Original Effective Date: 03/07/2024
Current Effective Date: 05/22/2026
Last P&T Approval/Version: 04/29/2026
Next Review Due By: 04/2027
Policy Number: C27175-A

Ojjaara (momelotinib)

PRODUCTS AFFECTED

Ojjaara (momelotinib)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Myelofibrosis (MF) with anemia

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. This clinical policy will be reviewed along with state and federal requirements, the benefit being administered, and formulary preferencing. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available. The Pharmacy and Therapeutics Committee has determined that biosimilars may be preferred.

A. MYELOFIBROSIS:
   1. Documented diagnosis of primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis
      AND

Molina Healthcare, Inc. confidential and proprietary © 2026
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare

2. Documentation member has intermediate or high-risk disease as defined by possessing TWO or more of the following criteria: Age > 65 years, Documented Hemoglobin < 10g /dL, Documented WBC > 25 x 10^9 / L, Circulating Blasts ≥ 1%, OR Presence of Constitutional Symptoms (weight loss > 10% from baseline or unexplained fever or excessive sweats persisting for more than 1 month)
   AND
3. Documentation that member is ineligible for allogeneic hematopoietic cell transplantation (HCT)
   AND
4. Documentation of anemia, measured by a Hgb <10g/dL [DOCUMENTATION REQUIRED]
   AND
5. Documentation of baseline assessment of disease [e.g., spleen size, Total Symptom Score as measured by the modified Myelofibrosis Symptom Assessment Form (e.g., fatigue, fever, night sweats, weight loss)] [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. MYELOFIBROSIS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation, or held for toxicity
   AND
2. Documentation of a positive response to treatment as evidenced by decrease in spleen size, or improvements in other myelofibrosis symptoms (e.g., fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.), or reduction in the Total Symptom Score from baseline as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF), or not requiring blood transfusion for ≥12 weeks with a Hgb of ≥8 g/dL [DOCUMENTATION REQUIRED]

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified oncologist or hematologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

200mg by mouth once daily

NOTE: Quantities approved should allow for dose adjustments for cytopenias and/or hepatic impairment, while using the least number of tablets per dose. See Other Special Considerations.

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral

DRUG CLASS:

Janus Associated Kinase (JAK) inhibitor

Molina Healthcare, Inc. confidential and proprietary © 2026

This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare

FDA-APPROVED USES:

Indicated for the 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

COMPENDIAL APPROVED OFF-LABELED USES:

Low risk, symptomatic Myelofibrosis (NCCN Myeloproliferative Neoplasms Version 1.2026 MF-1), Myeloid/ lymphoid neoplasms with eosinophilia and JAK2 rearrangement (NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Version 1.2026 MLNE-8)

APPENDIX

APPENDIX:

Dose adjustments from package insert based on adverse reactions

Thrombocytopenia		Dose Modification
Baseline platelet count	Platelet count	
>100 x 10^9/L	20 x 10^9/L to <50 x 10^9/L	Reduce daily dose by 50mg from last given dose
>100 x 10^9/L	<20 x 10^9/L	Interrupt treatment until platelets recover to 50 x 10^9/L. Restart Ojjaara at a daily dose of 50mg below the last given dose
≥50 x 10^9/L to <100 x 10^9/L	<20 x 10^9/L	Interrupt treatment until platelets recover to 50 x 10^9/L. Restart Ojjaara at a daily dose of 50mg below the last given dose
<50 x 10^9/L	<20 x 10^9/L	Interrupt treatment until platelets return to baseline. Restart Ojjaara at a daily dose of 50mg below the last given dose

Neutropenia	Dose Modification
Absolute neutrophil count (ANC) <0.5 x 10^9/L	Interrupt treatment until ANC ≥0.75 x 10^9/L. Restart Ojjaara at a daily dose of 50mg below the last given dose
Hepatotoxicity (unless other apparent causes)	**Dose Modification**
ALT and/or AST >5 x ULN (or >5 x baseline, if baseline is abnormal) and/or total bilirubin >2 x ULN (or >2 x baseline, if baseline is abnormal)	Interrupt treatment until ALT and AST ≤2 x ULN or baseline and total bilirubin ≤1.5 x ULN or baseline. Restart Ojjaara at a daily dose of 50mg below the last given dose. If recurrence of AST or ALT elevations >5 x ULN, permanently discontinue Ojjaara.
Other non-hematologic adverse effects	**Dose Modification**
Grade 3 or higher, using the National Cancer Institute Common Terminology Criteria for Adverse Events	Interrupt treatment until toxicity resolves to grade 1 or lower (or baseline). Restart Ojjaara at a daily dose of 50mg below the last given dose.

Molina Healthcare, Inc. confidential and proprietary © 2026

This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Myelofibrosis is a type of myeloproliferative neoplasms (MPN) that is caused by a disorder with the hematopoietic system. Other types of MPN include postpolycythemia vera (PV) and post-essential thrombocythemia (ET). MPN can have a wide variety of symptoms, but most commonly can present with hematologic lab abnormalities, splenomegaly, fatigue, and pruritus. Current treatment options depend on the severity of the disease, but treatment options for high risk patients include other JAK inhibitors, such as Jakafi (ruxolitinib), Inrebic (fedratinib), and Vonjo (pacritinib).

Ojjaara is the first and only FDA-approved medication to treat MF in adults with anemia. It is a JAK inhibitor of the wildtype JAK1/JAK2, as well as the JAK2 mutant, all which play a role in hematopoiesis and immune function. Anemia is common symptom of MF, as well as a side effect of most drugs used to treat MF. Development of anemia greatly affects the survival rate of patients with MF. Guideline recommendations for treating MF associated anemia include danazol or immunomodulatory agents with prednisone.

