PRESCRIPTION AND ENROLLMENT FORM FOR OPZELURA

IncyteCARES | Opzelura™ (ruxolitinib) cream 1.5%

TO SUBMIT, COMPLETE AND FAX THIS FORM TO **1-877-801-3840.**

SELECT PROGRAM

☐ **Commercial Access Program for OPZELURA**
For commercially insured patients only
Complete pages 1 and 2

☐ **IncyteCARES for OPZELURA Patient Assistance Program**
For uninsured or underinsured Medicare Part D patients only
Complete pages 1, 2, and 3

1. PATIENT INFORMATION

First Name _____ MI ____ Last Name _____ Date of Birth _____
Address _____ City _____ State _____ ZIP _____
Phone _____ ☐ Home ☐ Mobile Best time to call ☐ 8 am–12 pm ☐ 12–4 pm ☐ 4–8 pm
Email _____ Is patient a resident of the United States or Puerto Rico? ☐ Yes ☐ No
Caregiver Contact (If Applicable) Full Name _____
Relationship to Patient _____ Phone _____

2. PATIENT INSURANCE INFORMATION

☐ **CHECK IF PATIENT DOES NOT HAVE PRESCRIPTION INSURANCE**

Primary Insurance
Primary Insurance Name _____ Primary Insurance Phone _____
Policyholder Name _____ Policyholder Date of Birth _____
Policy ID Number _____ Group Number _____

Prescription (Rx) Insurance
Rx Insurance Name _____ Rx Policy ID Number _____ Rx Group ID Number _____ Rx BIN _____ Rx PCN _____

For Medicare Part D plans – please provide address:
Address _____ City _____ State _____ ZIP _____

3. PRESCRIBER INFORMATION

First Name _____ Last Name _____
Practice Name _____ State License Number _____ NPI Number _____
Address _____ City _____ State _____ ZIP _____
Practice Contact Name _____ Phone _____ Fax _____

4. PRESCRIPTION FOR OPZELURA

Primary Diagnosis ICD-10 Code(s) ☐ L20 Atopic Dermatitis ☐ L80 Vitiligo ☐ Other ICD-10 _____

Medication Name: **OPZELURA (ruxolitinib) cream, 1.5%** Tube size: 60 grams Number of Tubes _____ Refill(s) _____
Directions _____

I certify that I am the Healthcare Professional who has prescribed this medication, that it is medically necessary for the patient, and that the information provided is accurate to the best of my knowledge. I authorize Incyte, and its affiliates, agents, and service providers to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy.

If you are a prescriber based in New York state, please use a New York state prescription form.

PRESCRIBER SIGNATURE X _____ X _____ _____
Dispense as written **Substitutions allowed** Date

5. PRESCRIBER DECLARATION

By my signature, I certify that I have obtained any and all authorizations and consents from the patient or the patient's authorized personal representative necessary under HIPAA and state law to release protected health information, including that contained on this form, to Incyte and its employees or agents for purposes relating to Incyte's patient support programs.

FOR COMMERCIAL ACCESS PROGRAM ENROLLMENT ONLY – PA Denial Information Required for Commercial Access Program Only

FOR PATIENTS WITH ATOPIC DERMATITIS:
☐ **By checking this box, I certify** my patient has mild to moderate atopic dermatitis, has tried and failed a topical prescription therapy, and the Prior Authorization (PA) was denied.

FOR PATIENTS WITH NONSEGMENTAL VITILIGO:
☐ **By checking this box, I certify** my patient has nonsegmental vitiligo and that the Prior Authorization (PA) was denied.

PA Denial Date: _____ PA Denial Reason: _____

PRESCRIBER SIGNATURE X _____ _____
Date

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Provide a copy of the HIPAA authorization to your patient for their records.

HIPAA AUTHORIZATION

By signing this form, you are giving your permission to your physicians, pharmacies, laboratories, and other healthcare providers ("Healthcare Professionals") and your health insurers to share your health information with Incyte, its agents, and the IncyteCARES for OPZELURA program (collectively, "Incyte"). You understand that your health information includes information relating to your medical condition, treatment, and insurance coverage, as well as identifying information about you (including, for example, your name, address, and date of birth). Your health information will be shared with Incyte so that Incyte may provide you with various support and information to help you access OPZELURA, which may include the following (collectively, "Patient Support Programs"):

- Providing benefits investigations/verification and reimbursement support, including assisting with identification of your insurer's prior authorization requirements and requirements for appealing a denied claim
- Determining your eligibility for and helping you access copay support for OPZELURA
- Communicating with your Healthcare Professionals about OPZELURA and Patient Support Programs
- Providing you with financial assistance resources and information if you are eligible

You agree to be contacted by Incyte regarding the Patient Support Programs using phone, email, text, or an autodialer or prerecorded voice using the information provided to enable fulfillment of the Patient Support Programs described above.

You understand that you do not have to sign this form and choosing not to sign will not affect your ability to receive treatment from your Healthcare Professionals or payment from your health insurer.

However, if you do not sign this form, IncyteCARES for OPZELURA will not be able to provide you with assistance.

You understand that once your health information is shared, it may no longer be protected by federal privacy law. However, Incyte agrees to protect your health information and to use it only for the purposes described in this form or as required or permitted by law.

