PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Vonjo Prior Authorization Policy
- Vonjo™ (pacritinib capsules – CTI BioPharma/Sobi)

REVIEW DATE: 02/07/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Vonjo, an inhibitor of Janus Associated Kinase (JAK)2 and FMS-like tyrosine kinase, is indicated for the treatment of intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 10^9/L in adults.

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for myeloproliferative neoplasms (version 1.2024 – December 21, 2023) classify risk stratification into two groupings: lower-risk disease and higher-risk disease.[2] NCCN guidelines recommend Vonjo for symptomatic lower-risk myelofibrosis if platelet count is < 50 × 10^9/L (category 2A) as "Useful in Certain Circumstances.". In this setting, Vonjo can also be used if the patient did not have a response or loss of response to initial therapy (e.g. Jakafi® [ruxolitinib tablets], Pegasys® [peginterferon alfa-2a subcutaneous injection], Ojjaara™ (momelotinib tablets), hydroxyurea if not previously used) [category 2A]. Vonjo is also recommended as "Preferred Regimen" for higher-risk myelofibrosis if the patient is not a transplant candidate or transplant is not currently feasible and platelet count is < 50 × 10^9/L (category 1). Vonjo is also recommended for higher-risk myelofibrosis if platelet count is ≥ 50 × 10^9/L as initial therapy (category 2B) or in situations where the patient did not respond to or lost response

to an alternative prior JAK inhibitor (Jakafi, Inrebic® [fedratinib capsules], or Ojjaara) [category 2B].[2] Vonjo is also recommended for the management of myelofibrosis-associated anemia with symptomatic splenomegaly and/or constitutional symptoms (category 2A) or without symptomatic splenomegaly and/or constitutional symptoms (category 2B).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Vonjo. All approvals are provided for the duration noted below.

- **Vonjo™ (pacritinib capsules (CTI BioPharma/Sobi)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Myelofibrosis.** Approve for 1 year if the patient meets the following (A and B):
   Note: This includes Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis, and Post-Essential Thrombocythemia Myelofibrosis
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets one of the following (i, ii or iii):
     - **i.** Patient has a platelet count of less than 50 × 10^9/L (< 50,000/mcL) and meets one of the following (a or b):
       - **a)** Patient meets both of the following (1 and 2):
         - **(1)** Patient has intermediate-risk or high-risk disease; AND
         - **(2)** Patient is not a candidate for transplant; OR
       - **b)** Patient has lower-risk disease; OR
     - **ii.** Patient has a platelet count of greater than or equal to 50 × 10^9/L (≥ 50,000/mcL) and meets all of the following (a, b, and c):
       - **a)** Patient has high-risk disease; AND
       - **b)** Patient is not a candidate for transplant; AND
       - **c)** Patient has tried Jakafi (ruxolitinib tablets), Inrebic (fedratinib capsules), or Ojjaara (momelotinib tablets); OR
     - **iii.** Patient has myelofibrosis-associated anemia with symptomatic splenomegaly and/or constitutional symptoms.

CONDITIONS NOT COVERED

Vonjo™ (pacritinib capsules (CTI BioPharma/Sobi)
is(are) considered experimental, investigational or unproven for ANY other use(s).

REFERENCES

1. Vonjo™ capsules [prescribing information]. Seattle, WA: CTI BioPharma; August 2023.
2. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 31, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/22/2023
Early Annual Revision	**Myelofibrosis**: The qualifier of "Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis, and Post-Essential Thrombocythemia Myelofibrosis" was removed from the condition of approval and added as a Note. For a patient with a platelet count of less than 50 × 10^9/L (< 50,000/mcL) and lower-risk disease, the requirement that "patient has tried one prior therapy" with the Note of examples of prior therapy were removed. The following was added as an option for approval, "Patient has myelofibrosis-associated anemia with symptomatic splenomegaly and/or constitutional symptoms."	02/07/2024