

**OJJAARA
(momelotinib)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Ojjaara (momelotinib) is an inhibitor of wild type Janus Kinase 1 and 2 (JAK1/JAK2) and mutant JAK2^{V617F}, which contribute to signaling of a number of cytokines and growth factors that are important for hematopoiesis and immune function. Ojjaara and its major human circulating metabolite, M21, have higher inhibitory activity for JAK2 compared to JAK3 and tyrosine kinase 2 (TYK2). Ojjaara and M21 additionally inhibit activin A receptor type 1 (ACVR1), also known as activin receptor like kinase 2 (ALK2), which produces subsequent inhibition of liver hepcidin expression and increased iron availability resulting in increased red blood cell production. Myelofibrosis (MF) is a myeloproliferative neoplasm associated with constitutive activation and dysregulated JAK signaling that contributes to inflammation and hyperactivation of ACVR1. JAK signaling recruits and activates STAT (signal transducers and activation of transcription) proteins resulting in nuclear localization and subsequent regulation of gene transcription (1).

Regulatory Status

FDA-approved indications: Ojjaara is a kinase inhibitor indicated for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia (1).

Treatment with Ojjaara can result in an increase risk of infections, thrombocytopenia and neutropenia, hepatotoxicity, major adverse cardiovascular events (MACE), thrombosis and malignancies. Monitor for signs and symptoms of infection, including reactivation of hepatitis B, and initiate appropriate treatment promptly. Assess complete blood counts (CBC), including platelet and neutrophil counts, before initiating treatment and periodically during treatment as clinically indicated. Liver function tests should be conducted at baseline and every month for 6 months during treatment, then periodically as clinically indicated. Consider the benefits and risks for patients being treated with Ojjaara, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Another JAK inhibitor increased the risk of lymphoma and other malignancies. Consider the benefits and risks for patients who have history or risk factors for malignancies (1).

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



**BlueCross
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Federal Employee Program.

OJJAARA (mometinib)

Summary

Ojjaara (mometinib) is a kinase inhibitor indicated for treatment of patients with intermediate or high-risk MF, including primary MF or secondary MF, post-polycythemia vera and post-essential thrombocythemia, in adults with anemia. Ojjaara has been associated with an increased risk of infection, thrombocytopenia and neutropenia, hepatotoxicity, major adverse cardiovascular events, thrombosis, and malignancies. The safety and effectiveness of Ojjaara in pediatric patients have not been established (1).

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

References

1. Ojjaara [package insert]. Durham, NC: GlaxoSmithKline; September 2023.
2. NCCN Drugs & Biologics Compendium® Mometinib 2024. National Comprehensive Cancer Network, Inc. Accessed on April 24, 2024.