The MOMENTUM trial compared Ojjaara to danazol for patients with MF and anemia by evaluating total symptom score, transfusion requirements, and spleen size. Results showed a significant benefit from Ojjaara compared to danazol regarding a larger reduction in symptoms and spleen size, as well as improved transfusion independence. The SIMPLIFY-1 trial compared Ojjaara to Jakafi (ruxolitinib) regarding spleen volume, in which Ojjaara was found to be noninferior to Jakafi. However, Ojjaara was found to be associated with decrease transfusion requirements. Some of the most common adverse effects of Ojjaara based on results from the MOMENTUM trial include thrombocytopenia (28%), diarrhea (22%), hemorrhage (22%), and fatigue (21%). The most common fatal adverse reaction was viral infections (5%).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Ojjaara (momelotinib) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Ojjaara (momelotinib) include: no labeled contraindications.

OTHER SPECIAL CONSIDERATIONS:
Starting dose for patients with severe hepatic impairment (Child Pugh Class C) should be 150mg once daily. Dose adjustments can also be made in cases of thrombocytopenia, neutropenia, and hepatotoxicity.

Ojjaara Dose Modification Program
https://ojjaarahcp.com/content/dam/cf-pharma/hcp-ojjaara-v3/en_US/pdf/ojjaara-dose-modification-enrollment-program-form.pdf
The OJJAARA Dose Modification Program is available for patients who require mid-cycle dose adjustments of their current tablet strength. A 30-count bottle of Ojjaara will be provided at no cost up to 2 times.

Obtain the following blood tests prior to starting treatment with Ojjaara, periodically during treatment, and as clinically indicated: complete blood count with platelets, and hepatic panel.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina*

Molina Healthcare, Inc. confidential and proprietary © 2026
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare

adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Ojjaara TABS 100MG
Ojjaara TABS 150MG
Ojjaara TABS 200MG

REFERENCES

1. Ojjaara (momelotinib) tablets, for oral use [prescribing information]. Durham, NC: GlaxoSmithKline; March 2026.
2. Verstovsek, S., Gerds, A., Vannucchi, A., & Al-Ali, H. (2022, December 22). A Randomized, Double-blind, Phase 3 Study to Evaluate the Activity of Momelotinib (MMB) Versus Danazol (DAN) in Symptomatic, Anemic Subjects With Primary Myelofibrosis (PMF), Post-polycythemia Vera (PV) Myelofibrosis, or Post-essential Thrombocythemia (ET) Myelofibrosis Who Were Previously Treated With JAK Inhibitor Therapy. CTG Labs – NCBI. https://clinicaltrials.gov/study/NCT04173494
3. Gerds, A. T., Gotlib, J., Ali, H., Bose, P., Dunbar, A., Elshoury, A., George, T. I., Gundabolu, K., Hexner, E., Hobbs, G. S., Jain, T., Jamieson, C., Kaesberg, P. R., Kuykendall, A. T., Madanat, Y., McMahon, B., Mohan, S. R., Nadiminti, K. V., Oh, S., Pardanani, A., Podoltsev, N., Rein, L., Salit, R., Stein, B. L., Talpaz, M., Vachhani, P., Wadleigh, M., Wall, S., Ward, D. C., Bergman, M. A., & Hochstetler, C. (2022). Myeloproliferative Neoplasms, Version 3.2022, NCCN Clinical Practice Guidelines in Oncology. *Journal of the National Comprehensive Cancer Network*, *20*(9), 1033-1062. Retrieved Oct 25, 2023, from https://doi.org/10.6004/jnccn.2022.0046
4. National Comprehensive Cancer Network. 2023. Myeloproliferative Neoplasms (Version 2.2023). [online] Available at: < https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf> [Accessed 23 October 2023].
5. Mesa, R. A., Kiladjian, J. J., Catalano, J. V., Devos, T., Egyed, M., Hellmann, A., McLornan, D., Shimoda, K., Winton, E. F., Deng, W., Dubowy, R. L., Maltzman, J. D., Cervantes, F., & Gotlib, J. (2017). SIMPLIFY-1: A Phase III Randomized Trial of Momelotinib Versus Ruxolitinib in Janus Kinase Inhibitor-Naïve Patients With Myelofibrosis. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology*, *35*(34), 3844–3850. https://doi.org/10.1200/JCO.2017.73.4418
6. National Comprehensive Cancer Network. 2023. Myeloproliferative Neoplasms (Version 3.2023). [online] Available at: <mpn.pdf (nccn.org)> [Accessed 9 November 2023].
7. National Comprehensive Cancer Network. 2024. Myeloproliferative Neoplasms (Version 1.2024). [online] Available at: < mpn.pdf (nccn.org) > [Accessed 10 April 2024].
8. National Comprehensive Cancer Network. 2025. Myeloproliferative Neoplasms (Version 1.2025). [online] Available at: < mpn.pdf (nccn.org) > [Accessed 8 April 2025].
9. National Comprehensive Cancer Network. 2026. Myeloproliferative Neoplasms (Version 1.2026). [online] Available at: < mpn.pdf (nccn.org) > [Accessed 7 April 2026].

Molina Healthcare, Inc. confidential and proprietary © 2026
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Compendial Approved Off-Labeled Uses References	Q2 2026
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Compendial Approved Off-Labeled Uses Other Special Considerations References	Q2 2025
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Other Special Considerations References	Q2 2024
NEW CRITERIA CREATION	Q1 2024

Molina Healthcare, Inc. confidential and proprietary © 2026
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare