Clinical Policy: Eltrombopag (Promacta)

Reference Number: PA.CP.PHAR.180
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for eltrombopag (Promacta®).

FDA Approved Indication(s)
Promacta is indicated:

- For the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
- For the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy
- For the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy

Limitation(s) of use:

- Promacta should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.
- Promacta should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Promacta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Thrombocytopenia (must meet all):

1. Diagnosis of one of the following (a, b, or c):
   a. Chronic immune (idiopathic) thrombocytopenia (ITP) and the following (i-v):
      i. Prescribed by or in consultation with a hematologist;
      ii. Age ≥ 1 year;
      iii. Member has had an insufficient response to the following first line agents: corticosteroids and immunoglobulins;
      iv. Member has relapsed after splenectomy, or has a contraindication to splenectomy;
      v. Platelet count is < 30 x 10^9/L or member has an active bleed;
      vi. Prescribed dose of Promacta does not exceed 75 mg daily;
   b. Chronic hepatitis C-associated thrombocytopenia and the following (i-v):
      i. Promacta will be used concomitantly with interferon-based therapy;

ii. Age ≥ 18 years;
iii. Prescribed by or in consultation with a hematologist, hepatologist, gastroenterologist or infectious disease specialist;
iv. The degree of thrombocytopenia has prevented the initiation of interferon-based therapy or limited the ability to maintain interferon-based therapy;
v. Platelet count is < 75 x 10^9/L;
vi. Prescribed dose of Promacta does not exceed 100 mg daily;

c. Severe aplastic anemia and the following (i-iv):
i. Member has had an insufficient response to immunosuppressive therapy (e.g., antithymocyte globulin, cyclosporine A, cyclophosphamide);
ii. Age ≥ 18 years;
iii. Prescribed by or in consultation with a hematologist;
iv. Platelet count is < 50 x 10^9/L;
v. Prescribed dose of Promacta does not exceed 150 mg daily.

Approval Duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

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

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;
2. Documentation of positive response to therapy (e.g.; for ITP or hepatitis C-associated thrombocytopenia: increase in platelet count from baseline levels; for aplastic anemia any of the following hematologic responses: 1) platelet count increases to 20 x 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 red blood cell (RBC) transfusions for 8 consecutive weeks; 3) absolute neutrophil count (ANC) increase of 100% or an ANC increase greater than 0.5 x 10^9/L);
3. Current (dated within that last 90 days) platelet count is < 400 x 10^9/L;
4. If diagnosis of chronic hepatitis C-associated thrombocytopenia, continuation of antiviral therapy;
5. Prescribed dose of Promacta does not exceed the following:
   a. If diagnosis of chronic ITP: 75 mg daily;
   b. If diagnosis of chronic hepatitis C-associated thrombocytopenia: 100 mg daily;
   c. If diagnosis of severe aplastic anemia: 150 mg daily.

Approval Duration: 12 months or
6 months for hepatitis C-associated thrombocytopenia

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.CMN.53

Background
Description/Mechanism of Action:
Promacta contains eltrombopag olamine, a small molecule thrombopoietin (TPO) receptor agonist for oral administration. Eltrombopag interacts with the transmembrane domain of the TPO receptor leading to proliferation and differentiation from bone marrow progenitor cells and increased platelet production.

Formulations:
Tablets: 12.5 mg, 25 mg, 50 mg, 75 mg, and 100 mg
For oral suspension: 25 mg

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Appendices
Appendix A: Abbreviation Key
ITP: immune thrombocytopenia
IVIg: immunoglobulin
TPO: thrombopoietin
ANC: Absolute neutrophil count

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Added age restriction per PI. References reviewed and updated.	02/18	

References

i. Promacta Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2017. Available at https://www.us.promacta.com/. Accessed November 14, 2017.

ii. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. Blood. 2011; 117(16): 4190-4207.
iii. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.