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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	October 13, 2023
Subject:	Ojjaara	**Page:**	1 of 4

Last Review Date: March 8, 2024

Ojjaara

Description

Ojjaara (momelotinib)

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).

Related policies
Inrebic, Jakafi, Vonjo

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Ojjaaro may be considered **medically necessary** if the conditions indicated below are met.

Ojjaaro may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Primary myelofibrosis
2. Secondary myelofibrosis
3. Post-polycythemia vera myelofibrosis
4. Post-essential thrombocythemia myelofibrosis

AND ALL of the following for **ALL** indications:

a. **NO** serious infections
b. Hemoglobin < 10 g/dl
c. Prescriber agrees to monitor CBC and platelet counts

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Primary myelofibrosis
2. Secondary myelofibrosis
3. Post-polycythemia vera myelofibrosis
4. Post-essential thrombocythemia myelofibrosis

AND ALL of the following for **ALL** indications:

a. A reduction in palpable spleen length, spleen volume and/or symptomatic improvement
b. Prescriber agrees to monitor CBC and platelet counts

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 90 tablets per 90 days

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Ojjaara (momelotinib) 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® Momelotinib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2024.

Policy History

Date	Action
October 2023	Addition to PA
December 2023	Annual review
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.