

Nplate® (romiplostim) (Subcutaneous)

Document Number: OHSU HEALTHSERVICES-0089

Last Review Date: 02/03/2026

Date of Origin: 01/01/2012

Dates Reviewed: 12/2011, 02/2013, 02/2014, 12/2014, 10/2015, 09/2016, 12/2016, 03/2017, 06/2017, 12/2017, 03/2018, 06/2018, 10/2018, 01/2019, 12/2019, 02/2020, 02/2021, 02/2022, 02/2023, 02/2024, 02/2025, 02/2026

I. Length of Authorization ¹

- Initial: Prior authorization validity will be provided initially for 3 months (90 days).
- Renewal: Prior authorization validity may be renewed every 3 months (90 days) thereafter (unless otherwise specified).
 - Management of Immune Checkpoint Inhibitor-Related Toxicities AND Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS): Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- ITP, CIT, Immune Checkpoint Inhibitor-Related Toxicities: 1250 billable units weekly
- MDS: 1000 billable units weekly
- HS-ARS: 1250 billable units x 1 dose

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

Universal Criteria ¹

- Patient is not on concurrent treatment with any other thrombopoietin receptor agonist or mimetic or fostamatinib; **AND**
- Romiplostim therapy will be used to decrease the risk of bleeding from thrombocytopenia (i.e., will NOT be used in an attempt to normalize platelet counts); **AND**
- Laboratory values for platelet count are current (i.e., drawn within the previous 28 days); ****_AND**
****NOTE: Does not apply to patients receiving treatment for Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)**

Immune (idiopathic) Thrombocytopenia (ITP) † Φ^{1,5}

- The patient is at increased risk for bleeding as indicated by platelet count less than $30 \times 10^9/L$ ($30,000/mm^3$); **AND**
 - Patient has acute ITP; **AND**
 - Patient is at least 18 years of age; **AND**
 - Patient has previously failed any of the following treatments for ITP:
 - Corticosteroids; **OR**
 - Immunoglobulins; **OR**
 - Splenectomy; **OR**
 - Patient has had chronic ITP for at least 6 months (or meets the corticosteroid requirement below); **AND**
 - Patient is at least 1 year of age; **AND**
 - Patient has previously failed any of the following treatments for ITP:
 - Corticosteroids (i.e., patient had no response to at least a 3-month trial or is corticosteroid-dependent); **OR**
 - Immunoglobulins; **OR**
 - Splenectomy

Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS) † Φ¹

- Patient has suspected or confirmed exposure to radiation levels greater than 2 gray (Gy)

Chemotherapy-Induced Thrombocytopenia (CIT) ‡^{2,15-19}

- Patient is at least 18 years of age; **AND**
- Patient has a platelet count less than $100 \times 10^9/L$ ($100,000/mm^3$) for at least 3 to 4 weeks after the last chemotherapy administration and/or after delays in chemotherapy initiation related to thrombocytopenia

Myelodysplastic Syndromes (MDS) ‡^{2,3,13,14,20,21}

- Patient is at least 18 years of age; **AND**
- Patient has lower risk disease [i.e., IPSS-R (Very Low, Low, Intermediate)]; **AND**
- Patient has severe or refractory thrombocytopenia (i.e., platelet count $<50 \times 10^9/L$); **AND**
- Patient progressed, had no response to, or relapsed after hypomethylating agents (e.g., azacitidine, decitabine, etc.) or immunosuppressive therapy

Management of Immune Checkpoint Inhibitor-Related Toxicities ‡^{2,23}

- Patient is at least 18 years of age; **AND**

- Patient has been receiving therapy with an immune checkpoint inhibitor; **AND**
- Patient has thrombocytopenia related to immunotherapy; **AND**
- Used as additional therapy for G3 or G4 disease if no response to corticosteroids after 1-2 weeks

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); ◊ Orphan Drug

IV. Renewal Criteria ¹

Prior authorization validity can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: thrombotic/thromboembolic complications, risk of progression of myelodysplastic syndromes to acute myelogenous leukemia, loss of response to romiplostim/presence of neutralizing antibodies to romiplostim, etc.; **AND**

Immune (idiopathic) Thrombocytopenia (ITP) † ¹

- Disease response as indicated by the achievement and maintenance of a platelet count of at least $50 \times 10^9/L$ (not to exceed $400 \times 10^9/L$) as necessary to reduce the risk for bleeding

