BlueCross BlueShield Federal Employee Program

**OLUMIANT (baricitinib)**

## RATIONALE FOR INCLUSION IN PA PROGRAM

### Background

Olumiant (baricitinib) is a Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes or hematopoiesis and immune cell function. Janus kinase inhibitors inhibit one or more Janus family of enzymes (JAK1, JAK2, JAK3, TYK2), interfering with the JAK-STAT signaling pathway. Within the signaling pathway, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression. Olumiant modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs (1).

The use of Olumiant for the treatment of COVID-19 should be billed under the medical benefit.

The use of Olumiant for the treatment of alopecia areata is excluded from coverage.

### Regulatory Status

FDA approved indications: Olumiant is a Janus kinase (JAK) inhibitor indicated for: (1)

- 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: Olumiant should not be used in combination with other JAK inhibitors, biological DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.
- the treatment of COVID-19 in hospitalized adult patients requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.
- the treatment of adult patients with severe alopecia areata.
    - Limitations of Use: Olumiant should not be used in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants.

In addition, the FDA has approved the emergency use of Olumiant for the treatment of COVID-19 in hospitalized pediatric patients (2).

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Olumiant carries several boxed warnings: (1)

1. Serious infections
    a. Increased risk for serious infections, including tuberculosis and bacterial, invasive fungi, viral and other opportunistic infections that may lead to hospitalization. If a serious infection develops, interrupt Olumiant until the infection is controlled. Prior to the initiation of Olumiant, a test for latent tuberculosis must be conducted. If the test is positive, start treatment for tuberculosis prior to starting Olumiant. Monitor all patients for active tuberculosis during treatment, even if the initial latent tuberculosis test is negative.
2. Mortality
    a. RA patients 50 years of age and older with at least one cardiovascular risk factor showed a higher rate of all-cause mortality, including sudden cardiovascular death, in patients treated with JAK inhibitors compared to TNF blockers.
3. Malignancies
    a. Lymphoma and other malignancies have been observed in patients treated with Olumiant.
    b. In RA patients treated with a JAK inhibitor, a higher rate of malignancies was observed when compared with TNF blockers.
4. Major adverse cardiovascular events (MACE)
    a. RA patients 50 years of age and older with at least one cardiovascular risk factor treated with a JAK inhibitor showed a higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) when compared to TNF blockers. Patients who are current or past smokers are at increased risk. Olumiant should be discontinued in patients that have experienced a myocardial infarction or stroke.
5. Thrombosis
    a. Thrombosis, including deep vein thrombosis, pulmonary embolism, and arterial thrombosis, have occurred in patients treated with Olumiant. Many of these adverse events were serious and some resulted in death.
    b. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with a JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers.

The safety and effectiveness of Olumiant in pediatric patients have not been established (1).

**Summary**

Olumiant (baricitinib) is indicated for the treatment of adult patients with rheumatoid arthritis (RA), for the treatment of COVID-19 in hospitalized patients, and for the treatment of adults with severe alopecia areata. Olumiant has several boxed warnings including increased risk for: serious infections, mortality, malignancies, MACE, and thrombosis. The safety and effectiveness of Olumiant in pediatric patients have not been established (1).

The use of Olumiant for the treatment of COVID-19 should be billed under the medical benefit.

The use of Olumiant for the treatment of alopecia areata is excluded from coverage.

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Olumiant while maintaining optimal therapeutic outcomes.

**References**

1. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; June 2022.
2. Baricitinib EUA Letter of Authorization. May 2022. Available at: https://www.fda.gov/media/143822/download?utm_medium=email&utm_source=govdelivery

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