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).
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 in patients 18 years of age and older with chronic liver disease and thrombocytopenia who are scheduled for a medical or dental procedure and if the conditions indicated below are met.

Mulpleta is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age
18 years of age and older

Diagnosis

The 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

Policy History

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<tbody>
<tr>
<td>August 2018</td>
<td>Addition to PA</td>
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<tr>
<td>November 2018</td>
<td>Annual review. Changed diagnosis to thrombocytopenia with chronic liver disease and added renewal requirements per SME</td>
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<tr>
<td>September 2019</td>
<td>Annual review and reference update</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.