

**VONJO
(pacritinib)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Vonjo (pacritinib) is an oral kinase inhibitor with activity against wild type Janus associated kinase 2 (JAK2), mutant JAK2^{V617F}, and FMS-like tyrosine kinase 3 (FLT3), which contribute to signaling several cytokines and growth factors that are important for hematopoiesis and immune function. Myelofibrosis is often associated with dysregulated JAK2 signaling (1).

Myelofibrosis is a disease in which the bone marrow is replaced by scar tissue resulting in blood cells being made in organs such as the liver and the spleen. This disease is marked by an enlarged spleen, anemia, decreased white blood cells and platelets, and myelofibrosis-related symptoms (2).

Polycythemia vera occurs when too many red blood cells are made in the bone marrow. Patients may also experience an increase in white blood cells and platelets. An overabundance of blood cells can cause the spleen to swell, bleeding problems and blood clots in the veins near the skin surface (phlebitis). In addition, it puts patients at increased risk of stroke or heart attack (2).

Regulatory Status

FDA-approved indication: Vonjo 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 with a platelet count below $50 \times 10^9/L$ (1).

Prior to starting Vonjo, a complete blood count (CBC; including white blood cell count differential and platelet count), coagulation testing (prothrombin time, partial thromboplastin time, thrombin time, and international normalized ratio), and a baseline electrocardiogram (ECG) should be performed. These should also be monitored as clinically indicated while the patient is on treatment (1).

Vonjo should be discontinued 7 days prior to elective surgery or invasive procedures because of the risk of hemorrhage and should be restarted only after hemostasis is assured (1).

Vonjo carries warnings regarding the following: hemorrhage; diarrhea; thrombocytopenia;



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prolonged QT interval; major adverse cardiac events (MACE); thrombosis; secondary malignancies; risk of infection; and interactions with CYP3A4 inhibitors or inducers (1).

The safety and effectiveness of Vonjo in pediatric patients less than 18 years of age have not been established (1).

Summary

Vonjo (pacritinib) is an oral kinase inhibitor with activity against JAK2. Abnormal activation of JAK2 is associated with myeloproliferative neoplasms, including myelofibrosis and polycythemia vera. Vonjo carries warnings regarding the following: hemorrhage; diarrhea; thrombocytopenia; prolonged QT interval; major adverse cardiac events (MACE); thrombosis; secondary malignancies; risk of infection; and interactions with CYP3A4 inhibitors or inducers. The safety and effectiveness of Vonjo in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Vonjo while maintaining optimal therapeutic outcomes.

References

1. Vonjo [package insert]. Seattle, WA: CTI BioPharma Corp.; August 2023.
2. Clinical manifestations and diagnosis of primary myelofibrosis. UpToDate. Accessed on April 24, 2024.
3. NCCN Drugs & Biologics Compendium® Pacritinib 2024. National Comprehensive Cancer Network, Inc. Accessed on April 24, 2024.