PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 03/02/2022; selected revision 06/22/2022 and 8/10/2022

OVERVIEW

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

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for myeloproliferative neoplasms (version 2.2022 – April 13, 2022) 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 with no response or loss of response to Jakafi® (ruxolitinib tablets), Pegasys® (peginterferon alfa-2a subcutaneous injection), or hydroxyurea. Vonjo is recommended for higher-risk myelofibrosis if the patient is not a transplant candidate and platelet count is $< 50 \times 10^9$/L; and if platelet count is $\geq 50 \times 10^9$/L in situations when the patient did not respond to or lost response to one prior JAK inhibitor (Jakafi or Inrebic® [fedratinib capsules]).[2]

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 Indications

1. **Myelofibrosis, including Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis, and Post-Essential Thrombocythemia Myelofibrosis.** Approve for 1 year if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets one of the following criteria (i or ii):
     - **i.** Patient has a platelet count of less than 50×10^9/L (< 50,000/mcL) and meets one of the following criteria (a or b):
       - **a)** Patient meets both of the following criteria (1 and 2):
         - **(1)** Patient has intermediate-risk or high-risk disease; AND
         - **(2)** Patient is not a candidate for transplant; OR
       - **b)** Patient meets both of the following criteria (1 and 2):
         - **(1)** Patient has lower-risk disease; AND
         - **(2)** Patient has tried at least one prior therapy; OR
           Note: Examples of prior therapy include: Jakafi (ruxolitinib tablets), Pegasys (peginterferon alfa-2a subcutaneous injection), or hydroxyurea.

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 criteria (a, b, and c):
- **a)** Patient has high-risk disease; AND
- **b)** Patient is not a candidate for transplant; AND
- **c)** Patient has tried Jakafi (ruxolitinib tablets) or Inrebic (fedratinib capsules).

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; February 2022.
2. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 2.2022 – April 13, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 1, 2022.