Opzelura® (ruxolitinib) cream 1.5%

Opzelura OnTrac™

GET YOUR PATIENTS STARTED

AN OPZELURA PA SHOULD INCLUDE:

Patient Age	The patient must be 12 years of age or older.
Diagnosis	OPZELURA is indicated for: • Mild to moderate atopic dermatitis • Nonsegmental vitiligo
ICD-10 Diagnosis Code*	L20.9 Atopic Dermatitis L20.89 Other Atopic Dermatitis L80 Vitiligo
Step Through Medications	Typically a 4-week trial of a topical corticosteroid (TCS) and/or a topical calcineurin inhibitor (TCI) within the past year. **Document tried/failed medications and reason for ineffectiveness, intolerance, and/or experienced side effects. Also include duration of use and discontinuation dates.**
BSA That Will Be Treated	• Atopic dermatitis is up to 20% • Nonsegmental vitiligo is up to 10%
Not Approved for Combination Use	Confirm OPZELURA will **not** be used with: • Therapeutic biologics • Other JAK inhibitors • Potent immunosuppressants • Other brand products for atopic dermatitis
Chart Notes	Be sure the information above is documented for each OPZELURA patient. Some plans will require a copy of the chart notes in the PA submission.

PA APPROVED
PAY AS LITTLE AS **$0** PER TUBE†

Through the Copay Savings Program, eligible patients may pay as little as $0 per tube.
GET A COPAY SAVINGS CARD AT OPZELURA.COM.

PA DENIED
$35 PER TUBE‡

Through the Commercial Bridge Program, eligible patients pay $35 per tube.
This Program is exclusively offered through the enhanced services SP network.
FIND A PARTICIPATING SPECIALTY PHARMACY.

WE'RE HERE TO HELP!

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

*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.

†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.

‡Terms and conditions apply. Terms of this Program may change at any time. OPZELURA is widely available at pharmacies. Other offers or services may apply.

Please see Important Safety Information on page 2 and Full Prescribing Information, including Boxed Warning.

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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 (≥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 ≥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.