

Applicable Drugs: Ojjaara (mometotinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 11/18/2024

Date Last Reviewed / Revised: 6/4/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

- I. Documentation of the following diagnoses AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

- A. Intermediate or high-risk myelofibrosis (MF) including primary MF or secondary MF (post-polycythemia vera [PV] or post-essential thrombocytopenia [ET] in adults with anemia and documentation of all the following (i and ii):
- i. Hemoglobin (Hgb) < 10 g/dL.
 - ii. Symptomatic splenomegaly and/or constitutional symptoms (eg, weight loss, night sweats, fever, etc).

Other Uses With Supportive Evidence

- A. Higher-risk MF
- B. Accelerated/blast phase myeloproliferative neoplasms
- C. Myeloid/lymphoid neoplasms with eosinophilia with tyrosine kinase gene fusions and intolerance/unavailability of ruxolitinib

- II. Minimum age requirement: ≥ 18 years old.
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- None

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Thirty tabs/30 days

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** 6 months with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. Ojjaara. Prescribing information. GlaxoSmithKline; May 2026. Accessed June 4, 2026. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Ojjaara/pdf/OJJAARA-PI-PIL.PDF
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Myeloproliferative Neoplasms. Version 1.2026. Updated January 22, 2026. Accessed June 4, 2026.
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions. Version 1.2026. Updated October 3, 2025. Accessed June 4, 2026.
4. Gerds AT, Verstovsek S, Vannucchi AM, et al. Mometotinib versus danazol in symptomatic patients with anaemia and myelofibrosis previously treated with a JAK inhibitor (MOMENTUM): an updated analysis of an international, double-blind, randomised phase 3 study. *Lancet Haematol.* 2023 ;10(9):e735-e746. doi: 10.1016/S2352-3026(23)00174-6
5. Mesa RA, Kiladjian JJ, Catalano JV, et al. SIMPLIFY-1: A phase III randomized trial of mometotinib versus ruxolitinib in janus kinase inhibitor-naïve patients with myelofibrosis. *J Clin Oncol.* 2017;35(34):3844-3850. doi: 10.1200/JCO.2017.73.4418

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.