Original Effective Date: 04/28/2022
Current Effective Date: 05/22/2026
Last P&T Approval/Version: 04/29/2026
Next Review Due By: 04/2027
Policy Number: C23019-A

Vonjo (pacritinib)

PRODUCTS AFFECTED

Vonjo (pacritinib)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Cytopenic myelofibrosis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. This clinical policy will be reviewed along with state and federal requirements, the benefit being administered, and formulary preferencing. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available. The Pharmacy and Therapeutics Committee has determined that biosimilars may be preferred.

A. MYELOFIBROSIS:
1. Documented diagnosis of primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis
   AND

Molina Healthcare, Inc. confidential and proprietary © 2026
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare

2. Documentation member has intermediate or high-risk disease as defined by possessing TWO or more of the following criteria: a) Age > 65, b) documented hemoglobin < 10 g/dL, c) documented WBC >25 x 10^9/L, d) circulating blasts ≥1% OR e) presence of constitutional symptoms (weight loss >10% from baseline or unexplained fever or excessive sweats persisting for more than 1 month)
   AND
3. Documentation of baseline complete blood count (CBC) with platelet count below 50 x 10^9/L
   AND
4. Documentation member has splenomegaly based on palpable spleen length or spleen volume [DOCUMENTATION REQUIRED]
   AND
5. Documentation that member is ineligible for allogeneic hematopoietic cell transplantation (HCT)
   AND
6. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review. [Contraindications to Vonjo (pacritinib) include: Concomitant use of strong or moderate CYP3A4 inhibitors or inducers, avoid use in patients with active bleeding, avoid use in patients with baseline QTc >480 msec, delay starting therapy until active serious infection have resolved, avoid concomitant use of sensitive substrates of P- gp, BCRP, OCTI, avoid use In patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment, avoid use in patients with eGFR <30 ml/min]

CONTINUATION OF THERAPY:

A. MYELOFIBROSIS:

1. Documentation member has not had a splenectomy
   AND
2. Documentation of a positive response to treatment with a reduction in spleen volume from pretreatment baseline as measured by CT or MRI [DOCUMENTATION REQUIRED]
   AND
3. Adherence to therapy at least 85% of the time as verified by the prescriber or member's medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation, or held for toxicity

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a hematologist or oncologist, or transplant specialist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

200mg orally twice daily

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral

HIGH RISK ALERT

Molina Healthcare, Inc. confidential and proprietary © 2026
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare

DRUG CLASS:
Janus Associated Kinase (JAK) Inhibitors

FDA-APPROVED USES:
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.

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).

COMPENDIAL APPROVED OFF-LABELED USES:
Low risk, symptomatic Myelofibrosis (NCCN Myeloproliferative Neoplasms Version 1.2026 MF-1), Myeloid/ lymphoid neoplasms with eosinophilia and JAK2 rearrangement (NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Version 1.2026 MLNE-8)

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Myelofibrosis (MF) is a type of myeloproliferative neoplasm (MPN). Symptoms of MPN often include constitutional symptoms, fatigue, pruritis, weight loss, symptoms from splenomegaly, and variable lab abnormalities including erythrocytosis, thrombocytosis, and leukocytosis. The mutations most likely involved in patients with MPN are JAK2, CALR, and MPL mutations.

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 both contribute to signaling of several cytokines and growth factors that are important for hematopoiesis and immune function.
Myelofibrosis is often associated with dysregulated JAK2 signaling. Pacritinib has higher affinity for JAK2 compared to JAK3 and TYK2. At clinically relevant concentrations, if does not have affinity for JAK1 thereby causing less myelosuppression.

The accelerated approval of pacritinib for MF is based on results from the Phase 3 PERSIST-2 trial where 29% of patients with intermediate- or high-risk MF with splenomegaly and platelets below 50 x 10^9/L had a 35% reduction in spleen volume compared to 3% of patients receiving best available therapy. There was no statistically significant difference in overall survival between treatment arms
in the study. The most commonly reported nonhematological adverse events (≥15%) were gastrointestinal, fatigue, peripheral edema, and dizziness. The majority of common nonhematologic adverse events were grade 1 or 2 in severity. Diarrhea was the most frequently observed adverse event (53%) and most often occurred in weeks 1 to 8. The most common adverse events leading to discontinuation were thrombocytopenia (pacritinib once daily [not approved] 4%), and anemia (pacritinib twice daily 3%). The rate of study death was lowest with pacritinib twice daily (6%) compared to BAT (9%) and pacritinib once daily [not approved] (14%).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Vonjo (pacritinib) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Vonjo (pacritinib) include: Concomitant use of strong or moderate CYP3A4 inhibitors or inducers, avoid use in patients with active bleeding, avoid use in patients with baseline QTc >480 msec, delay starting therapy until active serious infection have resolved, avoid sensitive substrates of P-gp, BCRP, OCTI, avoid use in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment, avoid use in patients with eGFR <30 ml/min.

