

## KEY INFORMATION TO INCLUDE IN PRIOR AUTHORIZATIONS

<b>Patient Age</b>	The patient must be 12 years of age or older.
<b>Indication</b>	OPZELURA is indicated for: <ul style="list-style-type: none"><li>• Mild to moderate atopic dermatitis</li><li>• Nonsegmental vitiligo</li></ul>
<b>ICD-10 Diagnosis Code*</b>	<b>L20.9 Atopic Dermatitis</b> <b>L80 Vitiligo</b>
<b>Step Through Medications</b>	This may include a 4-week trial of a topical corticosteroid (TCS) and/or a topical calcineurin inhibitor (TCI) within the past year. <b>When submitting your chart notes, include discontinuation dates of any other tried/failed medications.</b>
<b>Body Surface Area (BSA)</b>	Indicate the <b>BSA that will be treated:</b> <ul style="list-style-type: none"><li>• Atopic dermatitis is up to 20%</li><li>• Nonsegmental vitiligo is up to 10%</li></ul>
<b>Not Approved for Combination Use</b>	Confirm OPZELURA will <b>not</b> be used with: <ul style="list-style-type: none"><li>• Therapeutic biologics</li><li>• Other JAK inhibitors</li><li>• Potent immunosuppressants</li><li>• Other brand products for atopic dermatitis</li></ul> OPZELURA was studied as a monotherapy treatment. Many plans do not approve combination use.



### **APPROVED COVERAGE**

Eligible patients with commercial insurance may pay as little as \$0<sup>†</sup> per tube.  
**To obtain a copay savings card, patients can visit [opzelura.com](https://www.opzelura.com) or scan the QR code.**

## WE'RE HERE TO HELP!

**Don't wait on your PA questions.**  
Call your Incyte dermatology representative today.

### **DID YOU INCLUDE...**

- A diagnosis from the Prescribing Information?
- The ICD-10 code and diagnosis that aligns to the patient's condition?
- Other products tried and the reasons for ineffectiveness? (If applicable, address intolerance or experienced side effects.)
- The BSA % intended to be treated?
- The patient's most recent chart notes?
- An explanation for discontinued therapies like potent immunosuppressants, other JAK inhibitors, or therapeutic biologics?



**INFORM YOUR PATIENTS** THAT THEY WILL RECEIVE A CALL FROM THE PHARMACY.

\*This information is background and not intended as guidance for coding, billing, and claim submissions. Decisions on which codes best describe the services provided must be made by the individual prescriber. Incyte cannot guarantee payment of any claim. Payers may provide specific information on their reimbursement policies.

<sup>†</sup>Eligibility required. For use only with commercial prescription insurance. The card may not be used if the patient is enrolled in a government-funded prescription insurance program or if they pay cash for their prescription. Individual out-of-pocket cost may vary. Maximum benefits per tube and per calendar year apply. Must be used for an FDA-approved indication. Additional [Terms and Conditions](#) apply.

**Please see Important Safety Information on page 2 and [Full Prescribing Information](#), including [Boxed Warning](#), and [Medication Guide](#) for OPZELURA.**

## INDICATIONS

OPZELURA is indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric 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 indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

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

## IMPORTANT SAFETY INFORMATION

### 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. Carefully consider the benefits and risks of treatment prior to initiating OPZELURA in patients with chronic or recurrent infection. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with OPZELURA.**

Serious lower respiratory tract infections were reported in the clinical development program with topical ruxolitinib.

No cases of active tuberculosis (TB) were reported in clinical trials with OPZELURA. Cases of active TB were reported in clinical trials of oral Janus kinase inhibitors used to treat inflammatory conditions. Consider evaluating patients for latent and active TB infection prior to administration of OPZELURA. During OPZELURA use, monitor patients for the development of signs and symptoms of TB.

Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical trials with Janus kinase inhibitors used to treat inflammatory conditions including OPZELURA. If a patient develops herpes zoster, consider interrupting OPZELURA treatment until the episode resolves.

Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine aminotransferase and aspartate aminotransferase, have been reported in patients with chronic HBV infections taking oral ruxolitinib.

OPZELURA initiation is not recommended in patients with active hepatitis B or hepatitis C.

### 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.** Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OPZELURA.

### 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.**

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OPZELURA, particularly in patients with a known malignancy (other than successfully treated non-melanoma skin cancers), patients who develop a malignancy when on treatment, and patients who are current or past smokers.

Non-melanoma skin cancers, including basal cell and squamous cell carcinoma, have occurred in patients treated with OPZELURA. Perform periodic skin examinations during OPZELURA treatment and following treatment as appropriate. Exposure to sunlight and UV light should be limited by wearing protective clothing and using broad-spectrum sunscreen.

### 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.**

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OPZELURA, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur. Discontinue OPZELURA in patients that 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.**

### Thrombocytopenia, Anemia, and Neutropenia

Thrombocytopenia, anemia, and neutropenia were reported in the clinical trials with OPZELURA. Consider the benefits and risks for individual patients who have a known history of these events prior to initiating therapy with OPZELURA. Perform CBC monitoring as clinically indicated. If signs and/or symptoms of clinically significant thrombocytopenia, anemia, and neutropenia occur, patients should discontinue OPZELURA.

### Lipid Elevations

Treatment with oral ruxolitinib has been associated with increases in lipid parameters including total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides.

### Adverse Reactions

In atopic dermatitis, the most common adverse reactions ( $\geq 1\%$ ) are nasopharyngitis (3%), diarrhea (1%), bronchitis (1%), ear infection (1%), eosinophil count increased (1%), urticaria (1%), folliculitis (1%), tonsillitis (1%), and rhinorrhea (1%).

In nonsegmental vitiligo, the most common adverse reactions (incidence  $\geq 1\%$ ) are application site acne (6%), application site pruritus (5%), nasopharyngitis (4%), headache (4%), urinary tract infection (2%), application site erythema (2%), and pyrexia (1%).

### Pregnancy

There is a pregnancy registry that monitors pregnancy outcomes in pregnant persons exposed to OPZELURA during pregnancy. Pregnant persons exposed to OPZELURA and healthcare providers should report OPZELURA exposure by calling 1-855-463-3463.

### Lactation

Advise women not to breastfeed during treatment with OPZELURA and for approximately four weeks after the last dose (approximately 5-6 elimination half-lives).

**Please see Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.**

