PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Vonjo Prior Authorization Policy
- Vonjo™ (pacritinib capsules – CTI BioPharma/Sobi)

REVIEW DATE: 02/07/2024; selected revision 12/11/2024

OVERVIEW

Vonjo, an inhibitor of Janus Associated Kinase (JAK)2 and FMS-like tyrosine kinase, is indicated for the treatment of intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50×10^9/L in adults.

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for myeloproliferative neoplasms (version 2.2024 – August 8, 2024) classify risk stratification into two groupings: lower-risk disease and higher-risk disease.[2] NCCN guidelines recommend Vonjo for symptomatic lower-risk myelofibrosis if platelet count is $< 50 \times 10^9$/L (category 2A) as "Useful in Certain Circumstances". In this setting, Vonjo can also be used if the patient did not have a response or loss of response to initial therapy (e.g. Jakafi® [ruxolitinib tablets], Pegasys® [peginterferon alfa-2a subcutaneous injection], Ojjaara™ (momelotinib tablets), hydroxyurea if not previously used) [category 2A]. Vonjo is also recommended as "Preferred Regimen" for higher-risk myelofibrosis if the patient is not a transplant candidate or transplant is not currently feasible and platelet count is $< 50 \times 10^9$/L (category 1). Vonjo is also recommended for higher-risk myelofibrosis if platelet count is $\geq 50 \times 10^9$/L as initial therapy (category 2B) or in situations where the patient did not respond to or lost response to an alternative prior JAK inhibitor (Jakafi, Inrebic® [fedratinib capsules], or Ojjaara) [category 2B].[2] Vonjo is also recommended for the management of myelofibrosis-associated anemia with symptomatic splenomegaly and/or constitutional symptoms (category 2A) or without symptomatic splenomegaly and/or constitutional symptoms (category 2B).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Vonjo. All approvals are provided for the duration noted below.

Automation: none

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vonjo is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Myelofibrosis.** Approve for 1 year if the patient meets ONE of the following (A and B):
   Note: This includes Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis, and Post-Essential Thrombocythemia Myelofibrosis
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i, ii or iii):
     - **i.** Patient has a platelet count of less than 50×10^9/L (< 50,000/mcL) and meets ONE of the following (a or b):

a) Patient meets BOTH of the following (1 and 2):
(1) Patient has intermediate-risk or high-risk disease; AND
(2) Patient is not a candidate for transplant; OR
b) Patient has lower-risk disease; OR

ii. Patient has a platelet count of greater than or equal to 50×10^9/L ($\geq$ 50,000/mcL) and meets ALL of the following (a, b, and c):
a) Patient has high-risk disease; AND
b) Patient is not a candidate for transplant; AND
c) Patient has symptomatic splenomegaly and/or constitutional symptoms; OR

iii. Patient has myelofibrosis-associated anemia..

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vonjo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Vonjo™ capsules [prescribing information]. Seattle, WA: CTI BioPharma; November 2024.
2. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – August 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 4, 2024.