PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 02/14/2024

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 1.2024 – December 21, 2023) have recommendations for MF.[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" (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, 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, NCCN recommends Vonjo as a "preferred" therapy (category 1) and Ojjaara as "other recommended regimens" (category 2B). For lower-risk symptomatic patients with MF, Ojjaara (category 2B) 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. JAK inhibitors are also recommended for accelerated or blast phase myeloproliferative neoplasms in combination with hypomethylating agents (azacitidine or decitabine) for the palliation of splenomegaly or other disease-related symptoms. There is a footnote which states that there are very limited data regarding the use of Inrebic, Ojjaara, or Vonjo with hypomethylating agents.

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 the following (A, B, and C):
   Note: Examples of myelofibrosis include primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has intermediate-risk or high-risk disease; AND
   C) Patient meets one of the following (i or ii):
      i. Patient has anemia and meets both of the following (a and b):
         a) Patient has hemoglobin < 10 g/dL AND
         b) Patient has symptomatic splenomegaly and/or constitutional symptoms; OR
            Note: Examples of constitutional symptoms include weight loss, night sweats, and fever.
      ii. Patient has platelet count ≥ 50 X 10^9/L.

CONDITIONS NOT COVERED

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

is(are) considered experimental, investigational or unproven for ANY other use(s).

REFERENCES

1. Ojjaara™ tablets [prescribing information]. Durham, NC: GlaxoSmithKline; September 2023.
2. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 12, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/20/2023
Selected Revision	**Myelodysplastic Syndrome:** 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	**Myelodysplastic Syndrome:** 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