PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 02/19/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 2.2024 – August 8, 2024) classify risk stratification for MF into two groupings: lower-risk disease and higher-risk disease.[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 Regimen" (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 or transplant is not feasible and who have symptomatic splenomegaly and/or constitutional symptoms, 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 or transplant is not currently feasible, NCCN recommends Vonjo as a "Preferred Regimen" therapy (category 1) and Ojjaara as "other recommended regimens" (category 2B). For lower-risk symptomatic patients with MF, Ojjaara 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 (category 2B). JAK inhibitors are also recommended for accelerated or blast phase myeloproliferative neoplasms for the palliation of splenomegaly or other disease-related symptoms (category 2A). Some examples of disease-related symptoms of myeloproliferative neoplasms include fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis.

POLICY STATEMENT

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

- **Ojjaara™ (momelotinib tablets (GlaxoSmithKline)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Myelofibrosis.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   Note: This includes primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis.
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets ONE of the following (i, ii, or iii):
      i. Patient has higher-risk disease; OR
      ii. Patient meets BOTH of the following (a and b):
         a) Patient has lower-risk disease; AND
         b) Patient has at least one disease-related symptom; OR
            Note: Examples of disease-related symptoms include: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis.
      iii. Patient has myelofibrosis-associated anemia.

Other Uses with Supportive Evidence

2. **Accelerated or Blast Phase Myeloproliferative Neoplasm**. Approve for 1 year if the patient meets BOTH of the following (A and B)

A) Patient is ≥ 18 years of age; AND
B) Patient has at least one disease-related symptom.
Note: Examples of disease-related symptoms include: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis.

CONDITIONS NOT COVERED

- **Ojjaara™ (momelotinib tablets (GlaxoSmithKline)**

is(are) considered experimental, investigational or unproven for ANY other use(s); 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 2.2024 – August 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 5, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/20/2023
Selected Revision	**Myelofibrosis:** For a patient with anemia, criteria was added to require the patient to meet both of the following: Patient has hemoglobin < 10 g/dL AND patient has serum erythropoietin level ≥ 500 mU/mL. An alternative option of approval exception was added for a patient with platelet count ≥ 50 x 10^9/L.	11/08/2023
Early Annual Revision	**Myelofibrosis:** For a patient with anemia, the requirement that "patient has serum erythropoietin level ≥ 500 mU/mL" was removed and a requirement that the "patient has symptomatic splenomegaly and/or constitutional symptoms" was added.	02/14/2024
Annual Revision	**Myelofibrosis**: The following qualifier patient has "intermediate-risk or high-risk disease" was changed to "higher-risk disease." The following qualifier for approval was added, "patient has lower-risk disease and has at least one disease-related symptom" with a note of examples of disease-related symptoms. The qualifier of "anemia" was changed to "myelofibrosis-associated anemia." For a patient with myelofibrosis-associated anemia, the requirements of hemoglobin < 10 g/dL and symptomatic splenomegaly and/or constitutional symptoms with the note of examples of constitutional symptoms were removed. The following qualifier for approval "patient has platelet count ≥ 50 X 10^9/L" was removed. **Accelerated or Blast Phase Myeloproliferative Neoplasm:** Condition of approval and criteria were added to "Other Uses with Supportive Evidence."	02/19/2025