You understand that this form will remain in effect for 1 year from the date of your signature unless you provide written notice that you would like to withdraw your authorization to share your health information sooner.

If you would like to withdraw your authorization, you may contact IncyteCARES for OPZELURA at 1-800-932-1720 or 6000 Park Lane, Pittsburgh, PA 15275. You understand that if you withdraw your authorization, no new information will be collected from you; however, information collected prior to your withdrawal of authorization may continue to be used or kept to provide services previously described. You understand you may receive a copy of this form.

Incyte also may use your health information for quality assurance purposes and to evaluate and improve its operations and services. You also understand that the information you provide may be combined with that of other registrants to create aggregated, anonymized data and to use and share only the anonymized data for any legitimate business purpose.

You can learn more about how Incyte processes your personal information at www.incyte.com/privacy-policy.

PATIENT SIGNATURE X _____ _____

(If the patient is under 18 years of age, a legal representative should sign and print name) Date

Legal Representative Name (Print) _____

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Patient First Name _____ MI ____ Patient Last Name _____ Date of Birth _____

PATIENT ASSISTANCE PROGRAM APPLICANTS ONLY—Patients who are uninsured or underinsured with Medicare Part D coverage may be eligible to receive OPZELURA at no cost

Financial Information

Current Annual Household Income _____ Number of People in Household _____

Authorization for Electronic Income Verification

I, the applicant named above, understand that I am providing "written instructions" to IncyteCARES for OPZELURA under the Fair Credit Reporting Act authorizing IncyteCARES for OPZELURA or their designated agent to obtain information from my credit profile or other information from Experian® Income View℠ to verify my annual income (learn more at: https://www.experian.com/consumer-information/income-view). I authorize IncyteCARES for OPZELURA to obtain such information solely for the purpose of determining financial qualifications for the IncyteCARES for OPZELURA Patient Assistance Program. I also agree to provide additional financial documentation in a timely manner to IncyteCARES for OPZELURA which is solely necessary for determining my financial qualification for the program, if so requested. I understand that I am entitled to a copy of this authorization upon request. This authorization shall be valid for one (1) year from the date of the signature on this form (unless a shorter period is prescribed by law). I understand that I may cancel this authorization at any time by mailing a letter requesting such cancellation to IncyteCARES for OPZELURA at 6000 Park Lane, Pittsburgh, PA 15275. I understand that if I cancel my authorization, no new information will be collected from me; however, information collected prior to such cancellation may continue to be used or kept to fulfill the services described.

Providing your SSN allows IncyteCARES to confirm your income. You will not need to submit additional income or financial documentation.

Social Security Number _____

PATIENT SIGNATURE X _____ _____

(If the patient is under 18 years of age, a legal representative should sign and print name) Date

Legal Representative Name (Print) _____

Please note: If you do not provide an authorization signature, you are required to submit income verification via fax to 1-877-801-3840, or mail to IncyteCARES for OPZELURA at 6000 Park Lane, Pittsburgh, PA 15275.

Financial Attestation and Disclosure

By signing below, I certify that I cannot afford my medication, and I affirm that my answers are complete, true, and accurate to the best of my knowledge.

I understand that: Completing this form does not guarantee that I will qualify for the Patient Assistance Program. IncyteCARES may verify the accuracy of the information I have provided and may ask for more financial and insurance information. OPZELURA supplied by the IncyteCARES for OPZELURA Patient Assistance Program shall not be sold, traded, bartered, or transferred. IncyteCARES for OPZELURA reserves the right to change its Patient Assistance Program or terminate my enrollment at any time. The support provided through this program is not contingent on any future purchase. If I am enrolled in a Medicare Part D Plan and am eligible for the Patient Assistance Program, IncyteCARES for OPZELURA will notify my Part D Plan of my enrollment in the program.

I certify and attest that if I receive OPZELURA provided through the IncyteCARES for OPZELURA Patient Assistance Program, I will promptly contact IncyteCARES for OPZELURA at 1-800-932-1720 if my financial status or insurance coverage changes. I will not seek to have OPZELURA or any cost from it counted in my Medicare Part D true out-of-pocket costs for prescription drugs. I will not seek reimbursement or credit for OPZELURA from my prescription insurance provider or payor, including Medicare Part D plans. I will notify my insurance provider of the receipt of OPZELURA through the IncyteCARES for OPZELURA Patient Assistance Program.

For more information about Incyte and its privacy practices, please go to www.incyte.com/privacy-policy.

PATIENT SIGNATURE X _____ _____

(If the patient is under 18 years of age, a legal representative should sign and print name) Date

Legal Representative Name (Print) _____

PATIENT OPT-IN FOR ONGOING EDUCATION AND SUPPORT (OPTIONAL)

☐ By checking this box, I consent to Incyte and its agents to use my contact information (phone and email) to provide education and ongoing support services related to product, disease, and other related areas of interest. I understand that I may revoke my consent to be contacted for any of these purposes at any time by emailing privacy@incyte.com.

☐ By checking this box, I am indicating that I would also like to be contacted for future opportunities to participate in market research regarding my condition. I understand that I may revoke my consent to be contacted to participate in such market research at any time by emailing privacy@incyte.com.

X _____ _____

Patient Signature (If the patient is under 18 years of age, a legal representative should sign and print name) Date

Legal Representative Name (Print) _____

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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.