VONJO®
(pacritinib) capsules

Getting Started With VONJO® (pacritinib)

INDICATION

VONJO® (pacritinib) is a kinase inhibitor indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera [PPV] or post-essential thrombocythemia [PET]) 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).

IMPORTANT SAFETY INFORMATION

Contraindication

VONJO is contraindicated in patients concomitantly using strong CYP3A4 inhibitors or inducers.

Please see additional Important Safety Information throughout and the full Prescribing Information for VONJO.

Accessing VONJO® (pacritinib)

VONJO Coverage

VONJO is covered nationwide, available for **[96%]** of Commercial and **[100%]** of Medicare-insured patients.[1]

VONJO has national coverage, with the majority of plans covering it with a prior authorization (PA) per the Prescribing Information or following clinical practice guidelines.[1]

Based on specialty pharmacy data, VONJO prescriptions are successfully filled over **[80%]** of the time with Commercial insurance and over **[90%]** of the time with Medicare.[2]

Sobi is here to support the process of getting started with VONJO. For more information, call VONJO Connect™ at **1-888-284-3678**, visit **VonjoConnectUS.com**, or contact your Field Reimbursement Manager (FRM).

VONJO Connect Overview

VONJO Connect offers access and reimbursement support to help patients access VONJO. VONJO Connect can provide information and evaluate a patient's eligibility for the following programs:

- The **VONJO Copay Assistance Program*** is for eligible patients with commercial prescription insurance. Patients may pay as little as $25 per prescription fill, up to a maximum benefit of $25,000 for a twelve-month period.
- The **VONJO Patient Assistance Program** (PAP),† which provides VONJO at no cost to patients that meet the PAP eligibility requirements.
- The **VONJO QuickStart Program,**† which provides a limited supply of VONJO, at no cost, to eligible, new patients experiencing an insurance-related delay in coverage.
- The **VONJO Bridge Program,**† which provides a limited supply of VONJO, at no cost, to eligible patients experiencing a gap in coverage for VONJO.

*In order to participate in the VONJO Copay Assistance Program ("Program"), a patient must have commercial insurance for VONJO. This Program is not valid for patients whose prescription claims are reimbursed, in whole or in part, by any state or federal government program, including (but not limited to) Medicaid, Medicare, Medigap, Department of Defense (DoD), Veterans Affairs (VA), TRICARE, Puerto Rico Government Insurance, or any state patient or pharmaceutical assistance program. This offer is not valid for patients paying with cash. The Program is void where prohibited by law. Certain rules and restrictions apply. Sobi reserves the right to revoke, rescind, or amend this offer without notice. This Program is not insurance.

†Program subject to eligibility requirements and program terms and conditions.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions:

- **Hemorrhage:** Serious (11%) and fatal (2%) hemorrhages have occurred in VONJO-treated patients with platelet counts <100 x 10^9/L. Serious (13%) and fatal (2%) hemorrhages have occurred in VONJO-treated patients with platelet counts <50 x 10^9/L. Grade ≥3 bleeding events (defined as requiring transfusion or invasive intervention) occurred in 15% of patients treated with VONJO compared to 7% of patients treated on the control arm. Due to hemorrhage, VONJO dose reductions, dose interruptions, or permanent discontinuations occurred in 3%, 3%, and 5% of patients, respectively.

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When an appropriate patient is prescribed VONJO, follow these steps to initiate treatment

1 COMPLETE THE REFERRAL PROCESS

Follow one of the processes below

Option 1: Referral to VONJO Connect™

- Enroll a patient in VONJO Connect

Enroll patients directly online	Download and complete the Prescription and Enrollment Form and fax it to 1-888-284-8084 or email it to VonjoConnect@assistrx.com	Call VONJO Connect at 1-888-284-3678
Enroll Now	Download Here	

Some VONJO Connect forms can be accessed directly from select electronic health records. Check your EMR system to see if this option is available.

