Opzelura®
(ruxolitinib) cream 1.5%

Opzelura OnTrac™

YOUR GUIDE TO PAs FOR OPZELURA®

DRIVE APPROVALS WITH COMPLETE DOCUMENTATION

To complete a prior authorization (PA) for OPZELURA, you need to capture specific information. Use this guide to help you create a consistent process to collect comprehensive patient notes – including automating note collection and prescription information in your electronic medical record (EMR) platform – and make the process for getting appropriate patients OPZELURA more predictable.

A COMPLETE PA FILE FOR OPZELURA INCLUDES:

- ☑ Comprehensive PA notes (see next page for more details)
- ☑ Patient's pharmacy drug benefit insurance cards (with Rx BIN, Rx PCN, Rx Group)
- ☑ "Face" sheet (i.e. "demo" sheet)
- ☑ A copy of the prescribing information

COMPREHENSIVE PA NOTES

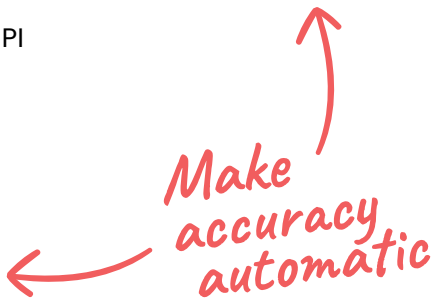
	PA NOTES FOR MILD TO MODERATE ATOPIC DERMATITIS	PA NOTES FOR NONSEGMENTAL VITILIGO
DECISION TO PRESCRIBE OPZELURA:	State the prescriber's decision to initiate a prescription for OPZELURA.	State the prescriber's decision to initiate a prescription for OPZELURA
DIAGNOSIS:	State the patient's diagnosis (note that OPZELURA is approved for mild-to-moderate atopic dermatitis).	State the patient's diagnosis (note that OPZELURA is approved for nonsegmental vitiligo).
AGE:	State the patient's age (note that OPZELURA is approved for patients aged 12 and over).	State the patient's age (note that OPZELURA is approved for patients aged 12 and over).
TRIED AND FAILED:	State medications the patient has tried and failed. Examples may include a topical corticosteroid such as clobetasol or triamcinolone and/or a topical calcineurin inhibitor such as Elidel or Protopic. Document why these treatments were ineffective or intolerable for the patient.	State medications the patient has tried and failed. Examples may include a topical corticosteroid such as clobetasol or triamcinolone and/or a topical calcineurin inhibitor such as Elidel or Protopic. Document why these treatments were ineffective or intolerable for the patient. If applicable, document that other causes of depigmentation were ruled out.
PATIENT'S CURRENT CONDITION:	Describe in the visit notes if the patient is not at treatment goal or condition is not adequately controlled.	Describe in the visit notes if the patient is not at treatment goal or condition is not adequately controlled. If applicable, include a note stating you will not treat with a non-FDA approved medication for this condition.
BODY SURFACE AREA (BSA) TO BE TREATED:	State the patient's BSA to be treated as a percentage (note that OPZELURA is approved to treat up to 20% BSA for mild-to-moderate atopic dermatitis).	State the patient's BSA to be treated as a percentage (note that OPZELURA is approved to treat up to 10% BSA for nonsegmental vitiligo).
DESCRIBE THE ITCH:	If applicable, describe itching symptoms for your AD patient. This could include an itch score and/or impact of itch on the patient's life.	_____
COMBINATION USE:	It is not recommended that OPZELURA be used with the following: • Biologics • Potent immunosuppressants • Other JAKs • Other **branded** AD products	It is not recommended that OPZELURA be used with the following: • Biologics • Potent immunosuppressants • Other JAKs
DOSING:	Use the language below: Instruct patients to apply a thin layer of OPZELURA twice daily to affected areas of up to 20% BSA. Do not use more than one 60-gram tube per week. OPZELURA is for topical use only. OPZELURA is not for ophthalmic, oral, or intravaginal use. Stop using when signs resolve. If signs and symptoms have not improved within 8 weeks, patients should be re-examined by their healthcare provider.	Use the language below: Instruct patients to apply a thin layer of OPZELURA twice daily to affected areas of up to 10% body surface area. Do not use more than one 60-gram tube per week. OPZELURA is for topical use only. OPZELURA is not for ophthalmic, oral, or intravaginal use. Satisfactory patient response may require treatment with OPZELURA for more than 24 weeks. If the patient does not find the repigmentation meaningful by 24 weeks, the patient should be re-evaluated by the healthcare provider.
QUANTITY:	60g tube	60g tube
DOSING SCHEDULE:	BID	BID
DURATION OF THERAPY:	_____	Document the duration of therapy deemed necessary by the prescriber (for example, number of weeks).
PRESCRIBING INFORMATION:	Add a link to the Prescribing Information for OPZELURA so it may be attached to your electronic note. It is a good practice to include a copy of the PI to your prior authorization or appeal submission.	Add a link to the Prescribing Information for OPZELURA so it may be attached to your electronic note. It is a good practice to include a copy of the PI to your prior authorization or appeal submission.

LEVERAGE YOUR EMR

If your office uses EMA (Modernizing Medicine)

Set up two Protocols for OPZELURA.

- **Two protocols should be created:** one for OPZELURA for mild to moderate atopic dermatitis and OPZELURA for nonsegmental vitiligo
- Within the Protocol, the **Plan** section includes tabs for **Details, Tried and Failed,** and **OPZELURA Counseling**. Add the text from the Comprehensive PA Notes table on the previous page and a link to the Prescribing Information and Medication Guide
- Include prescription information in your protocol:
  - # of days such as 28 or 30
  - BID: twice daily per the dosing instructions within the PI
  - # of refills
  - OPZELURA tube size: 60g



If your office uses Nextech

Set up Visit Finding Stamps.

- Navigate to the **Medication Plan** section of your Nextech interface
- Consider adding the patient notes information described above to streamline your process

FIND MORE INFORMATION FOR PRIOR AUTHORIZATIONS AND APPEALS AT OPZELURA ON TRAC™

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 orextrapulmonary 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.

Incyte Dermatology