

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 Indications

1. Nplate is indicated for the treatment of thrombocytopenia in:
  - a. Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
  - b. Pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
2. Nplate is indicated to increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS]).

###### B. Compendial Uses

1. Myelodysplastic syndromes, for lower risk disease in patients with severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents or immunosuppressive therapy
2. Severe thrombocytopenia post cancer chemotherapy

All other indications are considered experimental/investigational and not medically necessary.

##### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. Immune thrombocytopenia: pretreatment and current platelet counts
- B. Severe thrombocytopenia post cancer chemotherapy: pretreatment and current platelet counts

##### III. EXCLUSIONS

Coverage will not be provided for members with the following exclusion: concomitant use of Nplate with other thrombopoietin receptor agonists (e.g., Promacta, Doptelet, Mupleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse)

##### IV. CRITERIA FOR INITIAL APPROVAL

###### A. Immune thrombocytopenia (ITP)

Authorization of 6 months may be granted for treatment of ITP when both of the following criteria are met:

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1. Inadequate response or intolerance to prior therapy with corticosteroids, immunoglobulins, or splenectomy.
2. Untransfused platelet count at any point prior to the initiation of the requested medication 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 VI).

**B. Hematopoietic syndrome of acute radiation syndrome (HSARS)**

Authorization of 1 month may be granted for treatment of hematopoietic syndrome of acute radiation syndrome (acute exposure to myelosuppressive doses of radiation).

**C. Myelodysplastic Syndromes**

Authorization of 12 months may be granted for treatment of myelodysplastic syndromes when both of the following criteria are met:

1. Member has lower risk disease defined as Revised International Prognostic Scoring System (IPSS-R) (Very Low, Low, Intermediate), International Prognostic Scoring System (IPSS) (Low/Intermediate-1), WHO classification-based Prognostic Scoring System (WPSS) (Very Low, Low, Intermediate).
2. Member has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents (such as azacitidine and decitabine) or immunosuppressive therapy.

**D. Severe thrombocytopenia post cancer chemotherapy**

Authorization of 6 months may be granted for treatment of severe thrombocytopenia post cancer chemotherapy when the platelet count is less than  $50 \times 10^9/L$ .

**V. CONTINUATION OF THERAPY**

**A. Immune thrombocytopenia (ITP)**

1. Authorization of 3 months may be granted to members with current platelet count less than  $50 \times 10^9/L$  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  $50 \times 10^9/L$  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  $50 \times 10^9/L$  to  $200 \times 10^9/L$ .
4. Authorization of 12 months may be granted to members with current platelet count greater than  $200 \times 10^9/L$  to less than or equal to  $400 \times 10^9/L$  for whom Nplate dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

**B. Hematopoietic syndrome of acute radiation syndrome (HSARS)**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**C. Myelodysplastic Syndromes**

Authorization of 12 months may be granted for continued treatment of myelodysplastic syndromes in members who experience benefit from therapy (e.g., increased platelet counts, decreased bleeding events, reduced need for platelet transfusions).

**D. Severe thrombocytopenia post cancer chemotherapy**

Authorization of 6 months may be granted for continued treatment of severe thrombocytopenia post cancer chemotherapy in members who experience benefit from therapy (e.g., increased platelet counts,

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decreased bleeding events, reduced need for platelet transfusions) and the platelet count remains less than  $100 \times 10^9/L$ .

## VI. 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 member to trauma

## VII. REFERENCES

1. Nplate [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2021.
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4. Nuenert C, Terrel DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv* 2019;3(23):3829–3866.
5. Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Adv* 2019;3(22): 3780–3817.
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