

Reference number(s)
1927-A

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 prior therapy with corticosteroids, immunoglobulins, or splenectomy
2. Untransfused platelet count at time of diagnosis is less than $30 \times 10^9/L$ OR $30 \times 10^9/L$ to $50 \times 10^9/L$ 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

Chronic or persistent ITP

- A. Authorization of 12 months may be granted to members with current platelet count less than or equal to $200 \times 10^9/L$.
- B. Authorization of 12 months may be granted to members with current platelet count greater than $200 \times 10^9/L$ for whom Nplate dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

IV. APPENDIX

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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

1. Nplate [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2017.
2. Bose P, Hussein KK, Terrell DR, et al. Successful treatment of cyclic thrombocytopenia with thrombopoietin-mimetic agents: a report of two patients. *Am J Hematol.* 2009;84:459-461.
3. Rice L, Nichol JL, McMillan R, et al. Cyclic immune thrombocytopenia responsive to thrombopoietic growth factor therapy. *Am J Hematol.* 2001;68:210-214.
4. 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.
5. Provan D, Stasi R, Newland AC, et al. International consensus report on the investigation and management of primary immune thrombocytopenia. *Blood.* 2010;115(2):168-186.
6. Rodeghiero F, Stasi R, Gernsheimer T, et al. Standardization of terminology, definitions and outcome criteria in immune thrombocytopenic purpura of adults and children: report from an international working group. *Blood.* 2009;113(11):2386-2393.