**TEMPLATE LETTER OF APPEAL FOR NONSEGMENTAL VITILIGO**

When a prior authorization is denied, it can be appealed following the health plan’s process for appeals. **Please refer to the prior authorization denial letter to obtain the denial reason and information on the plan’s appeal submission process.**The denial reason should be directly addressed in the appeals letter.

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

The following template letter is only intended as a SAMPLE Letter of Appeal for nonsegmental vitiligo and outlines the information a payer may need when
reviewing an appeal.

The prescriber is responsible for customizing all bracketed information in magenta with the appropriate information.

**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.**

**TEMPLATE LETTER OF APPEAL FOR NONSEGMENTAL VITILIGO**

<<Physician’s Letterhead>>

<<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: Request for Appeal for OPZELURA® (ruxolitinib) cream 1.5%

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

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

**Diagnosis**: Nonsegmental vitiligo <<ICD-10-CM>>

**Group/Policy Number**: <<Number>>

**Policyholder**: <<Policyholder Name>>

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

To Whom It May Concern:

On behalf of my patient, this letter is to appeal the denial of coverage for OPZELURA for the treatment of nonsegmental vitiligo. The denial reason stated was <<insert coverage denial reason>>.

<<Patient Name>> is <<Age>> years old and has been diagnosed with nonsegmental vitiligo, <<ICD-10 code>>. After reviewing the denial letter, I maintain that OPZELURA is the appropriate therapy for my patient. <<Patient Name>> has been in my care since <<month, year>>. Listed below is a summary of the patient’s medical history and relevant clinical information that supports the use of OPZELURA for this patient.

<<Include your clinical rationale and reasons for prescribing the product, highlighting factors leading you to recommend use of this product, and be sure to address the prior authorization (PA) denial reason. You may want to confirm that other causes of depigmentation have been ruled out.>>

<<If applicable, provide information confirming the patient has met the plan’s step through requirements and/or why the patient is unable to take these drugs due to ineffectiveness, contraindications, and/or intolerance. Examples of step through drugs include topical corticosteroids (TCS) such as clobetasone or triamcinolone, or a topical calcineurin inhibitor (TCI) such as tacrolimus or pimecrolimus, and/or phototherapy. Note: many plans do not require use of a TCS if the drug is to be used in sensitive areas>>.

My patient has tried and failed other therapies for nonsegmental vitiligo, including:

Previous Therapies: Reasons for Discontinuation: Duration of Therapy:

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<<Physician’s Letterhead>>

<<If applicable, address body surface area: My patient has vitiligo located on <<insert location on the body>> with a total body surface area of <<enter % of patient’s body surface area. Note that plans typically require a total body surface area of less than or equal to 10%>>.

<<Addressing cosmetic use in your appeal: Vitiligo is an autoimmune disease and not a cosmetic disease. Include a supporting article in the appeal letter such as [https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-topical-treatment-addressing-repigmentation-vitiligo-patients-aged-12-and-older>](https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-topical-treatment-addressing-repigmentation-vitiligo-patients-aged-12-and-older)>.1

Please contact me at <<XXX-XXX-XXXX>> for any additional information you may require regarding this appeal. I look forward to your timely approval.

Thank you for your attention to this matter.

Sincerely,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

<<Prescribing Physician Name and Credentials>>

<<Name of Practice>>

<<NPI Number>>

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

**References:**

1. U.S. Food and Drug Administration. FDA approves topical treatment addressing repigmentation in vitiligo in patients aged 12 and older. FDA.gov. Updated July 19, 2022. Accessed [June 19, 2023]. <https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-topical-treatment-addressing-repigmentation-vitiligo-patients-aged-12-and-older>.

**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**

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).

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