Clinical Policy: Pacritinib (Vonjo)

Reference Number: CP.PHAR.583
Effective Date: 06.01.22
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Pacritinib (Vonjo®) is a kinase inhibitor.

FDA Approved Indication(s)

Vonjo is indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera [post-PV] or post-essential thrombocythemia [post-ET]) myelofibrosis (MF) with a platelet count below 50×10^9/L.*

**This indication is approved under accelerated approval based on spleen volume reduction. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).*

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Vonjo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Myelofibrosis (must meet all)**:**

1. Diagnosis of primary or secondary (post-PV or post-ET) MF;
2. Request meets one of the following (a or b, *see Appendix D*):
   a. Disease is lower-risk, and documentation of a recent (within the last 30 days) platelet count of $< 50 \times 10^9$/L;
   b. Disease is higher-risk;
3. Prescribed by or in consultation with a hematologist or oncologist;
4. Age ≥ 18 years;
5. For Vonjo requests, member must use pacritinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed both of the following (i and ii):
      i. 400 mg per day;
      ii. 4 capsules per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. NCCN Compendium Indications (off-label) (must meet all)**:**
1. Diagnosis of one of the following (a, b, or c):
   a. Anemia associated with myelofibrosis;
   b. Accelerated/blast phase myeloproliferative neoplasms (MPN);
   c. Myeloid, lymphoid, or mixed phenotype neoplasms with eosinophilia and JAK2 rearrangement;
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Age ≥ 18 years;
4. For myeloid, lymphoid, or mixed phenotype neoplasms, both of the following (a and b):
   a. Documentation that disease is in the chronic or blast phase;
   b. Failure of Jakafi®, unless unavailable, contraindicated, or clinically significant adverse effects are experienced;*
   **Prior authorization may be required for Jakafi*
5. For MPN, prescribed in one of the following ways (a or b):
   a. For transplant candidates, one of the following (i or ii):
      i. As a single agent near to the start of conditioning therapy for improvement of splenomegaly and other disease-related symptoms;
      ii. In combination with azacitidine or decitabine as bridging therapy;
   b. If not a candidate for transplant, in combination with azacitidine or decitabine for palliation of splenomegaly or other disease-related symptoms;
6. For Vonjo requests, member must use pacritinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed both of the following (i and ii):
      i. 400 mg per day;
      ii. 4 capsules per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line

of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Vonjo for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Vonjo requests, member must use pacritinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed both of the following (i and ii):
      i. 400 mg per day;
      ii. 4 capsules per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
MF: myelofibrosis
MPN: myeloproliferative neoplasms
post-ET: post-essential thrombocythemia
post-PV: post-polycythemia vera

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): concomitant use of strong CYP3A4 inhibitors or inducers
- Boxed warning(s): none

Appendix D: General Information

- The Dynamic International Prognostic Scoring System (DIPSS) was used in the pivotal trial for Vonjo (Persist-2) to determine disease risk. The scoring system and risk group stratification is provided below.

Prognostic Variable	Points		
	0	1	2
Age (years)	≤ 65	> 65	
White blood cell count ($x10^9$/L)	≤ 25	> 25	
Hemoglobin (g/dL)	≥ 10		< 10
Precent peripheral blood blast	< 1	≥ 1	
Constitutional symptoms (Yes or No)	No	Yes	

Risk Group	Points
Low	0
Intermediate-1 (INT-1)	1 or 2
Intermediate-2 (INT-2)	3 or 4
High	5 or 6

- The NCCN Myelofibrosis v1.2026 guideline stratifies risk for myelofibrosis into two categories, lower- and higher-risk. The categories include the following grading scales: mutation-enhanced IPSS for age ≤ 70 (MIPSS-70), mutation and karyotype-enhanced IPSS (MIPSS-70+ version 2.0) DIPSS, DIPSS-Plus and Myelofibrosis secondary to PV and ET-prognostic model (MYSEC-PM). The risk group with corresponding points scale is provided below. Please refer to the guidelines for additional details on the prognostic variables for each grading scale.

Risk Group	Points
Lower-risk	MIPSS-70 ≤ 3 MIPSS-70+ version 2.0: ≤ 3 DIPSS-Plus: ≤ 1 DIPSS: ≤ 2 MYSEC-PM: < 14
Higher-risk	MIPSS-70 ≥ 4

Risk Group	Points
	MIPSS-70+ version 2.0: ≥ 4 DIPSS-Plus: > 1 DIPSS: > 2 MYSEC-PM: ≥ 14

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MF	200 mg PO BID	400 mg/day

VI. Product Availability

Capsule: 100 mg

VII. References

1. Vonjo Prescribing Information. Seattle, WA: CTI BioPharma Corp.; October 2025. Available at: https://www.vonjohcp.com/ Accessed February 5, 2026.
2. Mascarenhas J, Hoffman R, Talpaz M, et al. Pacritinib vs best available therapy, including ruxolitinib, in patients with myelofibrosis: a randomized clinical trial. *JAMA Oncol*. 2018 May;4(5):652-659.
3. National Comprehensive Cancer Network. Myeloproliferative Neoplasms Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed February 5, 2026.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 5, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.08.22	05.22
Template changes applied to other diagnoses/indications.	10.07.22	
2Q 2023 annual review: for MF added criteria for lower-risk disease per NCCN 2A recommendation and added criteria for higher-risk disease with platelets ≥ 50 x 10^9/L per NCCN 1 recommendation; for continued therapy section updated FDA maximum dosing to mirror PI; provided details on risk stratification in Appendix D; references reviewed and updated.	02.20.23	05.23
2Q 2024 annual review: for MF, removed failure of therapeutic alternative drugs for lower-risk MF per NCCN 2A recommendation revised criteria to approve lower-risk MF with platelet count of <50 x 10^9/L, revised criteria to approve high-risk MF of any platelet count, and removed redundant intermediate risk stratification; added off-label criteria for MF-associated anemia per NCCN 2A recommendation; references reviewed and updated.	02.12.24	05.24
2Q 2025 annual review: revised section I.B title to NCCN Compendium Indications; added off-label diagnosis for	02.05.25	05.25

Reviews, Revisions, and Approvals	Date	P&T Approval Date
accelerated/blast please myeloproliferative neoplasms per NCCN; references reviewed and updated.		
2Q 2026 annual review: for NCCN compendium indications per NCCN 2A recommendation, added criteria for myeloid/lymphoid neoplasms with eosinophilia and JAK2 rearrangement, added criteria for MPN; for all indications, extended initial approval duration from 6 months to 12 months for this maintenance medication for a chronic condition; references reviewed and updated. Added ICHRA line of business.	03.31.26	05.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.