Letter of Medical Necessity Guide

olumiant®
(baricitinib) tablets
4 mg, 2 mg, 1 mg
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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 Lilly Support Services™ for Olumiant® at 1-800-LillyRx (1-800-545-5979).

Composing a Letter of Medical Necessity Guide

The purpose of a **Letter of Medical Necessity (LMN)** is to explain the prescribing healthcare provider's (HCP's) rationale and clinical decision-making for choosing a treatment.* Many health plans require that an LMN accompany submissions of Appeal, Formulary Exception Request, and Tiering Exception Request Letters.

This resource, **Letter of Medical Necessity Guide**, provides information on the process of drafting an LMN. The sample letter attached to this document features information that plans often require. Note that some plans have specific forms that must be utilized to document an LMN. Follow the patient's plan requirements when requesting **Olumiant® (baricitinib)** otherwise, treatment initiation may be delayed.

If interested in using alternative appeals resources, see available LMN examples from the National Alopecia Areata Foundation (NAAF).

Common clinical evidence required for Letters of Medical Necessity includes:

- 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
- 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)
- Previous therapies used, dates used, and reasons for discontinuation (if applicable)
- Clinical rationale for why other treatments are not appropriate, if applicable
- Clinically relevant and patient-specific information that makes Olumiant an appropriate therapy for the patient

Lilly Support Services™ will work with you to help navigate patient access

For more information, please visit https://olumiant.lilly.com/hcp/support-resources or call Lilly Support Services™ at 1-800-LillyRx (1-800-545-5979).

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 4-5. Please click to access Prescribing Information and Medication Guide.

*For Medicare beneficiaries, specific requirements need to be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please **click here**.

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This template can be used by HCPs for explaining medical necessity.

Sample Letter of Medical Necessity 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: Letter of Medical Necessity for Olumiant® (baricitinib)

To Whom it May Concern:

I am writing to request coverage for Olumiant, a medically necessary treatment that I have prescribed for <patient's name>. This letter includes information about my patient's medical history along with my rationale for prescribing Olumiant.

Medical History

<Please include overview of disease course for the patient, including date of diagnosis and assessment of severity of disease. If there have been any changes in this disease activity or patient assessment of condition, include that information as well.>

Treatment History

<Current therapies (including topicals, orals, injectables), start dates>

<History of previous therapies (including topicals, orals, injectables) and start/stop dates>

<Documentation of inadequate response and/or intolerable adverse events or reason for discontinuation (if applicable)>

Clinical Rationale

<Clinical rationale for why your patient's recent severity of symptoms and impact of the disease warrant treatment with Olumiant>

<For plans that have formulary exclusions or step therapy, include information on why other agents are not an appropriate option, including comorbidities and contraindications.>

<Renewal Requests-Response>

I am requesting renewal of coverage for my patient, who has been taking Olumiant since <date> and has shown clinical improvement. <Provide information on clinical response.> I have included documentation of positive clinical response.

[next page]

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

Provide information that is applicable to the primary diagnosis/diagnoses.

Provide a copy of the patient's medical records that include the following information: patient's 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.

Document current and prior treatments, treatment response, dates of therapy, and rationale for discontinuing (if applicable).

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Click here to access an exportable Microsoft Word document for use on your office letterhead.

Letter of Medical Necessity Guide

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This template can be used by HCPs for explaining medical necessity.

Sample Letter of Medical Necessity for Olumiant with instructions

<Physician's letterhead>

<Placeholder for tiering exception (Medicare)>

<Explain why lower-tiered formulary drugs would not be as medically appropriate as Olumiant. If the patient is currently being treated with Olumiant, explain the benefits that the patient has experienced since starting Olumiant and the expected outcomes if Olumiant was to be discontinued.>

Based on my professional experience, treatment with Olumiant is appropriate, medically necessary, and supported by their individual medical history. Attached are medical records to support my rationale.

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, clinical notes, medication history, severity assessments, documentation of positive clinical response, and other supporting information>

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

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Click here to access an exportable Microsoft Word document for use on your office letterhead.

Indication and Important Safety Information

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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 Medical Necessity 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: Letter of Medical Necessity for Olumiant® (baricitinib)

To Whom It May Concern:

I am writing to request coverage for Olumiant, a medically necessary treatment that I have prescribed for <patient's name>. This letter includes information about my patient's medical history along with my rationale for prescribing Olumiant.

Medical History

<Please include overview of disease course for the patient, including date of diagnosis and assessment of severity of disease. If there have been any changes in this disease activity or patient assessment of condition, include that information as well.>

Treatment History

<Current therapies (including topicals, orals, injectables), start dates>
<History of previous therapies (including topicals, orals, injectables) and start/stop dates>
<Documentation of inadequate response and/or intolerable adverse events or reason for discontinuation (if applicable)>

Clinical Rationale

<Clinical rationale for why your patient's recent severity of symptoms and impact of the disease warrant treatment with Olumiant>

<For plans that have formulary exclusions or step therapy, include information on why other agents are not an appropriate option, including comorbidities and contraindications.>

<Renewal Requests-Response>

I am requesting renewal of coverage for my patient, who has been taking Olumiant since <date> and has shown clinical improvement. <Provide information clinical response.> I have included documentation of positive clinical response.

<Physician's letterhead>
<Placeholder for tiering exception (Medicare)>
<Explain why lower-tiered formulary drugs would not be as medically appropriate as Olumiant. If the patient is currently being treated with Olumiant, explain the benefits that the patient has experienced since starting Olumiant and the expected outcomes if Olumiant was to be discontinued.>

Please note, the patient will not be taking Olumiant in combination with another biologic therapy or JAK (Janus kinase) inhibitor.

Based on my professional experience, treatment with Olumiant is appropriate, medically necessary, and supported by their individual medical history. Attached are medical records to support my rationale.

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, clinical notes, medication history, severity assessments, documentation of positive clinical response, and other supporting information>