UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1385-4
Program	Prior Authorization/Notification
Medication	Vonjo (pacritinib)
P&T Approval Date	5/2022, 7/2022, 7/2023, 7/2024
Effective Date	10/1/2024

1. Background:

Vonjo (pacritinib) is a kinase inhibitor indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) with a platelet count below 50×10^9/L.

The National Cancer Comprehensive Network (NCCN) recommends Vonjo in higher-risk MF if not a transplant candidate and platelets $<50 \times 10^9$/L or platelets $\geq 50 \times 10^9$/L with presence of symptomatic splenomegaly and/or constitutional symptoms with or without a response or loss of response to one prior Janus kinase (JAK) inhibitor. NCCN also recommends Vonjo for the treatment of symptomatic lower-risk MF and platelets $<50 \times 10^9$/L with or without a response or loss of response to ruxolitinib, peginterferon alfa-2a, momelotinib, or hydroxyurea. NCCN also recommends Vonjo in MF-associated anemia, and in accelerated/blast phase myeloproliferative neoplasms as conditioning therapy in transplant candidates for the improvement of splenomegaly and other disease-related symptoms, and as palliation of splenomegaly or other disease-related symptoms in combination with hypomethylating agents as bridging therapy prior to transplant, or if not a candidate for transplant.

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

1. **Vonjo** 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. <u>Myelofibrosis (MF)</u>

1. **<u>Initial Authorization</u>**

a. **Vonjo** will be approved based on **both** of the following criteria:

(1) **One** of the following diagnosis:

(a) Primary myelofibrosis

-OR-

(b) Post-polycythemia vera myelofibrosis

-OR-

(c) Post-essential thrombocythemia myelofibrosis

-OR-

(d) Accelerated/blast phase myeloproliferative neoplasm

-AND-

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

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

i. Patient has symptomatic lower-risk myelofibrosis

-AND-

ii. Patient has a platelet count < 50 x 10^9/L

-OR-

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

i. Patient has higher-risk myelofibrosis

-AND-

ii. Patient is not a transplant candidate or transplant not currently feasible

-AND-

iii. **One** of the following:

- Patient has a platelet count < 50 x 10^9/L

-OR-

- **Both** of the following:

- Patient has symptomatic splenomegaly and/or constitutional symptoms
- Patient has a platelet count ≥ 50 x 10^9/L

-OR-

(c) Used for treatment of myelofibrosis-associated anemia

-OR-

(d) Used for splenomegaly and other disease-related symptoms in **one** of the following:

i. Continued near the start of conditioning therapy of transplant candidates
ii. Palliation in combination with hypomethylating agents (azacitidine or decitabine) as bridging therapy prior to transplant, or if not a candidate for transplant

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Vonjo** will be approved based on the following criterion:

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

Authorization will be issued for 12 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 limits may be in place.

4. References:

1. Vonjo [package insert]. Seattle, WA: CTI BioPharma Corp.; February 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed May 28, 2024.

Program	Prior Authorization/Notification – Vonjo (pacritinib)
Change Control	
5/2022	New program
7/2022	Updated background with NCCN recommendations. Updated criteria to include that patient is not a transplant candidate. Added coverage criteria for platelets > 50 x 109/L and lower-risk MF. Added reference.
7/2023	Annual review. Updated Myelofibrosis background and criteria per NCCN guidelines. Added state mandate footnote.
7/2024	Annual review. Added accelerated/blast phase myeloproliferative neoplasm to list of MF subtypes. Updated criteria for low- and high-risk MF, MF-associated anemia, and splenomegaly and other disease-related symptoms per NCCN guidelines. Updated approval durations to 12 months. Updated background.