Pharmacy Medical Necessity Guidelines: Promacta® (eltrombopag)

Effective: September 12, 2017

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

This Pharmacy Medical Necessity Guidelines applies to the following:

Tufts Health Plan Commercial Plans

☐ Tufts Health Plan Commercial Plans – large group plans
☐ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans

☐ Tufts Health Direct – Health Connector
☐ Tufts Health Together – A MassHealth Plan
☒ Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products

☐ Tufts Health Freedom Plan - large group plans
☐ Tufts Health Freedom Plan - small group plans

Fax Numbers:

RXUM: 617.673.0988

OVERVIEW

FOOD AND DRUG ADMISTRATION-APPROVED INDICATIONS

Promacta (eltrombopag) is a thrombopoietin receptor agonist indicated for the:

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

Promacta (eltrombopag) should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Promacta (eltrombopag) should not be used to normalize platelet counts.

Promacta (eltrombopag) 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 of Promacta (eltrombopag) have not been established in combination with direct acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.

COVERAGE GUIDELINES

The plan may authorize coverage of Promacta (eltrombopag) for Members when **all** the following criteria are met:

Thrombocytopenia in Members with Chronic Immune (idiopathic) Thrombocytopenia Purpura or Another Type of Thrombocytopenic Condition

1. The Member has been evaluated by a specialist

AND

2. The Member has a diagnosis of thrombocytopenia associated with chronic immune (idiopathic) thrombocytopenia purpura or another type of thrombocytopenic condition

AND

3. Documentation of one of the following:the Member has previously tried and failed treatment with or the Member has a contraindication to both glucocorticoids (e.g. prednisone, dexamethasone) and intravenous immunoglobulin (IVIG) **OR** the member has not responded to splenectomy

Thrombocytopenia in Members with Chronic Hepatitis C Infection

1. The Member has a platelet count of <75,000 per µL

AND

2. The Member has a hemoglobin concentration ≥11.0 g/dL for men or ≥10.0 g/dL in women

AND

3. The Member has an absolute neutrophil count ≥750/mm^3

AND

4. Documentation of one of the following:
   a) The Member has already initiated Hepatitis C therapy with interferon

   OR

   b) The Member is new to Tufts Health Plan and is already receiving Promacta

Severe Aplastic Anemia

1. Documented diagnosis of severe aplastic anemia

AND

2. The Member is at least 18 years of age or older

AND

3. The Member has had an insufficient response or intolerance to immunosuppressive therapy

LIMITATIONS

1. Initial authorization for thrombocytopenia associated with chronic immune (idiopathic) thrombocytopenia purpura or another type of thrombocytopenic condition will be limited to six months. Subsequent authorization may be given in 12 month intervals based on submission of current progress notes from the physician documenting efficacy.
2. Initial authorization for the treatment of chronic hepatitis C-associated thrombocytopenia will be limited to three months. Subsequent authorizations may be given for the duration of the Members hepatitis C therapy when the Member meets the following criteria:
   a) The Member has an active prior authorization for current hepatitis C treatment

   AND

   b) The provider indicate the patient having a platelet count >90,000 per µL after use of Promacta

   AND

   c) The Member is currently receiving hepatitis C therapy
3. The plan will limit the supply for Promacta (eltrombopag) as follows:
   a) 12.5 mg, 25 mg, 50 mg and 75 mg: 30 tablets per 30 days

CODES

None

REFERENCES

1. Bussel JB, et al. Eltrombopag for the Treatment of Chronic Idiopathic Thrombocytopenic Purpura. *N Engl J Med.* November 2007;357(22):2237-47.
2. Cheng, G. Eltrombopag for the treatment of immune thrombocytopenia. *Expert Rev Hematol*. June 2011;4(3):261-69.
3. McHutchison JG, Dusheiko G, Shiffman ML, et al. Eltrombopag for thrombocytopenia in patients with cirrhosis associated with hepatitis C. *New Engl J Med.* 2007;357:2227–36.
4. Noronha, V., Philip, S.D., Joshi, A., et al. Prolonged remission from eltrombopag in chronic refractory idiopathic thrombocytopenic purpura. *Int J Hematol*. September 2012;96(3):380-2.
5. Promacta (eltrombopag) [package insert]. Research Triangle Park, NC: GlaxoSmithKline; July 2017.
6. Sharma, V., Randhawa, H., Sharma, A., et al. Eltrombopag- An oral thrombopoietin agonist. *Eur Rev Med Pharmaco*. June 2012;16(6):743-6.
7. Slim, J., Afridi, M.S. Managing Adverse Effects of Interferon-Alfa and Ribavirin in Combination Therapy for HCV. *Infec Dis Clin N AM*. December 2012;26(4): 968-78.

APPROVAL HISTORY

April 16, 2009: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- June 13, 2013: Reviewed by the Pharmacy and Therapeutics Committee.
- November 9, 2014: Reviewed by the Pharmacy and Therapeutics Committee.
- August 11, 2015: No changes
- September 1, 2015: Administrative change: Separated Medical Necessity Guidelines for Promacta and Nplate.
- January 1, 2016: Administrative change to rebranded template.

- October 18, 2016: Removed the age restriction for the treatment of ITP. Specified for the indication of hepatitis C that the member's hepatitis C regimen includes interferon.
- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- September 12, 2017: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink^{SM} Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.