Drug Coverage Policy

Effective Date 09/01/2025
Coverage Policy Number.....IP0156
Policy Title.....Mulpleta

Thrombocytopenia – Mulpleta

- Mulpleta® (lusutrombopag tablets – Shionogi/Quotient)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Mulpleta, a thrombopoietin receptor agonist, is indicated for the treatment of **thrombocytopenia** in adults with **chronic liver disease** who are scheduled to undergo a procedure.[1]

Begin Mulpleta treatment 8 to 14 days before the scheduled procedure. The recommended dose is 3 mg once daily with or without food for 7 days. In the pivotal clinical studies for the approved indication, patients had a platelet count < 50 x 10^9/L.

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POLICY STATEMENT
Prior Authorization is required for benefit coverage of Mulpleta. All approvals are provided for the duration noted below.

Documentation: Documentation is required where noted in the criteria. Documentation may include, but not limited to, chart notes, laboratory tests, claims records, and/or other information.

Mulpleta is considered medically necessary when the following are met:

FDA-Approved Indication

1. **Thrombocytopenia in a Patient with Chronic Liver Disease.** Approve for 7 days if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has a current platelet count < 50 x 10^9/L (< 50,000/mcL) **[documentation required]**; AND
   C) Patient is scheduled to undergo a procedure within 8 to 14 days after starting Mulpleta therapy.

Conditions Not Covered

Mulpleta for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Chronic Immune Thrombocytopenia.** Data are not available regarding use of Mulpleta in patients with persistent and chronic immune thrombocytopenia. Many other agents are FDA-approved for this condition and are recommended in standard guidelines and have established efficacy and safety.[2]

References

1. Mulpleta® tablets [prescribing information]. Florham Park, NJ and Philadelphia, PA: Shionogi and Quotient; April 2020.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv*. 2019;3(23):3829-3866.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	No criteria changes	08/01/2024
Annual Review	No criteria changes	06/15/2025

Selected Revision	**Added** documentation throughout the policy.	09/01/2025

The policy effective date is in force until updated or retired.