- VONJO Connect will perform a benefits investigation, identify the appropriate specialty pharmacy if required by the payer, and send a Summary of Benefits identifying any PA requirements as well as the appropriate PA form, when applicable.

Complete the PA form by adding the necessary clinical information, then sign and submit the form to the payer. VONJO Connect will follow up with the payer until the PA is approved, or the payer issues a denial.*

-OR-

Option 2: Referral to Specialty Pharmacy

- If not using VONJO Connect, please follow the steps below:
  - Conduct a benefits investigation.
  - Contact the plan to obtain any PA requirements and the appropriate PA form, when applicable.
  - Send the prescription to an internal pharmacy or an external contracted pharmacy for dispensing.

For information about the PA process, please contact your FRM and/or consult the **Prior Authorization Guide**.

*When the patient is enrolled in VONJO Connect. The VONJO Connect Enrollment Form can be found at **https://www.vonjohcp.com/**.

EMR=electronic medical record.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd):

- **Hemorrhage (cont'd):** Avoid use of VONJO in patients with active bleeding and hold VONJO 7 days prior to any planned surgical or invasive procedures. Assess platelet counts periodically, as clinically indicated. Manage hemorrhage using treatment interruption and medical intervention.

Please see additional Important Safety Information throughout and the full Prescribing Information for VONJO.

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Getting Started With VONJO® (pacritinib) (continued)

2 OBTAIN A DECISION

After receiving a PA decision, follow your office's dispensing protocol unless otherwise mandated by the payer.

PA Approval

- Communicate the approval to the patient.
- If the PA is approved, triage the prescription according to your office protocols or payer mandates. If the patient is enrolled in the HUB, VONJO Connect™ will triage on your behalf.

In the Case of a Denial

- Review the denial letter from the patient's plan to determine the reason and next steps.
  - In the case of an **administrative denial,** resubmit the request with complete and accurate information and use the proper PA submission method.
  - In the case of a **clinical denial,** submit an appeal using a letter of medical necessity or, in case of further denial, request a peer-to-peer discussion with a clinical representative or medical director at the health plan.

A letter of medical necessity should include background on your patient's condition, clinical validation, and patient-specific reasons for selecting VONJO, specific criteria your patient meets according to the health plan's medical policy and clinical guidelines, and additional documentation and literature to strengthen your request. **Click here** for a sample letter of medical necessity.

VONJO Connect and/or your FRM can provide examples of templates to help you with the denial and appeal process.*

*When the patient is enrolled in VONJO Connect. The VONJO Connect Enrollment Form can be found at **https://www.vonjohcp.com/**.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd):

- **Diarrhea:** VONJO caused diarrhea in approximately 48% of patients compared to 15% of patients treated on the control arm in clinical trials. The median time to resolution in VONJO-treated patients was 2 weeks. The incidence of reported diarrhea decreased over time with 41% of patients reporting diarrhea in the first 8 weeks of treatment, 15% in Weeks 8 through 16, and 8% in Weeks 16 through 24. Diarrhea resulted in treatment interruption in 3% of VONJO-treated patients. Serious diarrhea adverse reactions occurred in 2% of patients treated with VONJO compared to no such adverse reactions in patients in the control arm. In postmarketing reports, severe diarrhea leading to acute kidney injury and treatment discontinuation has been reported with VONJO.

  Control preexisting diarrhea before starting VONJO treatment. Manage diarrhea with antidiarrheal medications, fluid replacement, and dose modification. Upon initiation of therapy, prescribe an anti-diarrheal medication (e.g., loperamide) and instruct patient to treat diarrhea promptly at the first onset of symptoms (change in frequency or consistency of bowel movements) after starting VONJO. Interrupt or reduce VONJO dose in patients with significant diarrhea despite optimal supportive care.

Please see additional Important Safety Information throughout and the full Prescribing Information for VONJO.

