

Jurisdiction Specific Medicare Part B Nplate

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Nplate	romiplostim

Indications

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- Immune Thrombocytopenic Purpura/ Primary Immune Thrombocytopenia (ITP)
- Hematopoietic Syndrome of Acute Radiation Syndrome
- Myelodysplastic syndromes
- Chemotherapy-induced thrombocytopenia

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

Coverage Criteria

Immune Thrombocytopenic Purpura/Primary Immune Thrombocytopenia (ITP)

Authorization of 6 months may be granted for treatment of immune thrombocytopenic purpura when all of the following criteria are met:

- Documented lack of response of at least one first-line therapy
- Documented risk for bleeding with at least one of the following:
 - Severe ITP (bleeding symptoms)
 - Risk factors for bleeding are present
 - In preparation for procedures or surgery with risk of bleeding
 - Professional or lifestyle risk factors for trauma
- Persistent or chronic disease (>6 months)

Hematopoietic syndrome of acute radiation syndrome (HR-ARS)

Authorization of 1 month may be granted for treatment of hematopoietic syndrome of acute radiation syndrome when the member has been acutely exposed to myelosuppressive doses of radiation.

Myelodysplastic Syndromes

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

- 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), or WHO classification-based Prognostic Scoring System (WPSS) (Very Low, Low, Intermediate).
- Member has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents (such as azacitidine and decitabine) or immunosuppressive therapy.

Chemotherapy-induced thrombocytopenia

Authorization of 6 months may be granted for treatment of chemotherapy-induced thrombocytopenia (CIT) when either of the following criteria is met:

- The platelet count is less than $100 \times 10^9/L$ for at least 3 to 4 weeks following the last chemotherapy administration.
- Chemotherapy administration has been delayed related to thrombocytopenia.

References

1. Immune Thrombocytopenia (ITP) Therapy (L38268) Version R6. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. June 18, 2024.
2. Billing and Coding: Immune Thrombocytopenia (ITP) Therapy (A57160) Version R5. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. June 18, 2024.
3. Nplate [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2022.
4. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed June 10, 2024.
5. The NCCN Clinical Practice Guidelines in Oncology® Myelodysplastic Syndrome (Version 2.2024). © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed June 10, 2024.
6. The NCCN Clinical Practice Guidelines in Oncology® Hematopoietic Growth Factors (Version 3.2024). © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed June 10, 2024.