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5.85.030

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Hematological Agents	**Original Policy Date:**	June 29, 2018
Subject:	Doptelet	**Page:**	1 of 5

Last Review Date: June 13, 2024

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 indications: 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** if the conditions indicated below are met.

Doptelet 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

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

1. Doptelet [package insert]. Durham, NC: AkaRx, Inc.; July 2021.
2. Sheps, S. G. Doppler Ultrasound: What is it used for?: Mayo Clinic. December 17, 2016.

Policy History

Date	Action
June 2018	Addition to PA
September 2018	Annual editorial review, addition of no dual therapy with Mulpleta, 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
September 2020	Annual review
March 2021	Annual review and reference update
March 2022	Annual review and reference update
March 2023	Annual review. Changed policy number to 5.85.030
June 2023	Annual review
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.