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Getting Started With VONJO® (pacritinib) (continued)

3 ORDERING VONJO AFTER PA APPROVAL

Dispensing Options

The VONJO network gives providers and patients multiple dispensing options:

- Send the VONJO prescription to your in-office dispensing pharmacy using your standard dispensing process.
- Send the VONJO prescription to one of the specialty pharmacies in the VONJO network (Onco360 & Biologics), based on payer requirements.
- Alternatively, if you enrolled the patient in the HUB and there is no payer-mandated specialty pharmacy, VONJO Connect™ will triage the prescription to one of the specialty pharmacies in the VONJO network.

For more information about ordering VONJO, please consult the **Distribution and Access Leave Behind**.

Prior to Shipment

- The specialty pharmacy must speak with the patient or caregiver prior to shipment. The patient or caregiver should answer or return the call as soon as possible to avoid delays.
  - The patient or caregiver should inform their provider if the specialty pharmacy makes any changes.
  - In some cases, the office may need to notify the specialty pharmacy of PA approval prior to each shipment.

4 CONTINUUM OF CARE

Re-Authorization and Ongoing Therapy

- Follow the payer-specific PA requirements for each fill.
- Help with coordination between the specialty pharmacy and patients.

Review the plan's policy and resubmit PA forms as needed for reauthorization.

For more information, call VONJO Connect at **1-888-284-3678** or visit **VonjoConnectUS.com**

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd):

- **Thrombocytopenia:** VONJO can cause worsening thrombocytopenia. VONJO dosing was reduced due to worsening thrombocytopenia in 2% of patients with preexisting moderate to severe thrombocytopenia (platelet count <100 x 10^9/L). VONJO dosing was reduced due to worsening thrombocytopenia in 2% of patients with preexisting severe thrombocytopenia (platelet count <50 x 10^9/L).

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Preparing for VONJO® (pacritinib)

Pre-treatment considerations

Laboratory monitoring[3]:

- Complete blood count (including white blood cell count differential and platelet count)
- Coagulation testing (prothrombin time, partial thromboplastin time, thrombin time, and international normalized ratio)
- Baseline ECG
- Monitor as clinically indicated while the patient is on treatment.

Dose interruption for planned surgery[3]:

- Stop VONJO 7 days before elective surgery or invasive procedures because of the risk of hemorrhage, and resume only after hemostasis is assured.

Drug interactions[3]:

- Co-administration of VONJO with strong CYP3A4 inhibitors or inducers is contraindicated. Co-administration of VONJO with moderate CYP3A4 inhibitors can increase the exposure to VONJO.

Hepatic impairment[3]:

- For patients with severe hepatic impairment (Child-Pugh C), the recommended dosage is 100 mg, twice daily.

Renal impairment[3]:

- Avoid use of VONJO in patients with eGFR <30 mL/min.

Transitioning patients from other JAK inhibitors:

- In PERSIST-2, VONJO was initiated within 1 week after discontinuing previous MF therapy.[4]
- Before transitioning from another JAK inhibitor, taper or discontinue treatment according to the Prescribing Information prior to starting VONJO.[3]

ECG=electrocardiogram; eGFR=estimated glomerular filtration rate; JAK=Janus kinase; MF=myelofibrosis.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd):

- **Thrombocytopenia (cont'd):** Monitor platelet count prior to VONJO treatment and as clinically indicated during treatment. Interrupt VONJO in patients with clinically significant worsening of thrombocytopenia that lasts for more than 7 days. Restart VONJO at 50% of the last given dose once the toxicity has resolved. If toxicity recurs, hold VONJO. Restart VONJO at 50% of the last given dose once the toxicity has resolved.

Please see additional Important Safety Information throughout and the full Prescribing Information for VONJO.

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Managing Common Side Effects

To avoid treatment disruption, please familiarize yourself with some of the common side effects of VONJO® (pacritinib) and be prepared to manage them appropriately.

