SAMPLE LETTER OF MEDICAL NECESSITY – NONSEGMENTAL VITILIGO

Some payers may require that the prescriber document a patient’s medical necessity for treatment to get insurance coverage for a pharmaceutical product. The following letter is only intended as a SAMPLE Letter of Medical Necessity that outlines the information a payer may request. Health plan requirements vary, so the prescriber should refer to the information specific to their patient’s health plan before completing a Letter of Medical Necessity.

The prescriber is responsible for the content of this letter and may customize it as needed. Note that the bracketed information in magenta must be customized with the appropriate information.

The prescriber should refer to the Full Prescribing Information when determining whether the product is medically appropriate for a patient.

**Please see** [**Full Prescribing Information**](https://www.opzelura.com/prescribing-information.pdf)**, including Boxed Warning, and** [**Medication Guide**](https://www.opzelura.com/medication-guide.pdf) **for OPZELURA.**

**SAMPLE Letter of Medical Necessity – NONSEGMENTAL VITILIGO**

<<Date>>

<<Attention: Payer Contact Name/Payer Department>>

<<Insert Name of Health Insurance Company>>

<<Insert Health Plan’s Address for Appeal Submissions>>

<<City, State, ZIP Code>>

RE: Coverage Requested for OPZELURA® (ruxolitinib) cream 1.5%

**Patient:** <<Patient Name>>

**Date of Birth:** <<Date>>

**Diagnosis:** Nonsegmental Vitiligo, L80 **Group/Policy Number:** <<Number>> **Policyholder:** <<Policyholder Name>>

**Case or Request ID:** <<If applicable include case/request ID/reference # listed on PA denial letter>>

To Whom It May Concern:

On behalf of my patient, I am writing to request coverage for OPZELURA to treat their nonsegmental vitiligo.

**Patient Background**

My patient is <<age>> years old and has been in my care since <<month year>>.

<<Include information such as patient’s current symptoms and condition, treatment goals for this patient, and/or impact on quality of life, social/emotional, and/or career, and daily living

problems.>>

**Clinical Rationale**

<<Include your clinical rationale and reasons for prescribing the product, highlighting factors

leading you to recommend the use of this product, such as achieving relief or symptom control or how OPZELURA allows for a targeted approach to treating the disease. Additionally, confirm that OPZELURA is being used for an FDA-approved indication.>>

The Food and Drug Administration (FDA) granted OPZELURA a Priority Review designation for nonsegmental vitiligo, indicating that the FDA considers vitiligo a “serious condition” and

treatment medically necessary.1,2 OPZELURA is currently the **only** FDA-approved treatment to repigment nonsegmental vitiligo3 and should be considered the standard of care. Vitiligo is not a cosmetic condition,4,5 and consensus is growing in the United States to address vitiligo as a medical condition and expand coverage for treatment.6-8 Thus, OPZELURA should not be

treated any differently.

Vitiligo is a complex and chronic autoimmune condition caused by destruction of melanocytes beneath the surface of the skin, resulting in depigmentation.4,9,10 Patients seeking vitiligo

treatment aim to restore pigmentation.11,12

Vitiligo treatment can reduce inflammation to allow melanocytes to slowly regenerate and migrate from hair follicles to produce pigment over time.13

OPZELURA is a topical JAK inhibitor that regulates IFN-γ mediated JAK-STAT signaling, which is thought to reduce CD8+ T-cell–mediated destruction of melanocytes, a key driver of

depigmentation.3,14-17 This may create a more stable environment, enabling the return of melanocytes.18 The relevance of inhibition of specific JAK enzymes to therapeutic effectiveness is not currently known.3

**Summary of Patient’s Medical and Treatment History**

<<Include the list of prescription medications the patient has tried and failed that are related to their diagnosis and/or a justification of why these drugs are inadvisable due to ineffectiveness, contraindications, and/or intolerance, and/or use in a sensitive area. Note that common step-

through drugs include topical corticosteroids, such as clobetasone or triamcinolone, or a topical calcineurin inhibitor, such as tacrolimus or pimecrolimus, and/or phototherapies or bleaching agents.>>

Previous Therapies: Reasons for Discontinuation: Duration of Therapy:

**Conclusion**

Given the patient’s current condition, OPZELURA is medically necessary and reasonable to

treat this patient. **I request that someone with expertise in dermatology review the details of this case and the supporting documentation provided.**

I urge you to please consider coverage of OPZELURA on <<Patient Name’s>> behalf. Please refer to the enclosed supporting documents for further details, and do not hesitate to call me at

<<1-XXX-XXX-XXXX>> if you have any questions or if you require additional information.

# INDICATION

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 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 Registry**

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 or visiting [www.opzelura.pregnancy.incyte.com](http://www.opzelura.pregnancy.incyte.com/).

**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).

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Thank you for your attention to this matter. Sincerely,

<<Prescribing Physician Name and Credentials>>

<<NPI Number>>

<<1-XXX-XXX-XXXX>>

Enclosures: <<List any Enclosures, such as: Prescribing Information, Medication Guide, and Clinical Notes and Records>>

CD8+, cytotoxic T lymphocytes; IFN-γ, interferon gamma; JAK, Janus kinase; JAK-STAT, Janus kinase signal transducer and activator of transcription.

**References: 1.** US Food and Drug Administration. FDA approves topical treatment addressing repigmentation in vitiligo in patients aged 12 and older. Accessed January 13, 2025. https://[www.fda.gov/drugs/news-events-human-](http://www.fda.gov/drugs/news-events-human-) drugs/fda-approves-topical-treatment-addressing-repigmentation-vitiligo-patients-aged-12-and-older **2.** US Food and Drug Administration. Priority Review. Accessed January 13, 2025. https://[www.fda.gov/patients/fast-track-](http://www.fda.gov/patients/fast-track-) breakthrough-therapy-accelerated-approval-priority-review/priority-review **3.** OPZELURA Prescribing Information.

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