



PATIENT SUPPORT & PRIOR AUTHORIZATION RESOURCE

Steps to help adult patients start and stay on Olumiant for severe alopecia areata¹

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 pages 7 and 8 for [Important Safety Information](#), including Boxed Warning about Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis, and accompanying full [Prescribing Information](#), including [Medication Guide](#).

Understanding SALT scores in patients with alopecia areata^{2,3}

SALT measures scalp hair loss on a scale of 0 to 100

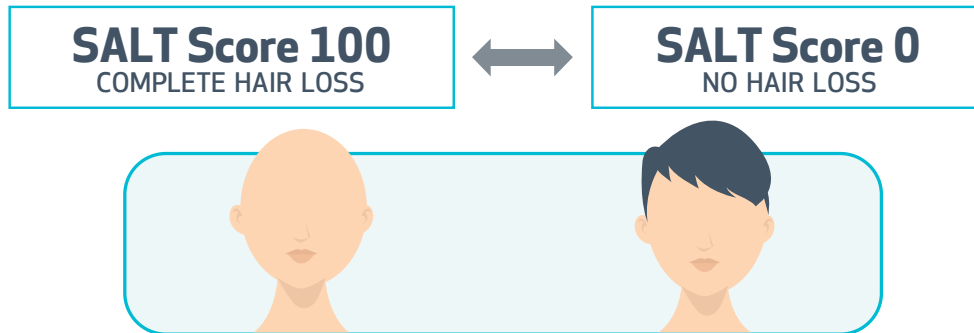


Image is for illustrative purposes only and is not representative of specific patients or efficacy data.

SALT score

Interpretation of SALT scores:

SALT score 100: Complete hair loss

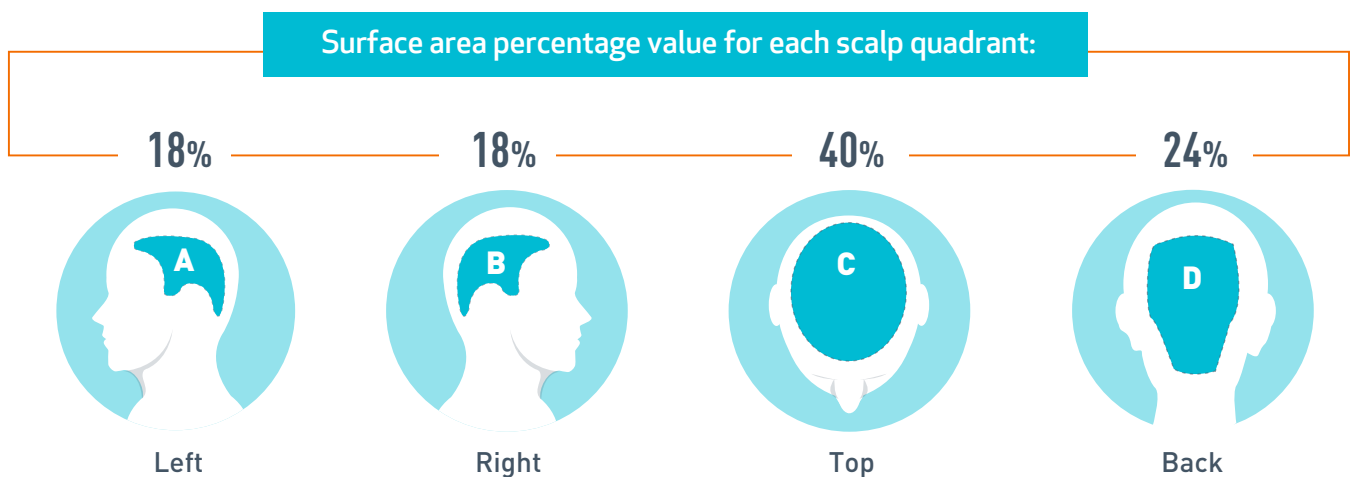
SALT score 50: 50% hair loss

SALT score ≤20: 20% or less hair loss

SALT score 0: No hair loss

Calculating SALT scores

SALT score = percentage of scalp hair loss in the respective quadrant multiplied by percentage of scalp surface area of the respective quadrant. The product of each quadrant is then added together to determine a total score.



SALT=Severity of Alopecia Tool.