Dose Modifications for Common Adverse Reactions

Diarrhea[3]

Most cases of diarrhea in PERSIST-2 with VONJO were low grade, rarely led to treatment interruption (3%), and typically resolved in 2 weeks.

Upon initiation, prescribe an anti-diarrheal medication (eg, loperamide) and instruct the patient to treat diarrhea promptly at the first onset of symptoms (change in frequency or consistency of bowel movements). Interrupt or reduce VONJO dose in patients with significant diarrhea despite optimal supportive care, including fluid replacement.

DOSE MODIFICATION FOR DIARRHEA

Toxicity	Management
New onset of diarrhea	▪ Initiate anti-diarrheal medications. ▪ Encourage adequate oral hydration.
Grade 3 or 4*	▪ Hold VONJO until the diarrhea resolves to Grade 1† or lower or baseline. Restart VONJO at the last given dose. ▪ Intensify anti-diarrheal regimen. Provide fluid replacement. ▪ If diarrhea recurs, hold VONJO until the diarrhea resolves to Grade 1† or lower or baseline. Restart VONJO at 50% of the last given dose once the toxicity has resolved. ▪ Concomitant anti-diarrheal treatment is required for patients restarting VONJO.

Thrombocytopenia[3]

Monitor platelet count prior to VONJO treatment and as clinically indicated.

DOSE MODIFICATION FOR THROMBOCYTOPENIA

Worsening Thrombocytopenia	Action
For clinically significant worsening of thrombocytopenia that lasts more than 7 days	▪ Hold VONJO. Restart VONJO at 50% of the last given dose once the toxicity as resolved. ▪ If toxicity recurs, hold VONJO. Restart VONJO at 50% of the last given dose once the toxicity has resolved.

*Increase of at least 7 stools per day over baseline, hospitalization indicated, severe increase in ostomy output over baseline, or if limiting self-care.[3]
†Increase of <4 stools per day over baseline or mild increase in ostomy output compared with baseline.[3]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd):

- **Prolonged QT Interval:** VONJO can cause prolongation of the QTc interval. QTc prolongation of >500 msec was higher in VONJO-treated patients than in patients in the control arm (1.4% vs 1%). QTc increase from baseline by 60 msec or higher was greater in VONJO-treated patients than in control arm patients (1.9% vs 1%). Adverse reactions of QTc prolongation were reported for 3.8% of VONJO-treated patients and 2% of control arm patients. No cases of torsades de pointes were reported.

  Avoid use of VONJO in patients with a baseline QTc of >480 msec. Avoid use of drugs with significant potential for QTc prolongation in combination with VONJO. Correct hypokalemia prior to and during VONJO treatment. Manage QTc prolongation using VONJO interruption and electrolyte management.

Please see additional Important Safety Information throughout and the full Prescribing Information for VONJO.

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Managing Common Side Effects (continued)

Dose Modifications for Common Adverse Reactions (continued)

Hemorrhage[3]

Avoid use of VONJO® (pacritinib) in patients with active bleeding and hold VONJO 7 days prior to planned surgical or invasive procedures. Assess platelet counts periodically, as clinically indicated. Manage hemorrhage using treatment interruption and medical intervention.

DOSE MODIFICATION FOR HEMORRHAGE

Toxicity	Action
Moderate bleeding; intervention indicated	▪ Hold VONJO until hemorrhage resolves. Restart VONJO at the last given dose. ▪ If hemorrhage recurs, hold VONJO until resolution then restart at 50% of the last given dose.
Severe bleeding; transfusion, invasive intervention, or hospitalization indicated	▪ Hold VONJO until hemorrhage resolves. ▪ Restart VONJO at 50% of the last given dose. ▪ If bleeding recurs, discontinue VONJO.
Life-threatening bleeding; urgent intervention indicated	▪ Discontinue VONJO.

QT Prolongation[3]

Avoid use of VONJO in patients with a baseline QTc of >480 msec. Avoid use of drugs with significant potential for QTc prolongation in combination with VONJO. Correct hypokalemia prior to and during VONJO treatment. Manage QTc prolongation using VONJO interruption and electrolyte management.

