BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.21.189

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	March 25, 2022
Subject:	Vonjo	**Page:**	1 of 4

Last Review Date: March 8, 2024

Vonjo

Description

Vonjo (pacritinib)

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 x 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; 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).

Related policies
Inrebic, Jakafi, Ojjaara

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Vonjo may be considered **medically necessary** if the conditions indicated below are met.

Vonjo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Primary myelofibrosis
2. Secondary myelofibrosis
3. Post-polycythemia vera myelofibrosis
4. Post-essential thrombocythemia myelofibrosis

AND ALL of the following:

a. Patient is considered intermediate risk or high-risk
b. Platelet count < 50 x 10^9/L
c. Prescriber agrees to perform a CBC, coagulation testing, and a baseline ECG prior to starting Vonjo
d. Prescriber agrees to counsel patient to discontinue Vonjo 7 days prior to elective surgery due to the risk of hemorrhage

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Primary myelofibrosis
2. Secondary myelofibrosis
3. Post-polycythemia vera myelofibrosis
4. Post-essential thrombocythemia myelofibrosis

AND ALL of the following:

a. Patient has had symptomatic improvement
b. Platelet count < 50 x 10^9/L
c. Prescriber agrees to counsel patient to discontinue Vonjo 7 days prior to elective surgery due to the risk of hemorrhage

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 360 capsules per 90 days

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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 January 8, 2024.
3. NCCN Drugs & Biologics Compendium® Pacritinib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2024.

Policy History

Date	Action
March 2022	Addition to PA
June 2022	Annual review and reference update
June 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.