental vitiligo treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors)

-AND-

(5) Patient is **not** receiving Opzelura in combination with a biologic medication or JAK inhibitor [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), Rinvoq (upadacitinib)]

-AND-

(6) 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 a biologic medication or JAK inhibitor [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib),

Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), 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.
^ Tried/Failed alternative(s) are supported by FDA labeling

* Elidel, Protopic/tacrolimus ointment, and Eucrisa require prior authorization.

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; September 2025.
2. Frazier W, Bhardwaj N. Atopic Dermatitis: Diagnosis and Treatment. Am Fam Physician. 2020;101(10):590-598.
3. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014;71(1):116-132.
4. Taieb A, Alomar A, Böhm M, et al. Guidelines for the management of vitiligo: the European Dermatology Forum consensus. *Br J Dermatol*. 2013;168(1):5-19.
5. Grimes PE. Vitiligo: Management and prognosis. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com. Accessed on August 15, 2022.
6. Bergqvist C, Ezzedine K. Vitiligo: A Review. *Dermatology*. 2020;236(6):571-592.

Program	Prior Authorization/Medical Necessity - Opzelura (ruxolitinib)
Change Control	
11/2021	New program.
4/2022	Changed initial authorization duration from 8 weeks to 12 months.
7/2022	Removed age requirement from criteria. Updated reference.
9/2022	Added coverage criteria for nonsegmental vitiligo. Updated background, examples, and reference.
9/2023	Annual review with no change to clinical criteria. Updated reference.
12/2024	Annual review. Updated vitiligo initial authorization to 12 months.

	Added FDA supported T/F footnote. Updated reference.
12/2025	Annual review. Updated combination examples and language with no change to clinical intent. Updated background to reflect new age recommendation for AD. Updated reference.