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5.85.031

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Hematological Agents	**Original Policy Date:**	August 10, 2018
Subject:	Mulpleta	**Page:**	1 of 3

Last Review Date: March 8, 2024

Mulpleta

Description

Mulpleta (lusutrombopag)

Background
Mulpleta (lusutrombopag) is a thrombopoietin (TPO) receptor agonist used to increase platelet counts in patients with chronic liver disease prior to surgery in order to decrease the need for blood transfusions. Mulpleta is an orally bioavailable, small molecule TPO receptor agonist that interacts with the transmembrane domain of human TPO receptors expressed on megakaryocytes to induce the proliferation and differentiation of megakaryocytic progenitor cells from hematopoietic stem cells and megakaryocyte maturation (1).

Regulatory Status
FDA-approved indication: Mulpleta is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure (1).

Begin Mulpleta dosing 8-14 days prior to a scheduled procedure. The recommended dosage of Mulpleta is 3mg taken orally once daily with or without food for 7 days. Patients should undergo their procedure 2-8 days after the last dose. Mulpleta has been investigated only as a single 7-day once daily dosing regimen in clinical trials in patients with chronic liver disease. Mulpleta should not be administered to patients with chronic liver disease in an attempt to normalize platelet counts (1).

The safety and effectiveness of Mulpleta in pediatric patients have not been established (1).

Related policies
Doptelet

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Mulpleta may be considered **medically necessary** if the conditions indicated below are met.

Mulpleta may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Thrombocytopenia with chronic liver disease

AND ALL of the following:

1. Undergoing a scheduled medical or dental procedure within the next 30 days
2. Baseline platelet count less than 50,000 platelets per microliter
3. **NO** dual therapy with Doptelet

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Quantity 7 tablets per 365 days

Prior - Approval Limits

Quantity 7 tablets

Duration 30 days

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Mulpleta is a thrombopoietin (TPO) receptor agonist used to increase platelet counts in patients with chronic liver disease prior to surgery in order to decrease the need for blood transfusions. Begin Mulpleta dosing 8-14 days prior to a scheduled procedure. The recommended dosage of Mulpleta is 3mg taken orally once daily with or without food for 7 days. The safety and effectiveness of Mulpleta in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Mulpleta while maintaining optimal therapeutic outcomes.

References

1. Mulpleta [package insert]. Florham Park, NJ: Shionogi Inc.; April 2020.

Policy History

Date	Action
August 2018	Addition to PA
November 2018	Annual review. Changed diagnosis to thrombocytopenia with chronic liver disease and added renewal requirements per SME
September 2019	Annual review and reference update
September 2020	Annual review and reference update
June 2021	Annual review
June 2022	Annual review
June 2023	Annual review. Changed policy number to 5.85.031
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.