Clinical Policy: Momelotinib (Ojjaara)

Reference Number: CP.PHAR.654
Effective Date: 12.01.23
Last Review Date: 11.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Momelotinib (Ojjaara) is a kinase inhibitor.

FDA Approved Indication(s)

Ojjaara is 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Ojjaara is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Myelofibrosis (must meet all)**:**

1. Diagnosis of MF (includes primary MF, post-PV MF, post-ET MF);
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Age ≥ 18 years;
4. Documentation of a recent (within the last 30 days) hemoglobin level < 10 g/dL;
5. For brand Ojjaara requests, member must use generic momelotinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed both of the following (i and ii):
      i. 200 mg per day;
      ii. 1 tablet per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Myeloproliferative Neoplasms (off-label) (must meet all):

1. Diagnosis of accelerated/blast phase myeloproliferative neoplasms (MPN);
2. Prescribed by or in consultation with a hematologist or oncologist;

3. Age ≥ 18 years;
4. Prescribed in one of the following ways (a or b):
   a. For transplant candidates, one of the following (i or ii):
      i. As a single agent near to the start of conditioning therapy for improvement of splenomegaly and other disease-related symptoms;
      ii. In combination with azacitidine or decitabine for bridging therapy;
   b. If not a candidate for transplant, in combination with azacitidine or decitabine for palliation of splenomegaly or other disease-related symptoms;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN [remove if not oncology*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

C. Myeloid/Lymphoid Neoplasms with Eosinophilia (off-label) (must meet all):
1. Diagnosis of myeloid or lymphoid neoplasm with eosinophilia and JAK2 arrangement;
2. Documentation that disease is in the chronic or blast phase;
3. Prescribed by or in consultation with a hematologist or oncologist;
4. Age ≥ 18 years;
5. For brand Ojjaara requests, member must use generic momelotinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed both of the following (i and ii):
      i. 200 mg per day;
      ii. 1 tabletper day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

D. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Ojjaara for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For brand Ojjaara requests, member must use generic momelotinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed both of the following (i and ii):
      i. 200 mg per day;
      ii. 1 tablet per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ET: essential thrombocythemia
FDA: Food and Drug Administration
MF: myelofibrosis
MPN: myeloproliferative neoplasms
NCCN: National Comprehensive Cancer Network
PV: polycythemia vera

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- Examples of positive response to therapy for myelofibrosis include: reduction in spleen size or improvement in symptoms such as pruritus, fatigue, night sweats, bone pain since initiation of therapy.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MF	200 mg PO QD	200 mg/day

VI. Product Availability

Tablets: 100 mg, 150 mg, 200 mg

VII. References

1. Ojjaara Prescribing Information. Durham, NC: GlaxoSmithKline; May 2026. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Ojjaara/pdf/OJJAARA-PI-PIL.PDF. Accessed July 10, 2026.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 24, 2026.
3. National Comprehensive Cancer Network. Myeloproliferative Neoplasms Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed July 21, 2026.
4. National Comprehensive Cancer Network. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed August 24, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	09.26.23	11.23
4Q 2024 annual review: no significant changes; references reviewed and updated.	07.15.24	11.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2025 annual review: added off-label criteria for MPN per NCCN category 2A; initial approval duration changed from 6 to 12 months; references reviewed and updated.	07.16.25	11.25
4Q 2026 annual review: added ICHRA line of business; added off-label criteria for myeloid or lymphoid neoplasm with eosinophilia and Janus kinase 2 arrangement per NCCN category 2A recommendation; references reviewed and updated.	07.10.26	11.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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