olumiant together™
(baricitinib) tablets

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

Coverage Authorization Requests and Appeals Guide

PREPARING AN APPEAL LETTER

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 third-party payers for specific information on their coverage policies. For more information, please call Olumiant Together™ at 1-844-OLUMIANT (1-844-658-6426).

INDICATION FOR ALOPECIA AREATA

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.

INDICATION FOR RHEUMATOID ARTHRITIS

Olumiant is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers.

Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants, such as azathioprine and cyclosporine.

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.**

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APPEAL LETTER: GUIDANCE, RECOMMENDATIONS, AND CONSIDERATIONS

If the Coverage Authorization Request Letter from **Drafting a Coverage Authorization Request Letter** is denied by the patient's health plan, or **Olumiant® (baricitinib) tablets** are subject to a National Drug Code block or not included on a health plan's formulary, the payer may require an Appeal Letter. Depending on the plan, there may be varying levels of appeal. If you are uncertain about a plan's appeal levels or specific procedures, always refer to the plan's appeal guidelines.

This resource, **Preparing an Appeal Letter**, provides information to HCPs when appealing a coverage authorization request for a patient's plan. A checklist is included below that can be followed when creating an Appeal Letter. In addition, a sample letter is attached to this document and features information that many plans require to process a coverage authorization appeal. Follow the patient's plan requirements when requesting Olumiant; otherwise, treatment may be delayed.

An Appeal Letter originates from the patient and the prescribing HCP.[1]* It should be submitted with the following 2 additional items: the patient's medical records and a Letter of Medical Necessity (LMN).

COVERAGE AUTHORIZATION: APPEAL CONSIDERATIONS

- ○ Include the patient's full name, plan identification number, and date of birth
- ○ Add the prescribing HCP's NPI number and specialty
- ○ Disclose that you are familiar with the plan's policy. Clearly document the basis for the plan's denial within the letter, along with the case identification number from the initial denial letter
- ○ Provide a copy of the patient's records with the following details:
  - The patient's history, diagnosis with specific ICD code(s), and present-day condition and symptoms
  - The patient's recent history of infection(s), along with any allergies and existing comorbidities
- ○ Document prior treatments, including plan-preferred formulary agents, and the duration of each
  - If applicable, provide the rationale for why a treatment was discontinued
- ○ Explain why the plan-preferred formulary agents are not appropriate for the patient
  - Provide examples as to why certain agents may not be appropriate for the patients, such as medical conditions, drug interactions, etc.
- ○ Provide the clinical rationale for treatment; this information may be found in the Olumiant Prescribing Information and/or clinical peer-reviewed literature
- ○ Summarize your recommendation at the end of the letter
- ○ Include an LMN

*For Medicare beneficiaries, there are specific requirements that need to be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please visit https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev.

HCP, healthcare provider; ICD, International Classification of Diseases; NPI, National Provider Identifier

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SAMPLE APPEAL LETTER

If the Coverage Authorization Request Letter is denied by the patient's health plan, it is necessary to proceed to **Preparing an Appeal Letter.** Some plans may require an LMN to accompany the Appeal Letter.

HCPs can follow this format for patients who are **NOT** currently receiving treatment with **Olumiant® (baricitinib) tablets**.

<Date>
<Prior authorization department>
<Name of health plan>
<Mailing address>

Re: **<Patient's name>**
<Plan identification number>
<Date of birth>

Sample wording from the last section on page 3 of this document can be placed after this sentence if this appeal has been previously denied by the plan.

To whom it may concern:

We have reviewed and recognize your guidelines for the responsible management of medications within this class. We are requesting that you reassess your recent denial of Olumiant® (baricitinib) coverage. We understand that the reason for your denial is **<copy reason verbatim from the plan's denial letter>**. However, we believe that Olumiant **<1 mg or 2 mg (for RA) / 1 mg, 2 mg, or 4 mg (for AA)>** once daily is the appropriate treatment for the patient. In support of our recommendation for Olumiant treatment, we have provided an overview of the patient's relevant clinical history below.

Patient's diagnosis*:
Patient has been diagnosed with **<moderately to severely active RA or severe alopecia areata>**.

Please provide the following:

Primary ICD-10 diagnosis code _____ Other ICD-10 diagnosis code (if applicable) _____

Please affirm with a check mark.

____ A **<rheumatologist or dermatologist>** has either been consulted or is the prescribing physician for Olumiant.

Patient treatment history and comorbidities:
Treatment history of inadequate response. Include rationale for why payer-preferred agent has not been tried, i.e., contraindications or comorbidities (if applicable).

Please detail all that apply and add additional lines as necessary.

Treatment	Dose	Start/stop dates	Reason(s) for discontinuation

Patient considerations:

Please affirm with a check mark.

____ Patient has been tested for TB and had a negative PPD test, IGRA, or chest x-ray
Date of the TB test __/__/__

Additional patient comorbidities or considerations:
<Please provide reason(s) that your patient would benefit from using this agent.>

<Please provide the clinical rationale for why your patient would benefit from using this agent prior to the payer-preferred agent.>

Supporting references for the recommendation:
<Provide clinical rationale for treatment; this information may be found in the Olumiant Prescribing Information and/or clinical peer-reviewed literature.>

<Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis or disease progression without treatment with Olumiant.>

Please feel free to contact me, **<HCP name>**, at **<office phone number>** or **<patient's name>** at **<phone number>** for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

_____
<Physician's name and signature>
<Physician's medical specialty>
<Physician's NPI>
<Physician's practice name>
<Phone #>
<Fax #>

_____
<Patient's name and signature if required by payer>

Encl: Medical records, supporting documentation, Letter of Medical Necessity, original denial letter

*Include patient's medical records and supporting documentation, including clinical evaluation and scoring forms.

IGRA, interferon gamma release assay; PPD, purified protein derivative; TB, tuberculosis

INFORMATION FOR PATIENTS WHO HAVE BEEN TREATED WITH OLUMIANT

HCPs can use the following language for patients who **HAVE** been treated with Olumiant and have experienced a clinical benefit:

Sample wording from the next section can be placed after this sentence if this appeal has been previously denied by the plan.

To whom it may concern:

We have reviewed and recognize your guidelines for the responsible management of medications within this class. We are requesting that you reassess your recent denial of Olumiant® (baricitinib) coverage. We understand that the reason for your denial is **<copy reason verbatim from the plan's denial letter>**. However, we believe that Olumiant **<1 mg or 2 mg (for RA) / 1 mg, 2 mg, or 4mg (for AA)>** once daily is the appropriate treatment for the patient. In support of our recommendation for Olumiant treatment, we have provided an overview of the patient's relevant clinical history below.

<In this section, highlight the clinical benefit the patient has received since the patient was first prescribed Olumiant. In addition, include a summary of the patient's clinical response to Olumiant and list improvements in symptoms and disease activity since treatment began. It may be necessary to review past medical records to gather this information.>

STEP THERAPY INFORMATION

If this Appeal Letter is intended to appeal a plan's step therapy through plan-preferred (formulary) requirement, sample copy should include the following:

This is our **<add level of request>** coverage authorization appeal. A copy of the most recent denial letter is attached for reference. The patient's medical records are also included in response to the denial.

<Please provide statement(s) indicating why these step therapies through plan-preferred (formulary) requirements are inappropriate for this patient. For RA patients, include examples of previous trials and failures with other therapies, including TNF inhibitors due to an inadequate response or intolerance to the drug.*>

*An external review board or hearing may apply in some situations.

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.

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,

IMPORTANT SAFETY INFORMATION FOR OLUMIANT (baricitinib) tablets (CONT'D)

THROMBOSIS (cont'd)

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).

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

BA HCP ISI RA-AA 13JUN2022

Source: 1. Centers for Medicare & Medicaid Services. Medicare Appeals. In: Medicare Prescription Drug Appeals & Grievances. Baltimore, MD: Centers for Medicare & Medicaid Services; 2022. https://www.medicare.gov/Pubs/pdf/11525-Medicare-Appeals.pdf. Accessed May, 2022.