UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1385-3
Program	Prior Authorization/Notification
Medication	Vonjo (pacritinib)
P&T Approval Date	5/2022, 7/2022, 7/2023
Effective Date	10/1/2023; Oxford only: 10/1/2023

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 no 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 no response or loss of response to ruxolitinib, peginterferon alfa-2a, or hydroxyurea. NCCN also recommends Vonjo for splenomegaly and other disease-related symptoms that is continued near the start of conditioning therapy of transplant candidate with higher-risk MF; splenomegaly and other disease-related symptoms that is continued in MF-associated anemia; splenomegaly and other disease-related symptoms that is continued near the start of conditioning therapy in MF-accelerated phase or MF-blast phase; and MF-accelerated phase or MF-blast phase with hypomethylating agents (azacitidine or decitabine) for induction therapy or for the palliation of splenomegaly or other disease-related symptoms.**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 6 months.

B. <u>Myelofibrosis (MF)</u>

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

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

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

(a) **One** of the following diagnoses:

i. Primary myelofibrosis

-OR-

ii. Post-polycythemia vera myelofibrosis

-OR-

iii. Post-essential thrombocythemia myelofibrosis

-AND-

(b) **One** of the following conditions:

i. **Both** of the following:

- Patient has higher-risk myelofibrosis

-AND-

- Patient is not a transplant candidate

-OR-

ii. **All** of the following:

- Patient has symptomatic lower-risk myelofibrosis

-AND-

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

-AND-

- History of no response or loss of response to Jakafi, peginterferon alfa-2a, or hydroxyurea

-OR-

iii. Used for splenomegaly and other disease-related symptoms that is continued in **one** of the following:
- MF-associated anemia
- Near the start of conditioning therapy in MF-accelerated phase or MF-blast phase
- Near the start of conditioning therapy of transplant candidate with

higher-risk MF

-OR-

iv. Used for induction therapy or for the palliation of splenomegaly or other disease-related symptoms in MF-accelerated phase or MF-blast phase with hypomethylating agents (azacitidine or decitabine)

Authorization will be issued for 6 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 6 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 6 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 June 6, 2023.

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.