Letter of Appeal Guide

olumiant®
(baricitinib) tablets
4 mg, 2 mg, 1 mg

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact the patient's health plan for specific information on their coverage policies. For more information, please call Olumiant Together™ at 1-844-OLUMIANT (1-844-658-6426).

Composing a Letter of Appeal Guide

If coverage is denied by the patient's health plan, the plan may require an **Appeal Letter**. The sample letter attached to this document features information that many plans require to process a coverage authorization appeal. Many health plans require that a Letter of Medical Necessity (LMN) accompany submissions of Appeal, therefore consider including an LMN upfront with appeal submission. Please see the LMN Guide for more details. Follow the patient's plan requirements when requesting **Olumiant® (baricitinib)**; otherwise, treatment initiation may be delayed. **An Appeal Letter originates from the patient and the prescribing HCP. It should be submitted with the following 2 additional items: the patient's medical records and a Letter of Medical Necessity (LMN).**

Appeal considerations to support coverage

General Clinical Information

Below are 3 tips that may be helpful when appealing a coverage denial:

1. Provide a copy of the patient's record with details on the patient's condition (diagnosis/diagnoses), International Classification of Diseases, Tenth Revision (ICD-10) code, and assessment of severity of disease for which Olumiant is being/will be used, including:
   - Severity of Alopecia Tool (SALT) score
   - alternative disease severity classification tool(s)
   - recent history of infection(s), along with any allergies and existing comorbidities
2. Provide information about the current treatment(s) being used for the patient's condition and how the patient is presenting clinically while taking the current treatment(s)
3. Document the previous therapies used, dates used, and reasons for discontinuation (if applicable)

Appeal-specific rationale

The following tips may help construct an appropriate appeal:

- Provide clinically relevant and patient-specific information that supports overturning denial
- If denial was due to the plan's preferred formulary agents not being used to treat this patient, provide the clinical rationale for why these agents are not appropriate for the patient
- Provide clinically relevant and patient-specific information that makes Olumiant an appropriate therapy for this patient

Clinical rationale should focus only on the stated denial reason.

Consider including disease severity classification tool in chart notes or attachments to support Appeal Letter (i.e., Alopecia Areata Scale)

Olumiant Together™ will work with you to help navigate patient access

For more information, please visit https://olumiant.lilly.com/hcp/support-resources or call Olumiant Together™ at 1-844-OLUMIANT (1-844-658-6426).

INDICATION

Olumiant is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with severe alopecia areata.

Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

SELECT IMPORTANT SAFETY INFORMATION: WARNING RELATED TO SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

SERIOUS INFECTIONS: **Olumiant-treated patients are at increased risk of serious bacterial, fungal, viral and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment with Olumiant if a serious infection occurs until the infection is controlled. Olumiant should not be given to patients with active tuberculosis. Test for latent TB before and during therapy, except for COVID-19; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test.**

MORTALITY: **Higher rate of all-cause mortality, including sudden cardiovascular death was observed with another Janus kinase (JAK) inhibitor vs. tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients.**

MALIGNANCIES: **Malignancies have also occurred in patients treated with Olumiant. Higher rate of lymphomas and lung cancers was observed with another JAK inhibitor vs. TNF blockers in RA patients.**

MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE): **Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) was observed with another JAK inhibitor vs. TNF blockers in RA patients.**

THROMBOSIS: **Thrombosis has occurred in patients treated with Olumiant. Increased incidence of pulmonary embolism, venous and arterial thrombosis was observed with another JAK inhibitor vs. TNF blockers.**

Please see Important Safety Information, including Boxed Warning about Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis on Pages 3-4. Please click to access Prescribing Information and Medication Guide.

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Letter of Appeal Guide

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This template can be used by HCPs when appealing a coverage denial.

Sample Letter of Appeal for Olumiant with instructions

<Physician's letterhead>
<Date>
<Health plan's name>
ATTN: <Department>
<Medical director's name>
<Health plan's address>
<City, State ZIP>

<Patient's name>
<Date of birth>
<Case ID number>
<Dates of service>

Re: Appeal of Denial for Olumiant® (baricitinib)

To Whom It May Concern:

I am writing to appeal your denial of coverage for Olumiant, which I have prescribed for <patient's name>. I understand you are denying coverage for <patient's name> because:

- <reason for the denial>
- <further reason(s) for the denial, if applicable>

However, I believe the treatment with Olumiant is reasonable, appropriate, and medically necessary for my patient based on my clinical experience, the patient's condition, and their medical history.

Clinical Information to Support Appeal

<Patient's name> has been diagnosed with <condition> since <date of diagnosis>.

