PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Vonjo Prior Authorization Policy
- Vonjo® (pacritinib capsules – Sobi)

REVIEW DATE: 02/11/2026

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.[1]

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).

Guidelines

Vonjo is discussed in the guidelines from the National Comprehensive Cancer Network (NCCN):

- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions:** NCCN guidelines (version 1.2026 – October 3, 2025) state to

consider Vonjo for the treatment of myeloid/lymphoid neoplasms with eosinophilia and *JAK2* rearrangement in chronic or blast phase [2] The guidelines also state to consider treatment in combination with acute lymphoblastic leukemia (ALL)- or acute myeloid leukemia (AML)-type induction chemotherapy, and followed by allogeneic hematopoietic cell transplant (HCT) [if eligible] for lymphoid, myeloid or mixed phenotype neoplasms with eosinophilia and *JAK2* rearrangement in blast phase. These recommendations are specifically for unavailability or intolerance to Jakafi® (ruxolitinib tablets), according to prescribing instructions (both category 2A).

- **Myeloproliferative Neoplasms**: NCCN guidelines (version 1.2026 – January 22, 2026) classify risk stratification for myelofibrosis into two groupings: lower-risk disease and higher-risk disease.[2] NCCN guidelines recommend Vonjo for symptomatic lower-risk myelofibrosis if platelet count is $< 50 \times 10^9$/L as "useful in certain circumstances" (category 2A). 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], or 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 $< 50 \times 10^9$/L (category 1). Vonjo is also recommended for higher-risk myelofibrosis if platelet count is $\geq 50 \times 10^9$/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]. 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). Vonjo is also recommended for accelerated/blast phase myeloproliferative neoplasm for the palliation of splenomegaly or disease-related symptoms (category 2A). Some examples of disease-related symptoms of myeloproliferative neoplasms include fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis.

POLICY STATEMENT

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

- **Vonjo® (pacritinib capsules - 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 BOTH of 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 has higher-risk disease; OR
  - **b)** Patient meets BOTH of the following (1 and 2):
    - **(1)** Patient has lower-risk disease; AND
    - **(2)** Patient has at least one disease-related symptom; OR
      Note: Examples of disease-related symptoms include: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis.
- **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 and b):
  - **a)** Patient has higher-risk disease; AND
  - **b)** Patient has at least one disease-related symptom; OR
    Note: Examples of disease-related symptoms include: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis.
- **iii.** Patient has myelofibrosis-associated anemia.

Other Uses with Supportive Evidence

2. **Accelerated or Blast Phase Myeloproliferative Neoplasm**. Approve for 1 year if the patient meets BOTH of the following (A and B)
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has at least one disease-related symptom.
     Note: Examples of disease-related symptoms include: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis.

3. **Myeloid or Lymphoid Neoplasms.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has eosinophilia; AND
   - **C)** The tumor has a Janus Associated Kinase 2 (*JAK2)* rearrangement; AND
   - **D)** Patient has tried Jakafi (ruxolitinib tablets).

CONDITIONS NOT COVERED

- **Vonjo® (pacritinib capsules - Sobi)**

is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Vonjo® capsules [prescribing information]. Waltham, MA: Sobi; November 2024.
2. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 1.2026 – October 3, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed February 2, 2026.
3. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 1.2026 – January 22, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 2, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
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
Selected Revision	**Myelofibrosis:** In high risk disease and platelet count greater than or equal to 50 x 10^9/L, added criterion that patient has symptomatic splenomegaly and/or constitutional symptoms. Deleted criterion referring to previous trial of other therapies. For myelofibrosis-associated anemia criterion, deleted qualifier "…with symptomatic splenomegaly and/or constitutional symptoms."	12/11/2024
Annual Revision	**Myelofibrosis:** For a patient with platelet count of less than 50 × 10^9/L (< 50,000/mcL), the qualifier of "intermediate-risk or high-risk disease" was changed to "higher-risk disease"; the qualifier that the patient is not a candidate for transplant was removed; and for a patient with lower-risk disease, the requirement that the patient has at least one disease-related symptom with a note of examples of disease-related symptoms was added. For a patient with a platelet count of greater than or equal to 50 × 10^9/L (≥ 50,000/mcL), the qualifier that the patient has "high-risk disease" was changed to "higher-risk disease"; the qualifier that the patient is not a candidate for transplant was removed; the qualifier that the patient has "symptomatic splenomegaly and/or constitutional symptoms" was reworded to "patient has at least one disease-related symptom" with a note of examples of disease-related symptoms. **Accelerated or Blast Phase Myeloproliferative Neoplasm:** Condition of approval and criteria were added to "Other Uses with Supportive Evidence."	02/19/2025
Annual Revision	**Myeloid or Lymphoid Neoplasms:** Condition of approval and criteria were added to "Other Uses with Supportive Evidence."	02/11/2026