

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Vonjo Prior Authorization Policy

- Vonjo™ (pacritinib capsules – CTI BioPharma)

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

OVERVIEW

Vonjo, an inhibitor of Janus Associated Kinase (*JAK*) 2 and FMS-like tyrosine kinase (*FLT3*), 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 1.2022 – February 28, 2022) state that Vonjo has demonstrated significant activity resulting in $\geq 35\%$ spleen volume reduction and symptom improvement, even in patients with severe baseline cytopenias.² Vonjo could be an appropriate treatment option for patients with low platelet counts, however it is not FDA approved yet. For patients with higher-risk myelofibrosis with platelet count $< 50 \times 10^9$ /L, the guidelines recommend either allogeneic hematopoietic stem cell transplant or enrollment in a clinical trial for those who are not candidates for transplant. The guidelines recommend Jakafi® (ruxolitinib tablets) and Inrebic® (fedratinib capsules) for patients with higher-risk myelofibrosis when platelet count is $\geq 50 \times 10^9$ /L (both category 1).

POLICY STATEMENT

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

Automation: none

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has intermediate risk or high risk disease; AND
 - C) Patient has a platelet count of less than 50×10^9 /L ($< 50,000$ /mcL).
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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 1.2022 – February 28, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on March 1, 2022

Type of Revision	Summary of Changes	Review Date
New Policy	--	03/02/2022
Selected Revision	Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF: The duration of approval was changed from 3 years to 1 year.	06/22/2022