DOSE MODIFICATION FOR PROLONGED QT INTERVAL

Toxicity	Action
QTc prolongation >500 msec or >60 msec from baseline	▪ Hold VONJO. ▪ If QTc prolongation resolves to ≤480 msec or baseline within 1 week, restart VONJO at the same dose. ▪ If time to resolution is greater than 1 week, restart VONJO at a reduced dose.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd):

- **Major Adverse Cardiac Events (MACE):** Another Janus associated kinase (JAK)-inhibitor has increased the risk of MACE, including cardiovascular death, myocardial infarction, and stroke (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which VONJO is not indicated.

  Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with VONJO particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur.

- **Thrombosis:** Another JAK-inhibitor has increased the risk of thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which VONJO is not indicated.

  Patients with symptoms of thrombosis should be promptly evaluated and treated appropriately.

- **Secondary Malignancies:** Another JAK-inhibitor has increased the risk of lymphoma and other malignancies excluding non-melanoma skin cancer (NMSC) (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which VONJO is not indicated. Patients who are current or past smokers are at additional increased risk.

  Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with VONJO, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

Please see additional Important Safety Information throughout and the full Prescribing Information for VONJO.

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Indication and Important Safety Information (cont'd)

Warnings and Precautions (cont'd):

- **Risk of Infection:** Another JAK-inhibitor increased the risk of serious infections (compared to best available therapy) in patients with myeloproliferative neoplasms. Serious bacterial, mycobacterial, fungal, and viral infections may occur in patients treated with VONJO. Delay starting therapy with VONJO until active serious infections have resolved.

  Observe patients receiving VONJO for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines.

- **Interactions With CYP3A4 Inhibitors or Inducers:** Coadministration of VONJO with strong CYP3A4 inhibitors or inducers is contraindicated. Monitor for increased adverse reactions of VONJO when administered with moderate CYP3A4 inhibitors.

Adverse Reactions

The most frequent serious adverse reactions occurring in ≥3% patients receiving VONJO 200 mg twice daily were anemia (8%), thrombocytopenia (6%), pneumonia (6%), cardiac failure (4%), disease progression (3%), pyrexia (3%), and squamous cell carcinoma of skin (3%).

Fatal adverse reactions among patients treated with VONJO 200 mg twice daily included events of disease progression (3%), and multiorgan failure, cerebral hemorrhage, meningorrhagia, and acute myeloid leukemia in <1% of patients, respectively.

The most common adverse reactions (reported in ≥20% of patients) include diarrhea, thrombocytopenia, nausea, anemia, and peripheral edema.

Specific Populations

Pregnancy: Advise pregnant women of the potential risk to a fetus. Consider the benefits and risks of VONJO for the mother and possible risks to the fetus when prescribing VONJO to a pregnant woman.

Lactation: It is not known whether VONJO is excreted in human milk. Because of the potential for serious adverse reactions in the breastfed child, advise patients that breastfeeding is not recommended during treatment with VONJO, and for 2 weeks after the last dose.

Infertility: Pacritinib reduced male mating and fertility indices in BALB/c mice. Pacritinib may impair male fertility in humans.

Hepatic Impairment: The recommended starting dose of VONJO in patients with severe hepatic impairment [Child-Pugh C] is 100 mg twice daily.

Renal Impairment: Avoid use of VONJO in patients with eGFR <30 mL/min.

Please see the full Prescribing Information for VONJO.

For statutory pricing disclosures, please click here for more information.

References: 1. Data on File. VONJO MMIT. Sobi, Inc. 2025. **2.** Data on File. VONJO initiation outcomes. Sobi, Inc. 2025. **3.** VONJO. Prescribing information. Sobi, Inc.; 2025. **4.** Data on File. PERSIST-2 Protocol. Cell Therapeutics, Inc. 2013.

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