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.

A. FDA-Approved Indications
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. Compendial Uses
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

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 any of the following criteria is met:
1. The member has previously received treatment with an immune globulin IV (IVIG) (e.g., Gammaplex, Privigen, Carimune NF) for the treatment of ITP.
2. The member had an inadequate response to corticosteroids.
3. There is a clinical reason to avoid treatment with both IVIG and corticosteroids.
4. The member has undergone a splenectomy.

B. 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.

III. CONTINUATION OF THERAPY

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

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 a diagnosis or condition enumerated in Section II.
C. The member is receiving benefit from therapy.

IV. REFERENCES

1. Nplate [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2019.
2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 13, 2019.
3. The NCCN Clinical Practice Guidelines in Oncology® Myelodysplastic Syndrome (Version 2.2019). © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 13, 2019.