

PRIOR AUTHORIZATION REQUEST FORM

Opzelura

For authorization, please answer each question and fax this form PLUS chart notes back to RealRx Medicaid Prior Authorization Department at 385-425-4052.

Failure to submit clinical documentation to support this request will result in a dismissal of the request.

If you have prior authorization questions, please call Pharmacy Customer Service for assistance.

- Healthy U: 855-856-5694
- Healthy U CHIP: 855-203-3633
- Health Choice Utah: 855-864-1404

Disclaimer: Prior authorization request forms are subject to change in accordance with Federal and State notice requirements.

Date:	Member Name:	ID#:
DOB:	Gender:	Physician:
Office Phone:	Office Fax:	Office Contact:

Height/Weight:

Product Requested: Opzelura (ruxolitinib) 1.5% cream

Directions for Use: _____

Criteria for Approval (ALL of the following criteria must be met):	Yes	No
1. Is the patient 2 years of age or older?	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the patient have any of the following diagnoses demonstrated by description of baseline symptoms present in the chart notes? <input type="checkbox"/> Mild to moderate atopic dermatitis with involvement estimated to be greater or equal to 3% of the body surface area (BSA), OR less than 3% of BSA with atopic dermatitis involvement to face, eyes/eyelids, skin folds, and/or genitalia <input type="checkbox"/> Nonsegmental Vitiligo (12 years of age or older only) <input type="checkbox"/> Other – Off Label or Compendia Use (specify): _____	<input type="checkbox"/>	<input type="checkbox"/>
3. Is the medication being prescribed by or in consultation with a dermatologist, allergist, immunologist, or provider specializing in disease treatment?	<input type="checkbox"/>	<input type="checkbox"/>
4. Has the member tried and failed at least ONE medium- to super-high-potency topical corticosteroid (TCS) AND a topical calcineurin inhibitor (TCI) at a minimum of 4 weeks*? (*If involvement to the face, eyes/eyelids, skin folds, and/or genitalia, trial and failure of TCS is not required) TCS Medication: _____ Date of therapy: _____ Details of Failure: _____ TCI Medication: _____ Date of therapy: _____ Details of Failure: _____	<input type="checkbox"/>	<input type="checkbox"/>
5. Does the requested medication and diagnosis follow FDA-approved age, dosing, monitoring and contraindications? If answer is No, go to PartII, section 7	<input type="checkbox"/>	<input type="checkbox"/>

6. Does the provider attest that the patient is not taking concurrent treatment or will not be used in combination with other therapeutic biologics, JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine?	<input type="checkbox"/>	<input type="checkbox"/>
Off Label or Compendia Use of FDA-Approved Drugs Additional Criterion:		
7. Does the clinical documentation show an adequate trial and failure with at least ONE FDA-labeled and Medicaid preferred medication, if applicable?	<input type="checkbox"/>	<input type="checkbox"/>
8. Provider attest the requested drug is being used for a medically accepted indication that is supported by information from the appropriate compendia* of current literature. Including at least (1) major multi-site study or three (3) smaller studies published in JAMA, NEJM, Lancet, or other peer review specialty medical journals in the most recent years? * Compendia use must be recommended by generally accepted compendia such as American Hospital Formulary Service Drug Information (AHFS), United States Pharmacopeia-Drug Information (USP-DI), the Micromedex Information System, Pediatric and Neonatal Lexi-Drugs, or clinical guidelines.	<input type="checkbox"/>	<input type="checkbox"/>
Reauthorization		
1. Has the provider submitted an updated letter with medical justification and updated chart notes demonstrating positive clinical response, including reduced BSA involvement and improvement in symptoms?	<input type="checkbox"/>	<input type="checkbox"/>
PRESCRIBER CERTIFICATION		
I hereby certify this treatment is indicated, necessary and meets the guidelines for use.		
Physician's Signature:	Date:	

Initial Authorization: Up to six (6) months

Reauthorization: Up to one (1) year

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Note:

- **WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS**
 - **SERIOUS INFECTIONS**
 - Patients treated with oral Janus kinase inhibitors for inflammatory conditions are at risk for developing serious infections that may lead to hospitalization or death
 - Reported infections include:
 - Active tuberculosis, which may present with pulmonary or extrapulmonary disease.
 - Invasive fungal infections, including cryptococcosis, and pneumocystosis.
 - Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.
 - Avoid use of OPZELURA in patients with an active, serious infection, including localized infections. If a serious infection develops, interrupt OPZELURA until the infection is controlled.
 - The risks and benefits of treatment with OPZELURA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.
 - Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with OPZELURA [see Warnings and Precautions (5.1)].
 - **MORTALITY**
 - In a large, randomized, postmarketing safety study in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor comparing an oral JAK inhibitor to tumor necrosis factor (TNF) blocker treatment, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor.
 - **MALIGNANCIES**
 - Malignancies were reported in patients treated with OPZELURA. Lymphoma and other malignancies have been observed in patients receiving JAK inhibitors used to treat inflammatory conditions. In RA patients treated with an oral JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer (NMSC)) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk.
 - **MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE)**
 - In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with an oral JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke), was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue OPZELURA in patients who have experienced a myocardial infarction or stroke.
 - **THROMBOSIS**

- Thromboembolic events were observed in trials with OPZELURA. Thrombosis, including pulmonary embolism (PE), deep venous thrombosis (DVT), and arterial thrombosis have been reported in patients receiving JAK inhibitors used to treat inflammatory conditions. Many of these adverse reactions were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with an oral JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid OPZELURA in patients at risk. If symptoms of thrombosis occur, discontinue OPZELURA and treat appropriately.

Policy: PHARM-HYB-183

Origination Date: 01/01/2026

Reviewed/Revised Date:

Next Review Date:

Current Effective Date: 01/01/2026

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