



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 17, 2012; March 27, 2013; August 14, 2013, February 4, 2015, June 23, 2015, October 9, 2015, July 31, 2018, January 18, 2019

PROMACTA® (eltrombopag)

LENGTH OF AUTHORIZATION:

- SIX MONTHS FOR ITP and FIRST LINE APLASTIC ANEMIA
- FOUR MONTHS FOR REFRACTORY APLASTIC ANEMIA

INITIAL THERAPY REVIEW CRITERIA:

Chronic Immune (Idiopathic) Thrombocytopenia (ITP)

1. Diagnosis (confirmed by supporting documentation) of an **adult** or pediatric patients 1 year and older with **chronic immune (idiopathic) thrombocytopenia purpura** with insufficient response to corticosteroids, immunoglobulins or splenectomy.
 - Documentation should include lab results of platelet count approximating less than 50,000 per microliter and/or signs and symptoms of a low platelet count (Bruising, petechiae, bleeding from nostrils, gums, etc. . .).
2. The beneficiary must have tried and failed intravenous immunoglobulin therapy or corticosteroid therapy, or have had a splenectomy.
 - (Refer to clinical notes for typical length of therapy).
3. The prescribing practitioner must be a hematologist/oncologist.

Thrombocytopenia in patients with Chronic Hepatitis C

1. The use of eltrombopag (Promacta) is indicated for the treatment of thrombocytopenia in patients with chronic hepatitis C ***to allow the initiation and maintenance of interferon-based therapy.*** If the patient is not receiving interferon based therapy for the treatment of Hepatitis C, eltrombopag (Promacta) should NOT be approved.

First Line Severe Aplastic Anemia

1. Diagnosis (confirmed by supporting documentation) of **severe aplastic anemia**
 - Documentation should include lab results of:
 - Platelet count approximating 30,000 per microliter or lower or patient is platelet transfusion dependent
 - Hemoglobin approximating 8.4 g/dL or lower or patient is dependent on transfusions of red blood cells (RBCs)
 - Absolute neutrophil count (ANC) approximating $0.5 \times 10^9/L$
2. Patient is ≥ 2 years of age
3. Use in combination with standard immunosuppressive therapy.
4. The prescribing practitioner must be a hematologist/oncologist

Refractory Severe Aplastic Anemia



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1. Diagnosis (confirmed by supporting documentation) of **severe aplastic anemia** with insufficient response to immunosuppressive therapy.
 - o Documentation should include lab results of:
 - Platelet count approximating 30,000 per microliter or lower or patient is platelet transfusion dependent
 - Hemoglobin approximating 8.4 g/dL or lower or patient is dependent on transfusions of red blood cells (RBCs)
 - Absolute neutrophil count (ANC) approximating $0.5 \times 10^9/L$
2. The beneficiary must have tried and failed at least one prior immunosuppressive therapy.
3. The prescribing practitioner must be a hematologist/oncologist.

CONTINUATION OF THERAPY REVIEW CRITERIA:

Chronic Immune Thrombocytopenia:

1. Platelet count greater than or equal to $50 \times 10^9/L$ for six out of the last eight weeks of the 26-week treatment period in the absence of rescue medication at any time.

Severe Aplastic Anemia: Patient must meet one or more of the following criteria:

1. Platelet count increases to $20 \times 10^9/L$ above baseline, or stable platelet counts with transfusion independence for a minimum of 8 weeks.
2. 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.
3. ANC increase of 100% or an ANC increase greater than $0.5 \times 10^9/L$.

If 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:

Chronic ITP: Initiate at 25 mg once daily for pediatric patients aged 1 to 5 years. Initiate at 50mg once daily for most adults and pediatric patients 6 and older. Adjust to maintain a platelet count $\geq 50 \times 10^9/L$. Do not exceed 75 mg per day.

Chronic Hepatitis C-associated thrombocytopenia: Initiate at 25 mg once daily for all patients. Adjust to achieve a target platelet count required to initiate antiviral therapy. Do not exceed a daily dose of 100 mg.

First Line Severe Aplastic Anemia with standard immunosuppressive therapy:

- Initiate 2.5mg/kg (in pediatric patients age 2 to 5 years of age) once daily
- 75mg (pediatric patients age 6-11 years of age) once daily
- 150mg (ages 12 years of age and older) once daily

Refractory Severe Aplastic Anemia: Initiate at 50 mg once daily. Adjust to maintain a platelet count $\geq 50 \times 10^9/L$. Do not exceed a dose of 150 mg daily

Dosage Form: 12.5 mg, 25 mg, 50 mg, and 75 mg, tablets; 12.5mg and 25mg oral suspension