Commercial/Healthcare Exchange PA Criteria

Effective: November 7th, 2018

Prior Authorization: Mulpleta

Products Affected: Mulpleta (lusutrombopag) tablet

Medication Description: Lusutrombopag is indicated to treat adults with chronic liver disease (CLD) who have thrombocytopenia and are scheduled to undergo a procedure. Lusutrombopag promotes megakaryocyte proliferation and differentiation, resulting in increased platelet production; this is an additive effect and does not alter TPO binding.

There are no specific guidelines currently published that focus on the treatment for thrombocytopenia in adult patients with CLD who are scheduled to undergo a procedure. Lusutrombopag is the second FDA-approved oral treatment option for thrombocytopenia in adult patients with CLD who are scheduled to undergo a procedure. Based on clinical trial data, Lusutrombopag demonstrated efficacy compared to placebo. Patients in the lusutrombopag group had a greater likelihood of not requiring platelet transfusion prior to the procedure or rescue therapy for bleeding from randomization through 7 days post-procedure compared to placebo.

Covered Uses: Treatment of adults with chronic liver disease (CLD) who have thrombocytopenia and are scheduled to undergo a procedure

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Chart notes
3. Baseline platelet count

Age Restrictions: 18 years of age or older

Prescriber Restrictions: N/A

Coverage Duration: 14 days

Other Criteria:

1. Patient must be 18 years of age or older; AND
2. Patient has a diagnosis of chronic liver disease (CLD); AND
3. Patient has a documented diagnosis of thrombocytopenia; AND
4. Patient has a documented baseline platelet count of $< 50 \times 10^9$/L taken within 14 days of the request; AND
5. Patient must have an invasive procedure scheduled; AND
6. Patient is scheduled to begin Mulpleta 8 to 14 days prior to the procedure, with the procedure occurring 2 to 8 days following the last dose of Mulpleta.

References:

1. Mulpleta [package insert]. Florham Park, NJ; Shionogi; July 2018.
2. Mitchell O, Feldman DM, Diakow M, et al. The pathophysiology of thrombocytopenia in chronic liver disease. Hepat Med. 2016; 8:39-50. DOI: 10.2147/HMER.S74612.
3. Hayashi H, Beppu T, Shirabe K, et al. Management of thrombocytopenia due to liver cirrhosis: a review. World J Gastroeneterol. 2014; 20(10): 2595-2605. DOI: 10.3479/wjg.v20.i10.2595.
4. Kaufman RM, Djulbegoric R, Gernsheimer T, et al. Platelet transfusion: A clinical practice guideline from the AABB. *Ann Intern Med.* 2015; 162(3):205-213. DOI: 10.7326/M14-1589
5. FDA.gov. FDA approves avatrombopag for thrombocytopenia in adults with chronic liver disease. Updated May 21, 2018. Available at: https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm608323.htm. Accessed September 12, 2018.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	11/7/18