Momelotinib (OJJAARA) in Myelofibrosis
Criteria for Use
January 2024

VA National Formulary Committee

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.

Exclusion Criteria

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

- ☐ Uncontrolled active infection
- ☐ Hepatitis B surface antigen (HBsAg)-positive and not on antiviral prophylaxis. Momelotinib may be initiated after starting antiviral prophylaxis.[1]
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with momelotinib.
- ☐ At increased risk of thrombosis or major adverse cardiovascular events where potential harms are expected to outweigh the anticipated benefits.
- ☐ Unmanageable drug interaction
- ☐ Inability to swallow the tablets whole
- ☐ Pregnancy unless the expected benefits to the mother are expected to outweigh the potential risks to the fetus
- ☐ Lactating

Inclusion Criteria

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

- ☐ Prescribed and monitored by a VA / VA Community Care hematologist / oncologist
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented
- ☐ Symptomatic intermediate or high-risk myelofibrosis (as determined on initial diagnosis), including primary myelofibrosis or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis
- ☐ Currently no plan for allogeneic hematopoietic stem cell transplant
- ☐ Splenomegaly by palpation (≥ 5 cm below the costal margin) or imaging
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2
- ☐ Obtained pretreatment complete blood count and hepatic panel
- ☐ Completed hepatitis B screening (at minimum, HBsAg, total antibody-to-hepatitis-B-core-antigen (anti-HBc) and antibody to hepatitis B surface antigen [anti-HBs]).

☐ Current or past completion of hepatitis C screening. (Momelotinib may be initiated while waiting for test results.)

Additional Inclusion Criteria

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

☐ Myelofibrosis-associated anemia (hemoglobin < 10 g/dL) with symptomatic splenomegaly or constitutional symptoms, and the primary reason for treatment is anemia [2]

☐ Myelofibrosis-associated anemia (hemoglobin < 10 g/dL) with neither symptomatic splenomegaly nor constitutional symptoms, and had a prior trial of ONE non-Janus kinase inhibitor (non-JAKI) treatment for myelofibrosis-associated anemia [2,3]

☐ Splenomegaly or symptoms, primary reason for treatment is platelet count < 50×10^9/L, and had a prior trial of pacritinib unless medically inadvisable – refer to the Exclusion Criteria in the Pacritinib in Myelofibrosis Criteria for Use

☐ Splenomegaly or symptoms, platelet count ≥ 50×10^9/L, and had a prior trial of ruxolitinib unless medically inadvisable (e.g., because of pre-existing severe anemia [hemoglobin < 8 g/dL] or thrombocytopenia with platelets < 50×10^9/L)

☐ Persistent grade 3 anemia (hemoglobin < 8.0 g/dL) despite ruxolitinib dosage reductions

Additional Inclusion Criteria

Select if appropriate.

☐ If HBsAg-negative but anti-HBc-positive: A GI / liver or infectious diseases expert has been consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.

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

☐ If patient has uncontrolled acute or chronic liver disease: Treatment is delayed until causes have been investigated and treated as clinically indicated.

☐ If patient has severe liver impairment (Child-Pugh Class C): Initial dosage of momelotinib is reduced to 150 mg once daily.

☐ If a Breast Cancer Resistance Protein (BCRP) substrate is used concomitantly: Dose of BCRP substrate has been decreased per its prescribing information. (Rosuvastatin dose should be 5 mg once daily initially then not more than 10 mg daily.)

☐ For patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for at least 1 week after the last dose.

☐ For patients who can lactate: Advised not to breastfeed during treatment and for at least 1 week after the last dose.

Other Justification

☐ _____

Footnotes

[1] Antiviral prophylaxis for HBV: Agents with high genetic barrier to resistance such as entecavir or tenofovir should be used.

[2] Hemoglobin is < 10 g/dL after coexisting causes of anemia were ruled out and treated (e.g., iron, folate, or vitamin B12 deficiency; bleeding; hemolysis).

[3] Examples of non-JAKI treatments for myelofibrosis-associated anemia: androgens, danazol, prednisone, thalidomide, lenalidomide, erythropoietin stimulating agents.

Prepared: January 2024 by Francine Goodman, PharmD, BCPS, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM).

Contact: Bernadette Heron, PharmD, BCOP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM).
