Vonjo (pacritinib)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Vonjo (pacritinib) drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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.

Compendial Uses

1. Symptomatic low-risk MF with a platelet count <50 × 10^9/L
2. Symptomatic high-risk MF with a platelet count ≥50 × 10^9/L
3. Symptomatic accelerated phase or blast phase myelofibrosis/acute myeloid leukemia

POLICY

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Pretreatment platelet count

Criteria for Initial Approval

Myelofibrosis/Acute Myeloid Leukemia

Authorization of 12 months may be granted for the treatment myelofibrosis/acute myeloid leukemia when any of the following criteria are met:

1. Member has a platelet count of $<50 \times 10^9$/L and any of the following:
   a. Symptomatic low-risk MF and has failed treatment with ruxolitinib, peginterferon alfa-2a, or hydroxyurea
   b. Intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) MF
2. Member has a platelet count of $\geq 50 \times 10^9$/L, symptomatic disease (e.g., splenomegaly and other disease-related symptoms) and any of the following:
   a. High-risk MF and is a candidate for transplant
   b. High-risk MF, is not a candidate for transplant, and has failed one prior JAK inhibitor (e.g., ruxolitinib or fedratinib)
   c. High-risk MF-associated anemia and is not a candidate for transplant
3. Member has symptomatic accelerated phase or blast phase myelofibrosis/acute myeloid leukemia

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Criteria for Initial Approval when there is no evidence of unacceptable toxicity and there has been an improvement in symptoms while on the current regimen.

Vonjo (pacritinib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Quantity Limit	FDA-recommended dosing
Vonjo (pacritinib) 100 mg capsules	120 per 30 days	Initial dose: 200 mg orally twice daily Dose adjustments are recommended for adverse reactions.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

1. Vonjo [package insert]. Seattle, WA: CTI BioPharma Corp.; February 2022.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 3, 2022.

POLICY HISTORY

Policy #: 05.04.67
Original Effective Date: September 2, 2022
Reviewed: October 2022
Revised:
Current Effective Date: September 2, 2022