BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.85.031

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

***Last Review Date:*** June 13, 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 |
| June 2024 | Annual review |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.**