Romiplostim (Nplate®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

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

- Nplate is indicated for the treatment of thrombocytopenia in:
  - Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
  - 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.
- 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 [HS-ARS]).

Compendial Uses

- Myelodysplastic syndromes (MDS)
- Chemotherapy-induced thrombocytopenia (CIT)
- Immune checkpoint inhibitor-related toxicity

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

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review ~~for immune thrombocytopenia (ITP) and chemotherapy-induced thrombocytopenia (CIT)~~:

Immune Thrombocytopenia (ITP) and Chemotherapy-Induced Thrombocytopenia (CIT):

- For initial requests: Untransfused ~~pretreatment~~ platelet count~~s~~
- For continuation requests: Current platelet count~~s~~

Myelodysplastic Syndromes (MDS) and Immune Checkpoint Inhibitor-Related Toxicity

- For continuation requests: Chart notes or medical record documentation supporting benefit from therapy

EXCLUSIONS

Coverage will not be provided when Nplate will be used concomitantly with other thrombopoietin receptor agonists (e.g., Promacta, Alvaiz, Doptelet, Mulpleta) or spleen tyrosine kinase inhibitors (e.g., Tavalisse).

PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a hematologist or oncologist.

COVERAGE CRITERIA

Immune Thrombocytopenia (ITP)

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

- Member has had an inadequate response or intolerance to prior therapy with corticosteroids, immunoglobulins, or splenectomy.
- Member has an untransfused platelet count at any point prior to the initiation of the requested medication of either of the following:
  - Less than $30x10^9$/L
  - $30x10^9$/L to $50x10^9$/L with symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma) or risk factors for bleeding (see Appendix)

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).

Myelodysplastic Syndromes

Authorization of 12 months may be granted for treatment of myelodysplastic syndromes (MDS)

Chemotherapy-Induced Thrombocytopenia (CIT)

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 $100x10^9$/L for at least 3 to 4 weeks following the last chemotherapy administration.
- Chemotherapy administration has been delayed related to thrombocytopenia.

Immune Checkpoint Inhibitor-Related Toxicity

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the requested medication will be used for immunotherapy-related G3 ($25,000/mm^3$-$50,000/mm^3$) or G4 (less than $25,000/mm^3$) thrombocytopenia if the member did not have a response to corticosteroids after 1 to 2 weeks.

CONTINUATION OF THERAPY

Immune Thrombocytopenia (ITP)

- Authorization of 3 months may be granted to members with current platelet count less than $50x10^9$/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.
- Authorization of 12 months may be granted to members with current platelet count less than $50x10^9$/L for whom the current platelet count is sufficient to prevent clinically important bleeding.
- Authorization of 12 months may be granted to members with current platelet count of $50x10^9$/L to $200x10^9$/L.
- Authorization of 12 months may be granted to members with current platelet count greater than $200x10^9$/L to less than or equal to $400x10^9$/L for whom Nplate dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Myelodysplastic Syndromes (MDS) and Immune Checkpoint Inhibitor-Related Toxicity

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

Chemotherapy-Induced Thrombocytopenia

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

- Member is experiencing benefit from therapy (e.g., increased platelet counts, decreased bleeding events, reduced need for platelet transfusions) to maintain a target platelet count goal of $100x10^9$/L to $200x10^9$/L.
- The requested drug is used to maintain dose schedule and intensity of chemotherapy.

APPENDIX

Examples of Risk Factors for Bleeding (not all inclusive)

- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidities for bleeding (e.g., peptic ulcer disease)
- Mandated anticoagulation therapy
- Profession (e.g., construction worker) or lifestyle (e.g., plays contact sports) that predisposes member to trauma

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Nplate [package insert]. Thousand Oaks, CA: Amgen Inc.; March 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 11, 2025.
3. The NCCN Clinical Practice Guidelines in Oncology® Myelodysplastic Syndrome (Version 2.2025). © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 11, 2025.
4. Neunert 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.
6. 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.
7. The NCCN Clinical Practice Guidelines in Oncology® Hematopoietic Growth Factors (Version 1.2025). © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 11, 2025.

EFFECTIVE DATE

ID_CHS_2025