Pharmacy Policy Bulletin: J-1200 Vonjo (pacritinib) – Commercial and Healthcare Reform	
Number: J-1200	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1200-002	**Original Date:** 04/06/2022
Effective Date: 04/12/2023	**Review Date:** 04/05/2023

Drugs Product(s):	• Vonjo (pacritinib)
FDA-Approved Indication(s):	• Treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) and a platelet count below 50 x 10^9/L.

Background:	• Vonjo inhibits Janus associated kinase 2 (JAK2); JAK2 signaling regulates hematopoiesis, and MF is most often associated with JAK2 malfunction. Inhibition of JAK2 prevents this malignant signaling and theoretically reduces inappropriate hematopoiesis, anemia, and cytopenia. Vonjo also inhibits FMS-like tyrosine kinase 3 (FLT3), which contributes to hematopoiesis. This is thought to improve symptoms of MF, including anemia and splenomegaly. • MF affects approximately 21,000 individuals in the United States, and one-third of those patients are cytopenic. Cytopenia in MF is associated with an increased risk of mortality. • MF is a myeloproliferative neoplasm characterized by dysfunctional hematopoiesis and fibrosis in the bone marrow. This leads to spleen enlargement, anemia, cytopenia, and an increased production of abnormal white blood cells. Some patients with MF can be asymptomatic, but classic symptoms of anemia (pallor, fatigue, headache, and shortness of breath) present as the disease progresses. • Prescribing Considerations: o Recommended dose is 200 mg orally twice daily; may be taken with or without food. Dose modifications are made for adverse reactions, thrombocytopenia, hemorrhage, and prolonged QT interval. o Vonjo has warnings or precautions for hemorrhage, diarrhea, thrombocytopenia, prolonged QT interval, major adverse cardiac events, thrombosis, secondary malignancies, and risk of infection. o Vonjo is contraindicated for use in patients concomitantly taking a strong CYP3A4 inhibitor or inducer. Avoid use with moderate CYP3A4 inhibitors

	or inducers. Coadministration of Vonjo can alter the concentration of drugs that are P-gp, BCRP, or OCT1 substrates.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Vonjo may be approved when all of the following criteria are met **(A., B., and C.):**

A. The member is 18 years of age or older.

B. The member has a diagnosis of myelofibrosis (ICD10: D75.81) that is intermediate or high-risk.

C. The member has a platelet count of less than 50 x 10^9/L.

II. Reauthorization

When a benefit, reauthorization of Vonjo may be approved when all of the following criteria are met **(A. and B.):**

A. The prescriber attests that the member is tolerating therapy and has experienced a therapeutic response defined as one (1) of the following **(1. or 2.)**:

1. Disease improvement

2. Delayed disease progression

B. The member has a platelet count platelet count less than 50 x 10^9/L.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

IV. Coverage of oncology drug(s) listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Vonjo [package insert]. Seattle, WA: CTI BioPharma Corp.; February 2022.

2. NORD. Primary myelofibrosis. Available at: https://rarediseases.org/rare-diseases/primary-myelofibrosis/. Accessed February 7, 2023.
3. National Comprehensive Cancer Network. NCCN Guidelines Version 3.2022 Myeloproliferative neoplasms. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed February 7, 2023.