Lusutrombopag (MULPLETA)
for Thrombocytopenia in Chronic Liver Disease
Criteria for Use
March 2022

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.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTRAnet* site for further information.

Note: Lusutrombopag is a small-molecule thrombopoietin receptor agonist (TPORA) used in patients with thrombocytopenia due to chronic liver disease to prophylactically and temporarily increase platelet counts prior to invasive procedures in order to decrease prophylactic platelet transfusion and the need for rescue therapy for bleeding.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive lusutrombopag.

- ☐ Past or present arterial or venous thrombotic or thromboembolic event(s) or prothrombotic conditions(s), including and not limited to portal or splenic mesenteric systemic thrombosis
- ☐ Thrombocytopenia (< 150 x 10^9/L) due to a cause <u>other</u> than chronic liver disease
- ☐ Uncontrolled generalized infection
- ☐ Exposure to eltrombopag or romiplostim in the previous 90 days or avatrombopag within the previous 35 days
- ☐ The planned invasive procedure is one for which routine preprocedural platelet transfusion is not recommended: bone marrow aspiration or biopsy, traction removal of tunneled central venous catheter, paracentesis
- ☐ Attempting to <u>normalize</u> platelet counts with lusutrombopag

Inclusion Criteria

ALL of the following criteria must be met.

- ☐ Care is provided by a VA / VA Community Care hepatologist or locally designated expert in chronic liver disease.
- ☐ Pretreatment platelet count less than 50 x 10^9/L (i.e., severe thrombocytopenia) in the 2 weeks prior to initiation of lusutrombopag
- ☐ Chronic liver disease (except that Child-Pugh class C chronic liver disease is conditionally not recommended[1])
- ☐ Scheduled to undergo an elective invasive procedure within the next 29 days
- ☐ Use of platelet transfusions is medically inadvisable (e.g., because of a risk of transfusion reaction, volume overload, platelet refractoriness, acute lung injury), or the patient declines any blood products.
- ☐ In the previous 6 months, either: (1) Absence of portal vein thrombosis on computed tomography (CT) or magnetic resonance imaging (MRI) OR (2) Presence of hepatopetal[2] portal vein blood flow on doppler ultrasonography.

Footnotes

1. Lusutrombopag clinical trials did not use Model for End-stage Liver Disease (MELD) scores in entry criteria. There is limited data on the use of lusutrombopag in patients with Child-Pugh class C (severe) cirrhosis. In patients with Child-Pugh class C cirrhosis, lusutrombopag C_{max} and AUC_{0-T} **de**creased by 20%–30% relative to values in mild to moderate hepatic impairment.
2. *Hepatopetal* means normal direction of blood flow towards the liver.

Prepared: March 2022. Separated TPORA CFU by individual drug. Changed Child-Pugh class C chronic liver disease (conditionally not recommended) from Exclusion to Inclusion. Formatted for Cerner.

Contact: Francine Goodman, PharmD, BCPS, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)