

## Clinical Policy: Avatrombopag (Doptelet)

Reference Number: PA.CP.PHAR.130

Effective Date: 10.17.18

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[Revision Log](#)

### Description

Avatrombopag (Doptelet®) is a thrombopoietin (TPO) receptor agonist.

### FDA Approved Indication(s)

Doptelet is indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with PA Health & Wellness® that Doptelet is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Thrombocytopenia (must meet all):

1. Diagnosis of chronic liver disease;
2. Prescribed by or in consultation with a hematologist, hepatologist, or gastroenterologist;
3. Recent (within the past 14 days) platelet count is  $< 50 \times 10^9/L$ ;
4. Member is scheduled to undergo a medical or dental procedure within the next 30 days;
5. Dose does not exceed (a or b):
  - a. Platelet count  $< 40 \times 10^9/L$ : 60 mg (3 tablets) per day for a total of 5 days;
  - b. Platelet count of 40 to  $< 50 \times 10^9/L$ : 40 mg (2 tablets) per day for a total of 5 days.

**Approval duration: 14 days (no more than 5 total days of treatment)**

##### B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

#### II. Continued Therapy

##### A. Thrombocytopenia

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

**Approval duration: Not applicable**

##### B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

**Approval duration: Duration of request or 6 months (whichever is less); or**

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

### **III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

### **IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

TPO: thrombopoietin

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

None reported

*Appendix D: General Information*

- Examples of chronic liver disease include: alcoholic liver disease, chronic viral hepatitis (e.g., hepatitis B and C), and nonalcoholic steatohepatitis.

### **V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Thrombocytopenia	Platelet count < 40 x 10 <sup>9</sup> /L: 60 mg PO QD for a total of 5 days	See regimen
	Platelet count of 40 to < 50 x 10 <sup>9</sup> /L: 40 mg PO QD for a total of 5 days	

### **VI. Product Availability**

Tablet: 20 mg

### **VII. References**

1. Doptelet Prescribing Information. Durham, NC: Dova Pharmaceuticals, Inc.; May 2018. Available at: <https://www.doptelet.com>. Accessed May 21, 2018.
2. Kumar A, Mhaskar R, Grossman BJ, et al on behalf of the AABB (American Association of Blood Banks) Platelet Transfusion Guidelines Panel. Platelet transfusion: a systematic review of the clinical evidence. *Transfusion*. 2015; 55: 1116-1127.
3. Hayashi H, Beppu T, Shirabe K, Maehara Y, and Baba H. Management of thrombocytopenia due to liver cirrhosis: a review. *World J Gastroenterol*. 2014; 20(10): 2595-2605.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10/18	