Molina Healthcare, Inc. confidential and proprietary © 2026
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare

Exclusion/Discontinuation:
Members who are on treatment with other kinase inhibitors before the initiation of Vonjo must taper or discontinue according to the prescribing information for that drug. Discontinue Vonjo in patients unable to tolerate a dose of 100 mg daily. Initiation of contraindicated CYP3A4 inhibitor or inducer.

OTHER SPECIAL CONSIDERATIONS:
Dose modification should be used for diarrhea, thrombocytopenia, hemorrhage, and prolonged QT interval. Dose levels are: 200mg twice daily (initial starting dose), 100mg twice daily (first dose reduction), 100mg once daily (second dose reduction). Vonjo should be discontinued in patients unable to tolerate a dose of 100mg once daily.

Perform 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), prior to starting Vonjo, and monitor as clinically indicated while the patient is on treatment.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Vonjo CAPS 100MG

REFERENCES

1. Vonjo (pacritinib) capsules, for oral use [prescribing information]. Seattle, WA: CTI BioPharma Corp.; October 2025.
2. Mesa, R., Vannucchi, A., Mead, A., Egyed, M., Szoke, A., Suvorov, A., Jakucs, J., Perkins, A., Prasad, R., Mayer, J., Demeter, J., Ganly, P., Singer, J., Zhou, H., Dean, J., te Boekhorst, P., Nangalia, J., Kiladjian,
J. and Harrison, C., 2017. Pacritinib versus best available therapy for the treatment of myelofibrosis irrespective of baseline cytopenias (PERSIST-1): an international, 9andomized, phase 3 trial. The Lancet Haematology, 4(5), pp.e225-e236.
3. Mascarenhas, J., Hoffman, R., Talpaz, M., Gerds, A., Stein, B., Gupta, V., Szoke, A., Drummond, M., Pristupa, A., Granston, T., Daly, R., Al-Fayoumi, S., Callahan, J., Singer, J., Gotlib, J., Jamieson, C., Harrison, C., Mesa, R. and Verstovsek, S., 2018. Pacritinib vs Best Available Therapy, Including Ruxolitinib, in Patients With Myelofibrosis. JAMA Oncology, 4(5), p.652.
4. Gerds, A., Savona, M., Scott, B., Talpaz, M., Egyed, M., Harrison, C., Yacoub, A., Vannucchi, A., Mead, A., Kiladjian, J., O'Sullivan, J., García-Gutiérrez, V., Bose, P., Rampal, R., Miller, C., Palmer, J., Oh, S., Buckley, S., Mould, D., Ito, K., Tyavanagimatt, S., Smith, J., Roman-Torres, K., Devineni, S., Craig, A.

Molina Healthcare, Inc. confidential and proprietary © 2026
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare

and Mascarenhas, J., 2020. Determining the recommended dose of pacritinib: results from the PAC203 dose-finding trial in advanced myelofibrosis. Blood Advances, 4(22), pp.5825- 5835.
5. NCCN Clinical Practice Guidelines in Oncology (Myeloproliferative Neoplasms (Version 1.2022). Retrieved 1 April 2022, from https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf.
6. National Comprehensive Cancer Network. 2023. Myeloproliferative Neoplasms (Version 3.2022). [online] Available at: < mpn.pdf (nccn.org) > [Accessed 2 April 2023].
7. National Comprehensive Cancer Network. 2024. Myeloproliferative Neoplasms (Version 1.2024). [online] Available at: < mpn.pdf (nccn.org) > [Accessed 10 April 2024].
8. National Comprehensive Cancer Network. 2025. Myeloproliferative Neoplasms (Version 1.2025). [online] Available at: < mpn.pdf (nccn.org) > [Accessed 8 April 2025].
9. National Comprehensive Cancer Network. 2026. Myeloproliferative Neoplasms (Version 1.2026). [online] Available at: < mpn.pdf (nccn.org) > [Accessed 7 April 2026].

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION-Notable revisions: Required Medical Information Duration of Approval Compendial Approved Off-Labeled Uses References	Q2 2026
REVISION-Notable revisions: Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q2 2025
REVISION-Notable revisions: Required Medical Information Continuation of Therapy Compendial Approved Off- Labeled Uses Contraindications References	Q2 2024
REVISION-Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements References	Q2 2023
NEW CRITERIA CREATION	Q2 2022

HIGH RISK ALERT

Molina Healthcare, Inc. confidential and proprietary © 2026
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare