Clinical Policy: Pacritinib (Vonjo)

Reference Number: ERX.SPA.472
Effective Date: 06.01.22
Last Review Date: 05.22
Line of Business: Commercial, 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 or post-essential thrombocythemia) 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Vonjo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) MF;
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Age ≥ 18 years;
4. Documentation of a recent (within the last 30 days) platelet count of < 50 × 10^9/L;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 400 mg (4 capsules) per day;
   b. Dose is supported by practice guideline 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:
Commercial – Length of Benefit
Medicaid – 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, 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. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 400 mg (4 capsules) per day;
   b. New dose is supported by practice guideline 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:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MF: myelofibrosis

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

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.; February 2022. Available at: https://www.ctibiopharma.com/wp-content/uploads/2022/03/VONJO_PI_02-2022.pdf. Accessed March 3, 2022.
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 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed March 3, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.08.22	05.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.