SPECIALTY GUIDELINE MANAGEMENT

NPLATE (romiplostim)

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 Indication
   Treatment of thrombocytopenia in patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy

B. Compendial Use
   Cyclic 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. Cyclic thrombocytopenia
   Authorization of 12 months may be granted to members who are prescribed Nplate for the treatment of cyclic thrombocytopenia.

III. CONTINUATION OF THERAPY

A. Chronic or persistent ITP
   1. Authorization of 3 months may be granted to members with current platelet count less than 50x10^9/L for whom the platelet count is not sufficient to prevent clinically important bleeding and who have not received a maximal Nplate dose for at least 4 weeks.
   2. Authorization of 12 months may be granted to members with current platelet count less than 50x10^9/L for whom the current platelet count is sufficient to prevent clinically important bleeding.
   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 Nplate dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

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