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| 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.

FDA-Approved Indication

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

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

II. CRITERIA FOR INITIAL APPROVAL

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:

- A. Inadequate response or intolerance to prior therapy with corticosteroids, immunoglobulins, or splenectomy
- B. 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).

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

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

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- 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.; October 2017.
2. CVS Caremark Clinical Programs Review. Focus on Immune Thrombocytopenia (ITP) Programs; October 2010.
3. 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.
4. Rice L, Nichol JL, McMillan R, et al. Cyclic immune thrombocytopenia responsive to thrombopoietic growth factor therapy. *Am J Hematol*. 2001;68:210-214.
5. 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.
6. 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.
7. 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.