SPECIALTY GUIDELINE MANAGEMENT

PROMACTA (eltrombopag)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
   1. 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
   2. Treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy
   3. Treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy

B. Compendial Use
   1. MYH9-related disease with thrombocytopenia

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Chronic or persistent primary immune thrombocytopenia (ITP)
   Authorization of 6 months may be granted to members with chronic or persistent ITP who meet all of the following criteria:
   1. Inadequate response or intolerance to documented prior therapy with corticosteroids, immunoglobulins, or splenectomy
   2. Untransfused platelet count at time of diagnosis is less than 30x10^9/L OR 30x10^9/L to 50x10^9/L with symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma) or risk factors for bleeding (see Section IV).

B. Thrombocytopenia associated with chronic hepatitis C
   Authorization of 6 months may be granted to members who are prescribed Promacta for the initiation and maintenance of interferon-based therapy for the treatment of thrombocytopenia associated with chronic hepatitis C.

C. Severe aplastic anemia
   Authorization of 6 months may be granted to members for the treatment of severe aplastic anemia.

D. MYH9-related disease with thrombocytopenia
   Authorization of 12 months may be granted to members with thrombocytopenia associated with MYH9-related disease
III. CONTINUATION OF THERAPY

A. Chronic or persistent ITP
   1. Authorization of 12 months may be granted to members with current platelet count less than or equal to 200x10^9/L.
   2. Authorization of 12 months may be granted to members with current platelet count greater than 200 x10^9/L for whom Promacta dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

B. Thrombocytopenia associated with chronic hepatitis C
   Authorization of 6 months may be granted to members who are continuing to receive interferon-based therapy.

C. Severe aplastic anemia
   1. Authorization of up to 16 weeks total may be granted to members with current platelet count less than 50x10^9/L who have not received appropriately titrated therapy with Promacta for at least 16 weeks.
   2. Authorization of up to 16 weeks total may be granted to members with current platelet count less than 50x10^9/L who are transfusion-independent.
   3. Authorization of 12 months may be granted to members with current platelet count of 50x10^9/L to 200x10^9/L.
   4. Authorization of 12 months may be granted to members with current platelet count greater than 200 x10^9/L for whom Promacta dosing will be adjusted to achieve and maintain an appropriate target platelet count.

IV. APPENDIX

Examples of risk factors for bleeding (not all inclusive)
- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidity (e.g., peptic ulcer disease, hypertension)
- Mandated anticoagulation therapy
- Profession (e.g., construction worker) or lifestyle (e.g., plays contact sports) that predisposes patient to trauma

V. REFERENCES