UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1419-2
Program	Prior Authorization/Notification
Medication	Ojjaara™ (momelotinib)
P&T Approval Date	11/2023, 11/2024
Effective Date	2/15/2025

1. Background:

Ojjaara (momelotinib) is a kinase inhibitor indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [postpolycythemia vera (PV) and post-essential thrombocythemia (ET)] with anemia. The National Cancer Comprehensive Network (NCCN) also recommends Ojjaara for the treatment of lower-risk and higher-risk myelofibrosis, and accelerated/blast phase myeloproliferative neoplasms.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

1. **Ojjaara** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. Myeloproliferative Neoplasms

1. **Initial Authorization**

   a. **Ojjaara** will be approved based on **one** of the following criteria:

      (1) Diagnosis of symptomatic lower-risk myelofibrosis

      -OR-

      (2) **All** of the following:

         (a) Diagnosis of higher-risk myelofibrosis

-AND-

(b) Presence of symptomatic splenomegaly and/or constitutional symptoms

-AND-

(c) **<u>One</u>** of the following:

i. Used as continued therapy near the start of conditioning therapy in a transplant candidate
ii. Patient is not a transplant candidate or transplant not currently feasible

-OR-

(3) Diagnosis of myelofibrosis-associated anemia

-OR-

(4) **<u>Both</u>** of the following:

(a) Diagnosis of accelerated/blast phase myeloproliferative neoplasm

-AND-

(b) **<u>One</u>** of the following:

i. Used for the improvement of splenomegaly or other disease-related symptoms
ii. Continued treatment as a single agent near to the start of conditioning therapy in transplant candidates for the improvement of splenomegaly and other disease-related symptoms

Authorization will be issued for 6 months.

2. **<u>Reauthorization</u>**

a. **Ojjaara** will be approved based on **<u>one</u>** the following criteria:

(1) Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Ojjaara

Authorization will be issued for 6 months.

-OR-

(2) Documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Ojjaara, allow for dose titration with

discontinuation of therapy

Authorization will be issued for 2 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limit may be in place**.**

4. References:

1. Ojjaara [package insert]. Durham, NC: GlaxoSmithKline; September 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/ Accessed October 11, 2024.

Program	Prior Authorization/Notification – Ojjaara™ (momelotinib)
Change Control	
11/2023	New program.
11/2024	Annual review. Modified title of myelofibrosis to myeloproliferative neoplasms and updated coverage criteria based on NCCN guidelines.