Doptelet

Description

Doptelet (avatrombopag)

Background
Doptelet is a thrombopoietin (TPO) receptor agonist used to increase platelet counts. Doptelet (avatrombopag) is an orally bioavailable, small molecule TPO receptor agonist that stimulates proliferation and differentiation of megakaryocytes from bone marrow progenitor cells resulting in an increased production of platelets. Doptelet does not compete with TPO for binding to the TPO receptor and has an additive effect with TPO on platelet production (1).

Regulatory Status
FDA approved indication: Doptelet is a thrombopoietin receptor agonist indicated for the treatment of: (1)

1. Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.
2. Thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

Doptelet should not be administered to patients with chronic liver disease in an attempt to normalize platelet counts (1).
Doptelet is a thrombopoietin (TPO) receptor agonist and TPO receptor agonists have been associated with thrombotic and thromboembolic complications in patients with chronic liver disease. A Doppler ultrasound is a noninvasive test that can be used to estimate the blood flow through blood vessels by bouncing high-frequency sound waves (ultrasound) off circulating red blood cells. A Doppler ultrasound may help determine if Doptelet therapy is appropriate for a patient (1-2).

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

Related policies
Mulpleta

Policy

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

Doptelet may be considered medically necessary for patients 18 years and older with thrombocytopenia and if the conditions indicated below are met.

Doptelet may be 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

Patient must have the following:

Thrombocytopenia

AND ONE of the following:
1. Chronic liver disease AND undergoing a scheduled medical or dental procedure within the next 30 days
2. Chronic immune thrombocytopenia AND patient has had an inadequate response to a previous treatment

AND ALL of the following:
1. Baseline platelet count less than 50,000 platelets/mcL (50 x 10^9 platelets/L)
2. NO dual therapy with Mulpleta

Prior–Approval Renewal Requirements

Age
18 years of age and older

Diagnosis

Patient must have the following:

Thrombocytopenia

AND ONE of the following:
1. Chronic liver disease AND undergoing a scheduled medical or dental procedure within the next 30 days
   a. Baseline platelet count less than 50,000 platelets/mcL (50 x 10^9 platelets/L)
2. Chronic immune thrombocytopenia
   a. Platelet count greater than or equal to 50,000 platelets/mcL (50 x 10^9 platelets/L)

AND the following:
1. NO dual therapy with Mulpleta

Policy Guidelines

Pre–PA Allowance
None

Prior–Approval Limits
Thrombocytopenia with chronic liver disease

Quantity 15 tablets
Duration 30 days

Chronic Immune Thrombocytopenia

Quantity 180 tablets per 90 days
Duration 6 months

Prior–Approval Renewal Limits
Same as above

Rationale

Summary
Doptelet is a thrombopoietin (TPO) receptor agonist used to increase platelet counts. Doptelet (avatrombopag) is an orally bioavailable, small molecule TPO receptor agonist that stimulates proliferation and differentiation of megakaryocytes from bone marrow progenitor cells resulting in an increased production of platelets. Doptelet does not compete with TPO for binding to the TPO receptor and has an additive effect with TPO on platelet production. The safety and effectiveness of Doptelet in pediatric patients have not been established (1).

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

References

Policy History
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<th>Date</th>
<th>Action</th>
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<tr>
<td>June 2018</td>
<td>Addition to PA</td>
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September 2018  Annual editorial review, addition of no dual therapy with Muipleta, change of prior approval limits to 15 tablets per 365 days
Addition of thrombotic complications and Doppler ultrasound to regulatory status per SME

November 2018  Annual review. Changed diagnosis to thrombocytopenia with chronic liver disease and added renewal requirements per SME

July 2019  Addition of indication: chronic immune thrombocytopenia with an insufficient response to a previous treatment. Removal of standard allowance quantity

September 2019  Annual review

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