For example, if a patient has 20% hair loss on the left quadrant, 25% on the right, 30% on top, and 35% on the back, the SALT score would be: $(18 * 0.20) + (18 * 0.25) + (40 * 0.30) + (24 * 0.35) = 28.5$

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Choose the digital experience that works best for your office:

covermymeds®

&



Lilly Patient Support
Provider Portal

Both options allow your office to digitally enroll patients in Lilly Support Services™ for Olumiant® and utilize services to help with access and coverage

- ✓ New, **easy-to-use digital enrollment** in Lilly Support Services™
- ✓ **ePA** (electronic prior authorization) services
- ✓ **Convenient** options to obtain **patient HIPAA authorization signature**
- ✓ Prior Authorization **status updates**
- ✓ **Insurance eligibility** verification
- ✓ Patient **case management**
- ✓ **Field reimbursement manager support**



ENROLLING IN LILLY SUPPORT SERVICES™ WILL HELP COMMERCIAL PATIENTS GET ACCESS IF THE PRIOR AUTHORIZATION IS DENIED

Click the link below to access Olumiant appeals resources

**Coverage Authorization
Appeals Resource**

**Letter of Medical
Necessity**



IF THE PRIOR AUTHORIZATION IS DENIED, UTILIZE ONE OF THE ENHANCED SPECIALTY PHARMACY PARTNERS FOR A FASTER AND SMOOTHER START EXPERIENCE

Lilly Support Services™ is a support program designed to help patients navigate their treatment experience with Olumiant®.

Lilly Support Services™ provides:

1. Ongoing Support

- A Lilly Support Services™ team member can help:
 - Run a benefits investigation
 - This assistance includes helping with preliminary insurance investigations, identifying in-network specialty pharmacy options, and out-of-pocket costs
 - Coordinate with doctor's offices
 - Assist eligible, commercially insured patients with the Olumiant Savings Card**
- Help is available Monday through Friday from 8 AM to 10 PM ET

\$5

IF PATIENTS HAVE **COMMERCIAL DRUG INSURANCE WITH A PLAN THAT COVERS OLUMIANT**, PATIENTS MAY BE ELIGIBLE TO PAY AS LITTLE AS \$5 FOR A 30-DAY SUPPLY.†

\$25

IF PATIENTS HAVE **COMMERCIAL DRUG INSURANCE WITH A PLAN THAT DOES NOT COVER OLUMIANT**, PATIENTS MAY BE ELIGIBLE TO PAY AS LITTLE AS \$25 FOR A 30-DAY SUPPLY.†

Governmental beneficiaries excluded. Eligibility required, terms and conditions apply. Savings subject to monthly and annual limits. Month is defined as 30-days. Card eligibility and terms and conditions may be terminated, rescinded, revoked, or amended by Lilly at any time without notice and for any reason. **PROGRAM IS NOT INSURANCE.** Review full terms and conditions at <https://www.olumiant.lilly.com/savings-support>.

2. Enhanced Specialty Pharmacy Support

- Partners with insurance companies to get Olumiant® covered for patients
- Contacts patients regarding out-of-pocket cost, shipping times, and further delivery details

3. Field Reimbursement Support

The Field Reimbursement Manager is an experienced access professional who can help navigate the complex access and reimbursement environment to help patients get access to Olumiant.

Field Reimbursement Managers are:

- Knowledgeable
 - Understand Lilly Support Services™, access challenges, support, and affordability options for commercially insured patients
 - Help solve access challenges to Lilly medicines
- Connected
 - Integrated with the Lilly Support Services™ call center and understand the Olumiant Enhanced Specialty Pharmacy Network
- Committed
 - Provide information to support patient access to Olumiant

Helpful Reminders

- ✓ Don't forget to include chart notes in the "Attachments" section of the PA (include chart notes that include documentation for at least 12 months or for as long as the patient has been on Olumiant, if less than 12 months.)
- ✓ Don't forget to include an ICD-10 code directly on your PA (pg. 2)
- ✓ For additional support, your Field Reimbursement Manager is an experienced professional to help educate about the complex access and reimbursement environment.

References: **1.** Olumiant. Prescribing Information. Lilly USA, LLC. **2.** Olsen EA, Hordinsky MK, Price VH, et al. Alopecia areata investigational assessment guidelines—part II. *J Am Acad Dermatol.* 2004;51(3):440-447. **3.** Data on file. Lilly USA, LLC. DOF-BA-US-0065.

Please see pages 7 and 8 for [Important Safety Information](#), including [Boxed Warning about Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis](#), and accompanying full [Prescribing Information](#), including [Medication Guide](#).

IMPORTANT SAFETY INFORMATION



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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.

Please see the following page for additional Important Safety Information, including Boxed Warning about Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis, and accompanying full [Prescribing Information](#), including [Medication Guide](#).

IMPORTANT SAFETY INFORMATION (cont'd)

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

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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/mm³) 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/mm³.

Lymphopenia – Absolute lymphocyte count (ALC) <500 cells/mm³ 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/mm³.

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) ≥ 5 x upper

limit of normal (ULN) and increases of aspartate transaminase (AST) ≥ 10 x 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 ($\geq 1\%$) reported with Olumiant were: upper respiratory tract infections, nausea, herpes simplex, and herpes zoster.

In AA trials, the most common adverse reactions ($\geq 1\%$) 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/1.73m²).

BA HCP ISI RA-AA 14SEP2022

Please see accompanying full [Prescribing Information](#), including [Boxed Warning about Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis](#), and [Medication Guide](#).

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