MEDICAL MUTUAL®

Drug Policy

Policy:	Mulpleta (lusutrombopag)	Annual Review Date: 09/19/2024 Last Revised Date: 09/19/2024

OVERVIEW

Mulpleta is a thrombopoietin receptor agonist approved for the treatment of thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a procedure. It is only given 8-14 days before the scheduled procedure, which should be performed within 2-8 days after the last dose. Mulpleta is not for use in patients with chronic liver disease to normalize platelet counts or when no procedure is scheduled.

POLICY STATEMENT

This policy involves the use of Mulpleta. Prior authorization is recommended for pharmacy benefit coverage of Mulpleta. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Mulpleta as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Mulpleta be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Mulpleta is recommended in those who meet the following criteria:

1. **Treatment of Thrombocytopenia in Adult Patients with Chronic Liver Disease who are Scheduled to Undergo a Procedure***
   *Must be invasive and elective

   Patient must meet the following criteria

   For initial therapy, approve in patients who meet the following criteria (A, B, C, and D):
   A) Dosing of Mulpleta will begin 8-14 days before the procedure; AND
   B) The procedure will occur within 2-8 days of the last dose; AND
   C) The patient has a current platelet count < 50 x 10^9/L; AND
   D) The patient is at least 18 years of age

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Initial Approval
A) *Initial Approval:7 days*
Extended Approval
Extended approval is not warranted for this product, as the patient should only be getting one regimen per procedure. If a second procedure is being planned, it will be treated as a new indication for that patient. Therefore, another initial approval request must be submitted.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Mulpleta has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Chronic liver disease patients with abnormal platelet counts (including those with idiopathic thrombocytopenia).** Mulpleta should not be used to normalize platelet abnormalities in the absence of a procedure, even if the patient has chronic liver disease. Drugs with proven efficacy are available and should be used in place of Mulpleta.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Mulpleta tablets [prescribing information]. Florham Park, NJ: Shionogi & Co., Ltd: 2018.
2. Clinical Trial Identifier: NCT02389621. Safety and Efficacy Study of Lusutrombopag for Thrombocytopenia in Patients With Chronic Liver Disease Undergoing Elective Invasive Procedures (L-PLUS 2) Available at: https://clinicaltrials.gov/ct2/show/NCT02389621 Accessed on September 10, 2018.
3. Sato S, Miyake T, Kataoka M, et al. Efficacy of Repeated Lusutrombopag Administration for Thrombocytopenia in a Patient Scheduled for Invasive Hepatocellular Carcinoma Treatment. Intern Med. 2017:56(21);2887-2890.