Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 7, 2022 August 5, 2022, October 14, 2022, July 18, 2023

Thrombopoiesis Stimulating Agents

Non-Preferred Agents: Doptelet® (avatrombopag), Mulpleta® (lusutrombopag), Nplate® (romiplostim), Promacta® (eltrombopag), Tavalisse® (fostamatinib)

LENGTH OF AUTHORIZATION: Up to 6 months for *ITP*, *Severe Aplastic Anemia and HS-ARS*
Up to 4 months for *Chronic Hepatitis C-associated Thrombocytopenia*
Up to 1 week for *Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure*

INITIAL REVIEW CRITERIA:

- Diagnosis confirmed by supporting documentation.

Chronic immune (idiopathic) thrombocytopenia (ITP) - Avatrombopag (Doptelet®), Eltrombopag (Promacta®), Fostamatinib (Tavalisse®) or Romiplostim (Nplate®)

- Documentation of platelet count less than $50x10^9$/L ($50,000/mm^3$) and/or signs and symptoms of a low platelet count (bruising, petechiae, bleeding from nostrils, gums, etc.).
- Patient has history of failure, intolerance or contraindication to **ONE** of the following:
  - Glucocorticoids
  - Intravenous immune globulin (IVIG)
  - Rituximab
  - History of splenectomy

Severe aplastic anemia - Eltrombopag (Promacta®)

- Patient is ≥ 2 years of age.
- Lab documentation of the following:
  - Platelet count of less than $30x10^9$/L ($30,000/mm^3$) **or** patient is platelet transfusion dependent.
  - Hemoglobin 8.4 g/dL or lower **or** patient is dependent on transfusions of red blood cells (RBCs)
  - Absolute neutrophil count (ANC) approximating 0.5 x 10^9/L.
- Promacta® must be used in combination with standard immunosuppressive therapy. History of failure, intolerance or contraindication must be documented.

Chronic Hepatitis C-associated Thrombocytopenia - Eltrombopag (Promacta®)

- Documentation the hepatitis C treatment regimen is used in conjunction with interferon-based therapy.
- Documentation of platelet count less than $50x10^9$/L ($50,000/mm^3$).

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Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure - Avatrombopag (Doptelet®) or Lusutrombopag (Mulpleta®)

- Patient is ≥ 18 years of age.
- Documentation of platelet count less than $50x10^9$/L (50,000/mm^3)

Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS] - Romiplostim (Nplate®)

- Patient receiving myelosuppressive doses of radiation

CONTINUATION OF THERAPY REVIEW CRITERIA:

Chronic immune (idiopathic) thrombocytopenia (ITP) - Avatrombopag (Doptelet®), Eltrombopag (Promacta®), Fostamatinib (Tavalisse®) or Romiplostim (Nplate®)

- Documentation of platelet count greater than $50x10^9$/L (50,000/mm^3)

Severe aplastic anemia - Eltrombopag (Promacta®)

- Platelet count increases to 20 x 10^9/L above baseline, **or** stable platelet counts with transfusion independence for a minimum of 8 weeks.
- Hemoglobin increase by greater than 1.5 g/dL or a reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks.
- ANC increase of 100% or an ANC increase greater than 0.5 x 10^9 /L.

***If the patient has not met at least one of the above criteria after 16 weeks of treatment, continuation of therapy should NOT be approved.**

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/