



## Drug Coverage Policy

Effective Date ..... 8/1/2024  
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 and have discretion in making individual coverage determinations. 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.

## Cigna Healthcare Coverage Policy

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.<sup>1</sup>

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<sup>9</sup>/L.

## Medical Necessity Criteria

**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  $\geq 18$  years of age; AND
- B) Patient has a current platelet count  $< 50 \times 10^9/L$  ( $< 50,000/mcL$ ); AND
- C) Patient is scheduled to undergo a procedure within 8 to 14 days after starting Mulpleta therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

## Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, 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.<sup>2</sup>

## 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	8/1/2024

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

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