

# Drug Therapy Guidelines

Promacta® (eltrombopag)

*Applicable*

Medical Benefit		Effective: 1/1/18
Pharmacy- Formulary 1	x	Next Review: 12/18
Pharmacy- Formulary 2	x	Date of Origin: 3/10
Pharmacy- Formulary 3/Exclusive	x	Review Dates: 3/10, 9/10, 9/11, 9/12, 9/13, 9/14, 12/15, 12/16,
Pharmacy- Formulary 4/AON	x	12/17

## I. Medication Description

Idiopathic thrombocytopenia purpura (ITP) is a hematologic disorder marked by platelet counts below 100,000/mm<sup>3</sup> and mucocutaneous bleeding. Primary immune thrombocytopenic purpura occurs in the absence of another underlying disease. Promacta is an orally bioavailable, small-molecule TPO receptor agonist that interacts with the transmembrane domain of the human TPO-receptor and initiates signaling cascades that induce proliferation and differentiation of megakaryocytes from bone marrow progenitor cells.

## II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

## III. Policy

Coverage of Promacta is provided:

- For the treatment of thrombocytopenia in members age 1 and over with chronic immune thrombocytopenia (ITP) as defined by platelet counts below 100,000/mm<sup>3</sup> when the member has had an inadequate response to treatment with corticosteroids, immunoglobulins, or splenectomy **OR**
- For the treatment of thrombocytopenia in adult members with chronic hepatitis C
  - To allow the initiation and maintenance of interferon-based therapy when the degree of thrombocytopenia prevents the initiation of interferon therapy or limits the ability to maintain optimal interferon-based therapy and
  - Promacta is not used in combination with a direct-acting antiviral agent used without interferon **OR**
- For the treatment of severe aplastic anemia in adult members who have had an insufficient response to immunosuppressive therapy

## IV. Quantity Limitations

Coverage is available for pertinent indications as follows:

- Chronic ITP: 75 mg/day
- Thrombocytopenia in Hepatitis C: 100 mg/day
- Severe aplastic anemia: 150 mg/day

**V. Coverage Duration**

Coverage is provided for up to 6 months depending on need for therapy and may be renewed.

**VI. Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Demonstrated response to therapy **AND**
- Continued need for therapy as evidenced by platelet counts **AND**
- For chronic hepatitis C patients, coverage is limited to the duration of time that interferon therapy is still administered.

**VII. Billing/Coding Information**

Available as 12.5mg, 25mg, 50mg, and 75mg tablets

**VIII. Summary of Policy Changes**

- 12/15/12: renewal criteria changed to specify that continued need must be established via platelet counts; dosing adjustment recommendations added for Nplate; references to Nplate NEXUS and Promacta CARES programs removed.
- 12/2012: removed to own policy, addition of new indication for treatment of thrombocytopenia in chronic hepatitis C patients
- 12/15/13:
  - Update coverage renewal criteria language for use in chronic hepatitis C patients
  - Updated policy section to include limitation of use language for chronic hepatitis C patients
- 1/1/15: addition of severe aplastic anemia to criteria based on FDA approval
- 7/1/15: formulary distinctions made, age requirements outlined according to updated prescribing information for Promacta
- 3/16/15: age requirements updated to allow for coverage in patients 1 year of age or older
- 1/1/17: removed 100 mg tablets from policy as they are no longer available
- 1/1/18: updated quantity limits

**IX. References**

1. George, JN. Treatment and prognosis of immune (idiopathic) thrombocytopenic purpura in adults. In: Up-to-date, Basow, DS (Ed.), UpToDate, Waltham, MA, 2008.
2. Promacta® (eltrombopag). Prescribing Information. GlaxoSmithKline, Research Triangle Park, NC. Revised 10/2017.
3. Micromedex® 2.0 – Eltrombopag. micromedexsolutions.com. Accessed 10/2016.
4. U.S. Food and Drug Administration: Safety Alerts for Human Medical Products> Promacta (eltrombopag): Portal Venous System Thromboses in Study of Patients with Chronic Liver Disease. www.fda.gov.

5. Dear Healthcare Professional Letter- GlaxoSmithKline: Promacta® (eltrombopag) Notification Of Safety Information: Portal Venous System Thromboses in a Study of Patients With Chronic Liver Disease (ELEVATE). May 4, 2010.
6. Olnes, Matthew J. et al. Eltrombopag and Improved Hematopoiesis in Refractory Aplastic Anemia. N Engl J Med 2012; 367:11-9.
7. Afdhal, et al. Eltrombopag before Procedures in Patients with Cirrhosis and Thrombocytopenia. N Engl J Med;367:716-24.
8. Clinical Pharmacology- Eltrombopag. Accessed 10/2017.
9. Mayo Clinic. Idiopathic thrombocytopenia purpura (ITP). Mayoclinic.org. Accessed 10/17

*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.*

*The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.*

*The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*