UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2024 P 3178-2 |
| Program | Step Therapy |
| Medication | Ojjaara™ (momelotinib) |
| P&T Approval Date | 2/2024, 11/2024 |
| Effective Date | 2/1/2025 |

## 1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a patient trial of, or contraindication or intolerance to, Jakafi® (ruxolitinib) before providing coverage for Ojjaara (momelotinib) for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).

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.[1]

Jakafi (ruxolitinib) is a kinase inhibitor indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis. It is also indicated in patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea, steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older, and chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.[2]

Members currently on Ojjaara therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

**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,b]:

**A. <u>Patients less than 19 years of age</u>**

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. Myelofibrosis**

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

   a. **Both** of the following:

      (1) Diagnosis of lower-risk symptomatic myelofibrosis

      **-AND-**

      (2) History of failure, contraindication, or intolerance to **all** of the following:

         (a) Jakafi (ruxolitinib)

         (b) Pegasys (peginterferon alfa-2a)

         (c) Hydroxyurea

      **-OR-**

   b. **All** of the following:

      (1) Diagnosis of higher-risk myelofibrosis

      **-AND-**

      (2) Platelets are greater than or equal to 50 x $10^9$/L

      **-AND-**

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

      **-AND-**

      (4) History of failure, contraindication, or intolerance to Jakafi (ruxolitinib)

      **-OR-**

   c. **All** of the following:

      (1) Diagnosis of myelofibrosis-associated anemia

      **-AND-**

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

         (a) **Both** of the following:

i. Anemia with presence of symptomatic splenomegaly and/or constitutional symptoms

**-AND-**

ii. History of failure, contraindication, or intolerance to Jakafi (ruxolitinib) combination (e.g. Jakafi [ruxolitinib] in combination with erythropoietin stimulating agents or Reblozyl [luspatercept-aamt])

**-OR-**

(b) **Both** of the following:

i. Anemia without presence of symptomatic splenomegaly and/or constitutional symptoms

**-AND-**

ii. History of failure, contraindication, or intolerance to **all** of the following:

- Erythropoietin stimulating agents (e.g., Aranesp, Epogen, Procrit, Retacrit) if serum EPO < 500 mU/mL
- Reblozyl [luspatercept-aamt])
- Danazol

**-OR-**

d. **Both** of the following:

(1) As continuation of therapy

**-AND-**

(2) Patient has not received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from any Ojjaara related patient support program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Ojjaara*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from any Ojjaara related patient support program shall be required to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

**C. Other Indications**

1. **Ojjaara** will be approved

**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.
[b] Coverage of oncology medications may be approved based on state mandates.

**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 limits and/or Notification may be in place.
- Coverage of oncology medications may be approved based on state mandates.

**4. References:**


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


| Program | Step Therapy – Ojjaara™ (momelotinib) |
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| **Change Control** | |
| 2/2024 | New program. |
| 11/2024 | Updated clinical criteria based on NCCN update. |