

## PATIENT SUPPORT & PRIOR AUTHORIZATION RESOURCE

Steps to help adult patients start and stay on Olumiant for severe alopecia areata<sup>1</sup>

### 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](#).

# Help your patients get timely access to their treatment



## Your correctly completed prior authorization (PA) is essential

Many health plans will require a PA before they cover Olumiant. It is important that your PA request be completed accurately to facilitate a determination by your patient's plan and patient access to their medication. This brochure is designed to provide you and your office staff with an easy-to-follow guide to completing PA requests for Olumiant.

## Relevant information to be included in the PA request form for Olumiant

### MEDICAL INFORMATION

- 1. Medication Name:** Olumiant
- 2. Indication:** Treatment of severe alopecia areata for adults
- 3. Strength(s):** Olumiant is available as 1 mg, 2 mg, and 4 mg tablets
- 4. Dosing:** The recommended dosage is 2 mg once daily. Consider increasing the dosage to 4 mg once daily if treatment response is not adequate. For patients with nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss, consider treating with 4 mg once daily. Once patients achieve an adequate response to treatment with 4 mg once daily, decrease the dosage to 2 mg once daily. See full [Prescribing Information](#) for additional information on dosage adjustments
- 5. Continuation of Therapy:** If the patient has already received Olumiant, request continuation of therapy

### CLINICAL INFORMATION

- 1. Diagnosis:** Severe alopecia areata. Include severity of scalp hair loss and eyebrow/eyelash involvement
- 2. ICD-10 Codes:** Physicians should select appropriate disease-specific code(s) based on the individual patient's diagnosis
  - L63.0: Alopecia totalis
  - L63.1: Alopecia universalis
  - L63.2: Ophiasis
  - L63.8: Other Alopecia areata
  - L63.9: Alopecia areata, NOS
- 3. Prior Medications:** List all the therapies the patient has tried and failed for the treatment of severe alopecia areata

The above 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.

### SELECT IMPORTANT SAFETY INFORMATION RELATED TO SERIOUS INFECTIONS

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 Olumiant in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment prior to initiating Olumiant. Closely monitor patients for development of infections during and after Olumiant treatment. Interrupt Olumiant if the patient develops a serious infection, an opportunistic infection, or sepsis. Do not resume Olumiant until the infection is controlled.

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# Understanding SALT scores in patients with alopecia areata<sup>2,3</sup>

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

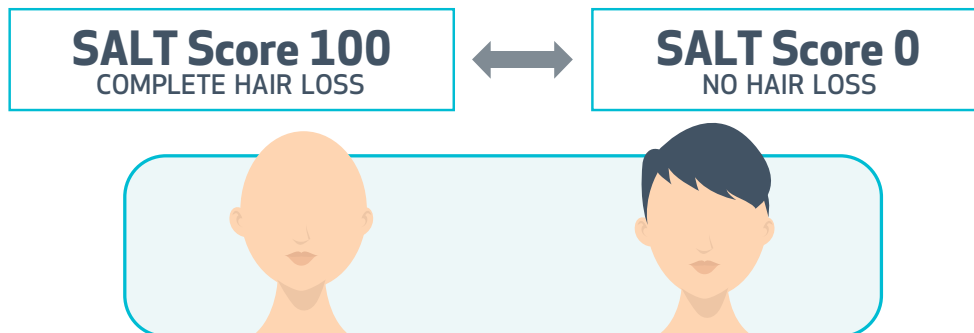


Image is for illustrative purposes only and is not representative of specific patients or efficacy data.

## SALT score

Interpretation of SALT scores:

**SALT score 100:** Complete hair loss

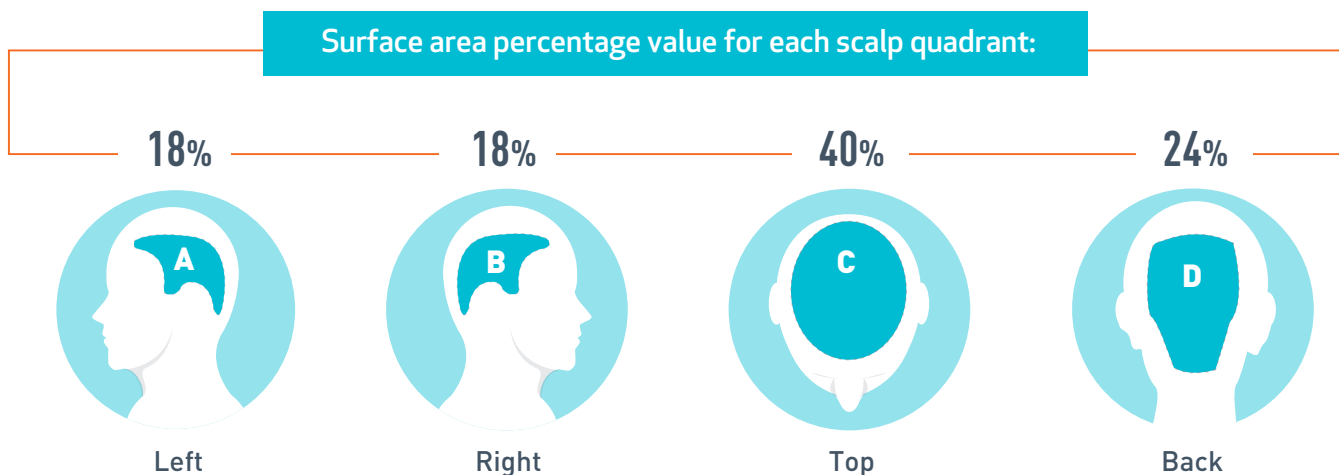
**SALT score 50:** 50% hair loss

**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 Olumiant Together and utilize services to help with access and coverage

