# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Ojjaara Prior Authorization Policy
- Ojjaara™ (momelotinib tablets – GlaxoSmithKline)

**REVIEW DATE:** 02/14/2024

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## OVERVIEW

Ojjaara, a Janus Kinase (JAK1/JAK2) inhibitor and activin A receptor type 1 (ACVR1) inhibitor (also known as activin receptor like kinase 2 [ALK2]), is indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF (post-polycythemia vera and post-essential thrombocythemia), in adults with anemia.[1]

## Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for myeloproliferative neoplasms (version 1.2024 – December 21, 2023) have recommendations for MF.[2] Ojjaara is recommended for the management of MF-associated anemia in patients with symptomatic splenomegaly and/or constitutional symptoms which is not controlled as "preferred" (category 2A) or currently controlled on a JAK inhibitor as "useful in certain circumstances" (category 2A). For patients with MF-associated anemia with no symptomatic splenomegaly and/or constitutional symptoms, Ojjaara is recommended as "other recommended regimens" (category 2B). For patients with higher-risk MF with platelet count ≥ 50 x $10^9$/L who are not transplant candidates, Jakafi® (ruxolitinib tablets) [category 1], Inrebic® (fedratinib capsules) [category 1], Ojjaara (category 2A), or Vonjo® (pacritinib capsules) [category 2B] are recommended; for patients who had no response or loss of response to initial therapy, Jakafi, Inrebic, Ojjaara (all category 2A), or Vonjo (category 2B) are recommended if they were not previously used. For patients with higher-risk MF with platelet count < 50 x $10^9$/L who are not candidates for transplant, NCCN recommends Vonjo as a "preferred" therapy (category 1) and Ojjaara as "other recommended regimens" (category 2B). For lower-risk symptomatic patients with MF, Ojjaara (category 2B) is considered "useful in certain circumstances" for first-line therapy or for patients who had no response or loss of response to first-line therapy. JAK inhibitors are also recommended for accelerated or blast phase myeloproliferative neoplasms in combination with hypomethylating agents (azacitidine or decitabine) for the palliation of splenomegaly or other disease-related symptoms. There is a footnote which states that there are very limited data regarding the use of Inrebic, Ojjaara, or Vonjo with hypomethylating agents.

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ojjaara. All approvals are provided for the duration noted below.

**Automation:** none

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ojjaara is recommended in those who meet the following criteria:

### FDA-Approved Indication

**1. Myelofibrosis.** Approve for 1 year if the patient meets the following (A, B, and C):

Note: Examples of myelofibrosis include primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis.

**A)** Patient is ≥ 18 years of age; AND

**B)** Patient has intermediate-risk or high-risk disease; AND

**C)** Patient meets one of the following (i or ii):

- **i.** Patient has anemia and meets both of the following (a and b):
  - **a)** Patient has hemoglobin < 10 g/dL AND
  - **b)** Patient has symptomatic splenomegaly and/or constitutional symptoms; OR
    Note: Examples of constitutional symptoms include weight loss, night sweats, and fever.
- **ii.** Patient has platelet count ≥ 50 X $10^9$/L.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ojjaara is not recommended in the following situations:

**1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Ojjaara™ tablets [prescribing information]. Durham, NC: GlaxoSmithKline; September 2023.
2. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 12, 2024.