Original Effective Date: 03/07/2024
Current Effective Date: 03/07/2024
Last P&T Approval/Version: 01/31/2024
Next Review Due By: 04/2024
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. 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 along with state and federal requirements, benefit being administered and formulary preferencing. 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.

A. MYELOFIBROSIS:
   1. Documentation of primary myelofibrosis (PMF), post-polycythemia vera or post-essential thrombocythemia myelofibrosis (post-PV/ET MF)
      AND

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 of anemia, measured by a Hgb <10g/dL [DOCUMENTATION REQUIRED]
   AND
4. Documentation of baseline assessment of disease of Total Symptom Score as measured by the modified Myelofibrosis Symptom Assessment Form (e.g., fatigue, fever, night sweats, weight loss)
   AND
5. Documentation member has splenomegaly based on palpable spleen length or spleen volume [DOCUMENTATION REQUIRED]
   AND
6. Prescriber attests that member is ineligible for allogeneic hematopoietic cell transplantation (HCT)
   AND
7. Prescriber attests that CBC with platelets and neutrophil count and hepatic panel will be assessed at baseline and periodically during treatment as clinically indicated per FDA label

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
      AND
   2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
      AND
   3. 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
      AND
   4. Prescriber attests that CBC with platelets and neutrophil count and hepatic panel are assessed periodically during treatment as clinically indicated per FDA label

DURATION OF APPROVAL:

Initial authorization: 6 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

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

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:
None

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.

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 option depends 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 MOMEMTUM 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: There are currently no labeled contraindications to Ojjaara.

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.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

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

REFERENCES

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6. National Comprehensive Cancer Network. 2023. Myeloproliferative Neoplasms (Version 3.2023). [online] Available at: <mpn.pdf (nccn.org)> [Accessed 9 November 2023].

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q1 2024