Treatment History

<Current and past treatment(s), including topicals, orals, and injectables>
<Start/stop dates>
<Reason(s) for discontinuation (if applicable)>

Clinical Rationale

<Restate the denial reason, your clinical rationale for why the denial should be overturned, and why **Olumiant** is appropriate and medically necessary for this patient.>

If you have any additional questions, please contact me at <physician's phone number> or via email at <physician's email>. Thank you for your time and consideration.

Sincerely,
<Physician's signature and specialty, if applicable>

Enclosed: <Medical records, denial letter, copies of original request, clinical notes, medication history, and other supporting information>

Include the patient's full name, date of birth, plan ID number, and case ID number (if applicable).

Review the denial letter to identify the reason for denial. Restate the reason for denial as close to verbatim as possible.

Provide a copy of the patient's medical records, circling key clinical information, including patient history (including prior treatments), ICD-10 code, present-day condition and symptoms (i.e., SALT score, alternative disease severity classification tool(s)), as well as any allergies and existing comorbidities.

Identify drug name, strength, dosage form, and therapeutic outcome.

Excess information beyond the denial reason may influence the plan to deny coverage again.

Attach any clinical documentation that supports overturning the decision to deny the request for coverage.

View an example on page 5 for use on your office letterhead.

Indication and Important Safety Information

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(baricitinib) tablets
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INDICATION

Olumiant is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with severe alopecia areata.

Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

IMPORTANT SAFETY INFORMATION FOR OLUMIANT (baricitinib) tablets

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

SERIOUS INFECTIONS - Patients treated with Olumiant are at risk for developing serious infections that may lead to hospitalization or death. Most patients with rheumatoid arthritis (RA) who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. If a serious infection develops, interrupt Olumiant until the infection is controlled. Reported infections include:

- **Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease. Olumiant should not be given to patients with active tuberculosis. Test patients, except those with COVID-19, for latent TB before initiating Olumiant and during therapy. If positive, start treatment for latent infection prior to Olumiant use.**
- **Invasive fungal infections, including candidiasis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, and other infections due to opportunistic pathogens.**

Carefully consider the risks and benefits of Olumiant prior to initiating therapy in patients with chronic or recurrent infection.

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with Olumiant including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

The most common serious infections reported with Olumiant included pneumonia, herpes zoster, and urinary tract infection. Among opportunistic infections, tuberculosis, multidermatomal herpes zoster, esophageal candidiasis, pneumocystosis, acute histoplasmosis, cryptococcosis, cytomegalovirus, and BK virus were reported with Olumiant. Some patients have presented with disseminated rather than localized disease, and were often taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Avoid use of Olumiant in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment prior to initiating Olumiant in patients: with chronic or recurrent infection; who have been exposed to TB; with a history of a serious or an opportunistic infection; who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or with underlying conditions that may predispose them to infection.

Consider anti-TB therapy prior to initiation of Olumiant in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but who have risk factors for TB infection.

Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies with Olumiant. If a patient develops herpes zoster, interrupt Olumiant treatment until the episode resolves. The impact of Olumiant on chronic viral hepatitis reactivation is unknown. Screen for viral hepatitis in accordance with clinical guidelines before initiating Olumiant.

MORTALITY

In a large, randomized, postmarketing safety study in RA patients 50 years of age and older with at least one cardiovascular risk factor comparing another Janus kinase (JAK) inhibitor to tumor necrosis factor (TNF) blockers, 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 Olumiant.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with Olumiant. In RA patients treated with another 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. A higher rate of lymphomas was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lung cancers and an additional increased risk of overall malignancies were observed in current or past smokers treated with the JAK inhibitor compared to those treated with TNF blockers.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients with a known malignancy (other than successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

NMSCs have been reported in patients treated with Olumiant. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction [MI], and stroke) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue Olumiant in patients that have experienced a myocardial infarction or stroke.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Inform patients about the symptoms of serious cardiovascular events and the steps to take if they occur.

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IMPORTANT SAFETY INFORMATION FOR OLUMIANT (baricitinib) tablets (Cont'd)

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THROMBOSIS

Thrombosis, including deep venous thrombosis (DVT) and pulmonary embolism (PE), has been observed at an increased incidence in patients treated with Olumiant compared to placebo. In addition, there were cases of arterial thrombosis. Many of these adverse events 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 another JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid Olumiant in patients at risk. Discontinue Olumiant and promptly evaluate patients with symptoms of thrombosis.

HYPERSENSITIVITY

Reactions such as angioedema, urticaria, and rash that may reflect drug hypersensitivity have been observed in patients receiving Olumiant, including serious reactions. If a serious hypersensitivity reaction occurs, promptly discontinue Olumiant while evaluating the potential causes of the reaction.

GASTROINTESTINAL PERFORATIONS

Gastrointestinal perforations have been reported in Olumiant clinical studies. Monitor Olumiant-treated patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis). Promptly evaluate patients who present with new onset abdominal symptoms for early identification of gastrointestinal perforation.

LABORATORY ABNORMALITIES

Neutropenia – Olumiant treatment was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] <1000 cells/mm^3) compared to placebo. Evaluate at baseline and thereafter according to routine patient management. In patients with RA or alopecia areata (AA), avoid initiation or interrupt Olumiant treatment in patients with an ANC <1000 cells/mm^3.

Lymphopenia – Absolute lymphocyte count (ALC) <500 cells/mm^3 were reported in Olumiant clinical trials. Lymphocyte counts less than the lower limit of normal were associated with infection in patients treated with Olumiant, but not placebo. Evaluate at baseline and thereafter according to routine patient management. In patients with RA or AA, avoid initiation or interrupt Olumiant treatment in patients with an ALC <500 cells/mm^3.

Anemia – Decreases in hemoglobin levels to <8 g/dL were reported in Olumiant clinical trials. Evaluate at baseline and thereafter according to routine patient management. In patients with RA or AA, avoid initiation or interrupt Olumiant treatment in patients with hemoglobin <8 g/dL.

Liver Enzyme Elevations – Olumiant treatment was associated with increased incidence of liver enzyme elevation compared to placebo. Increases of alanine transaminase (ALT) ≥5x upper limit of normal (ULN) and increases of aspartate transaminase (AST) ≥10x ULN were observed in patients in Olumiant clinical trials. Evaluate at baseline and thereafter according to routine patient management. Promptly investigate the cause of liver enzyme elevation to identify potential cases of drug-induced liver injury. If increases in ALT or AST are observed and drug-induced liver injury is suspected, interrupt Olumiant until this diagnosis is excluded.

Lipid Elevations – Treatment with Olumiant was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol. Assess lipid parameters approximately 12 weeks following Olumiant initiation in patients with RA or AA. Manage patients according to clinical guidelines for the management of hyperlipidemia.

VACCINATIONS

Avoid use of live vaccines with Olumiant. Update immunizations in patients with RA or AA prior to initiating Olumiant therapy in agreement with current immunization guidelines.

ADVERSE REACTIONS

In RA trials, the most common adverse reactions (≥1%) reported with Olumiant were: upper respiratory tract infections, nausea, herpes simplex, and herpes zoster.

In AA trials, the most common adverse reactions (≥1%) reported with Olumiant were: upper respiratory tract infections, headache, acne, hyperlipidemia, creatine phosphokinase increase, urinary tract infection, liver enzyme elevations, folliculitis, fatigue, lower respiratory tract infections, nausea, genital Candida infections, anemia, neutropenia, abdominal pain, herpes zoster, and weight increase.

PREGNANCY AND LACTATION

Based on animal studies, Olumiant may cause fetal harm when administered during pregnancy. Advise pregnant women and women of reproductive potential of the potential risk to a fetus. Consider pregnancy planning and prevention for women of reproductive potential. Advise women not to breastfeed during treatment with Olumiant and for 4 days after the last dose.

HEPATIC AND RENAL IMPAIRMENT

Olumiant is not recommended in patients with RA or AA and severe hepatic impairment or severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min/1.73m^2).

BA HCP ISI RA-AA 14SEP2022

Please click to access full Prescribing Information, including Boxed Warning about Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis, and Medication Guide.

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Sample Letter of Appeal for Olumiant® (baricitinib)

<Physician's letterhead>
<Date>
<Health plan's name>
ATTN: <Department>
<Medical director's name>
<Health plan's address>
<City, State ZIP>

<Patient's name>
<Date of birth>
<Case ID number>
<Dates of service>

Re: Appeal of Denial for Olumiant® (baricitinib)

To Whom It May Concern:

I am writing to appeal your denial of coverage for Olumiant, which I have prescribed for <patient's name>. I understand you are denying coverage for <patient's name> because

- <reason for the denial>
- <further reason(s) for the denial, if applicable>

However, I believe the treatment with Olumiant is reasonable, appropriate, and medically necessary for my patient based on my clinical experience, the patient's condition, and their medical history.

Clinical Information to Support Appeal

<Patient's name> has been diagnosed with <condition> since <date of diagnosis>.

Treatment History

<Current and past treatment(s), including topicals, orals, and injectables>

<Start/stop dates>

<Reason(s) for discontinuing, if applicable>

Clinical Rationale

<Restate the denial reason, your clinical rationale for why the denial should be overturned, and why Olumiant is appropriate and medically necessary for this patient.>

If you have any additional questions, please contact me at <physician's phone number> or via email at <physician's email>. Thank you for your time and consideration.

Sincerely,

<Physician's signature and specialty, if applicable>

Enclosed: <Medical records, denial letter, copies of original request, clinical notes, medication records, and other supporting information (i.e., disease severity scoring tool(s))>