Pacritinib (VONJO) in Myelofibrosis
Criteria for Use
May 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information. Also refer to the Pacritinib in Myelofibrosis Monograph available at the PBM INTRAnet.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for pacritinib.

- ☐ Concomitant therapy with strong CYP3A4 inhibitors or inducers, moderate CYP3A4 inhibitors or inducers, sensitive substrates of CYP1A2 or CYP3A4, or sensitive substrates of P-glycoprotein, BCRP,[1] or OCT1.[1]
- ☐ Active bleeding
- ☐ Uncontrolled diarrhea
- ☐ Baseline QTc > 480 msec
- ☐ Concomitant use of drugs with significant potential for QTc prolongation
- ☐ Untreated hypokalemia
- ☐ Uncontrolled active infection, including undrained abscess (however, pacritinib may be started / restarted once the infection is controlled)
- ☐ Moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment
- ☐ Estimated GFR < 30 mL/min
- ☐ Breastfeeding during therapy (and for 2 weeks after the last dose)

Inclusion Criteria

ALL of the following must be selected in order to meet criteria:

- ☐ Primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis
- ☐ Prescribed and monitored by a VA / VA Community Care hematologist / oncologist or locally designated myelofibrosis expert.
- ☐ Splenomegaly by palpation (≥ 5 cm below the costal margin) or imaging
- ☐ Obtained pretreatment complete blood count, coagulation testing (PT, PTT, TT, and INR),[1] and ECG.[1]

Additional Inclusion Criteria

ONE of the following must be selected in order to meet criteria:

- ☐ Higher risk myelofibrosis with platelet count (PLT) < 50×10^9/L and currently not a hematopoietic stem cell transplant (HSCT) candidate

☐ Higher risk myelofibrosis with PLT ≥ 50×10^9/L and currently not a HSCT candidate, after no response or loss of response to one initial Janus kinase inhibitor approved for myelofibrosis (e.g., ruxolitinib or fedratinib)

☐ Symptomatic lower risk myelofibrosis after no response or loss of response to initial therapy and PLT < 50×10^9/L. Initial therapy may be a clinical trial, ruxolitinib, peginterferon alfa-2a, or hydroxyurea.

Additional Inclusion Criteria

Select if appropriate.

☐ If taking another kinase inhibitor: The other kinase inhibitor has been discontinued as per its prescribing information.

☐ For patients who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception.

Other Justification

☐ _____

Footnotes

1. **Abbreviations**: **BCRP**, Breast Cancer Resistance Protein; **ECG**, Electrocardiogram; **INR**, International normalized ratio; **OCT1**, Organic cation transport 1; **PT**, Prothrombin time; **PTT**, Partial thromboplastin time; **TT**, Thrombin time

Prepared: May 2023.

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