- ✓ New, **easy-to-use digital enrollment** in Olumiant Together
- ✓ **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 OLUMIANT TOGETHER WILL HELP  
COMMERCIAL PATIENTS GET ACCESS IF THE PRIOR  
AUTHORIZATION IS DENIED**

# Olumiant Together appeals resources



## Olumiant Together overview

Olumiant Together is a support program designed to help patients navigate their treatment experience with Olumiant®.

### Olumiant Together provides:

#### 1. Ongoing Support

- An Olumiant Together Companion in Care™ 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. Subject to terms and conditions, which can be found at [olumiant.com](https://olumiant.com).**

**†Terms and Conditions:** Subject to Lilly USA, LLC's (Lilly's) right to terminate, rescind, revoke or amend the Olumiant Savings Card Program ("Program") and the Olumiant Savings Card ("Card") eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, the Card expires and savings end on 12/31/2026 or 24 months after you first use the Card, whichever comes first. **Card savings are not available to patients without commercial drug insurance or who are enrolled in any state, federal, or government funded healthcare program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medicare Advantage, Medigap, DoD, VA, TRICARE®/CHAMPUS, or any state prescription drug assistance program.**

**MONTHLY AND ANNUAL MAXIMUM SAVINGS: For patients with commercial drug insurance coverage for Olumiant:** You must have commercial drug insurance that covers Olumiant® (baricitinib) and a prescription consistent with FDA-approved product labeling to pay as little as \$5 for a 1-month prescription fill of Olumiant. Month is defined as 30-days. Card savings are subject to a maximum monthly savings of wholesale acquisition cost plus usual and customary pharmacy charges and a separate maximum annual savings of up to \$9,450 per calendar year. Card may be used for up to 13 prescription fills per year and up to a maximum of 24 prescription fills over the lifetime of the Program, subject to the maximum monthly and annual savings limit. Participation in the Program requires a valid patient HIPAA authorization upon enrollment into the Program. Subject to Lilly USA, LLC's right to terminate, rescind, revoke, or amend Card eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, Card expires and savings end on 12/31/2026 or 24 months after you first use the Card, whichever comes first.

**For patients with commercial drug insurance who do not have coverage for Olumiant:** You must have commercial drug insurance that does not cover Olumiant and a prescription consistent with FDA-approved product labeling to pay as little as \$25 for a 30-day supply of Olumiant. Month is defined as 30-days. Card savings are subject to a maximum monthly savings and a separate maximum annual savings. Card may be used for up to 13 prescription fills per year and up to a maximum of 24 prescription fills over the lifetime of the Program, subject to the maximum monthly and annual savings limit. Participation in the Program requires submission of a prior authorization (PA) prior to the first prescription fill. If coverage is denied, an appeal must be submitted prior to 5<sup>th</sup> month prescription fill. To remain eligible for the Program, a new PA, appeal, or medical exception must be submitted prior to the 13<sup>th</sup> prescription fill and as required by Lilly at its sole discretion. Participation in the Program requires a valid patient HIPAA authorization to remain in the Program. Subject to Lilly USA, LLC's right to terminate, rescind, revoke, or amend Card eligibility criteria and/or Card terms and conditions, which may occur at Lilly's sole discretion, without notice, and for any reason, Card expires and savings end on 12/31/2026 or 24 months after you first use the Card, whichever comes first.

#### ADDITIONAL TERMS AND CONDITIONS:

You are responsible for any applicable taxes, fees, and any amount that exceeds the monthly or annual maximum benefits. Card activation is required. This Card may be terminated, rescinded, revoked, or amended by Lilly at any time without notice and for any reason. Subject to additional terms and conditions. Eligibility criteria and terms and conditions for the Olumiant Savings Card Program may change from time to time at Lilly's sole discretion and for any reason; the most current version can be found at <https://olumiant.com>. Card benefits void where prohibited by law.

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## 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 eligible, commercially insured patients get access to Olumiant.

Field Reimbursement Managers are:

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

Scan the QR codes below to access important Olumiant Together appeals resources

Coverage Authorization  
Request Letter



Letter of Medical  
Necessity



Coverage Authorization  
Appeal Letter



**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.

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# IMPORTANT SAFETY INFORMATION



## **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.

**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](#).**

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.

# IMPORTANT SAFETY INFORMATION (cont'd)

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

## 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<sup>3</sup>) 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<sup>3</sup>.

**Lymphopenia** – Absolute lymphocyte count (ALC)  $<500$  cells/mm<sup>3</sup> 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<sup>3</sup>.

**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)  $\geq 5$ x upper limit

of normal (ULN) and increases of aspartate transaminase (AST)  $\geq 10$ 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/1.73m<sup>2</sup>).

## 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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