Reference number(s)
3371-A

STANDARD MEDICARE PART B 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 Indications

A. Nplate is indicated for the treatment of thrombocytopenia in:
   1. Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
   2. 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.
B. 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])

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Immune Thrombocytopenia (ITP)

Authorization of 12 months may be granted for treatment of ITP when both of the following criteria (A and B) are met:

1. Untransfused platelet count at any point prior to the initiation of the requested medication 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 (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes patient to trauma).
2. At least one of the following criteria is met:
   i. The member has previously received treatment with an immunoglobulin (e.g., Gammaplex, Privigen, Carimune NF) for the treatment of ITP.
   ii. The member had an inadequate response to corticosteroids.
   iii. There is a clinical reason to avoid treatment with both immunoglobulins and corticosteroids.
   iv. The member has undergone a splenectomy.

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).

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Immune Thrombocytopenia (ITP)
Authorization for 24 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Nplate.
B. Nplate is being used to treat ITP.
C. The member is receiving benefit from therapy.

IV. REFERENCES

1. Nplate [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2021.
2. Nuenert C, Terrel DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv* 2019;3(23):3829–3866.
3. 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.