Chemotherapy-Induced Thrombocytopenia (CIT) ‡ ^{2,15-19}

- Patient continues to receive chemotherapy; **AND**
- Disease response as indicated by the achievement and maintenance of a platelet count of at least $100 \times 10^9/L$ (not to exceed $400 \times 10^9/L$)

Myelodysplastic Syndromes (MDS) ‡ ^{2,3,21}

- Patient has not developed acute myeloid leukemia (AML) (Note: romiplostim induces an increase in immature white blood cells and peripheral blasts which is not indicative of development of AML); **AND**
- Disease response as indicated by an increase in platelet count compared to pretreatment baseline (not to exceed $450 \times 10^9/L$), reduction in bleeding events, or reduction in platelet transfusion requirements

V. Dosage/Administration ^{1,3,19,21,22}

Indication	Dose
ITP	<p><u>Adult and Pediatric patients:</u></p> <p><u>Initial:</u> 1 mcg/kg subcutaneously weekly</p> <ul style="list-style-type: none"> Adjust dose weekly by increments of 1 mcg/kg to achieve and maintain platelet count of $\geq 50 \times 10^9/L$ ($50,000/mm^3$) as necessary to reduce the risk for bleeding Do not exceed the maximum weekly dose of 10 mcg/kg Adjust the dose as follows for all patients: <ul style="list-style-type: none"> If the platelet count is $< 50 \times 10^9/L$, increase the dose by 1 mcg/kg. If platelet count is $> 200 \times 10^9/L$ and $\leq 400 \times 10^9/L$ for 2 consecutive weeks, reduce the dose by 1 mcg/kg. If platelet count is $> 400 \times 10^9/L$, do not dose. Continue to assess the platelet count weekly. After the platelet count has fallen to $< 200 \times 10^9/L$, resume Nplate at a dose reduced by 1 mcg/kg.
HS-ARS	<p><u>Adult and Pediatric patients:</u></p> <ul style="list-style-type: none"> 10 mcg/kg subcutaneously x 1 dose administered as soon as possible after suspected or confirmed exposure to radiation.
CIT	<p><u>Initial:</u> 2 to 4 mcg/kg subcutaneously weekly</p> <ul style="list-style-type: none"> Increase by no more than 1 to 2 mcg/kg per week to target platelet count of $100 \times 10^9/L$ to $150 \times 10^9/L$. Do not exceed the maximum weekly dose of 10 mcg/kg.
MDS	<p><u>Initial:</u> 750 mcg subcutaneously weekly</p> <ul style="list-style-type: none"> Adjust dose in 250 mcg increments (from 250 mcg every other week up to 1000 mcg weekly) based on platelet counts <ul style="list-style-type: none"> If platelet count is $< 50 \times 10^9/L$ for 3 consecutive weeks, then increase to the next highest dose level Withhold the dose if platelet count $> 450 \times 10^9/L$ <ul style="list-style-type: none"> Reinitiate at a reduced dose when platelet count is $< 200 \times 10^9/L$
Management of Immune Checkpoint Inhibitor-Related Toxicities	<p><u>Initial:</u> 1 mcg/kg subcutaneously weekly.</p> <ul style="list-style-type: none"> Adjust dose weekly by increments of 1 mcg/kg to maintain platelet count $\geq 50 \times 10^9/L$ ($50,000/mm^3$) as necessary to reduce the risk for bleeding Do not exceed the maximum weekly dose of 10 mcg/kg/week.

VI. Billing Code/Availability Information

HCPCS Code:

- J2802 – Injection, romiplostim, 1 microgram; 1 billable unit = 1 mcg

NDC(s):

- Nplate 125 mcg single-dose vial: 55513-0223-xx
- Nplate 250 mcg single-dose vial: 55513-0221-xx
- Nplate 500 mcg single-dose vial: 55513-0222-xx

VII. References

1. Nplate [package insert]. Thousand Oaks, CA; Amgen Inc; March 2025. Accessed January 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for romiplostim. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to www.nccn.org/. Accessed January 2026.
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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime’s assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C93.10	Chronic myelomonocytic leukemia not having achieved remission
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.4	Refractory anemia, unspecified
D46.9	Myelodysplastic syndrome, unspecified
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.Z	Other myelodysplastic syndromes
D69.3	Immune thrombocytopenic purpura
D69.59	Other secondary thrombocytopenia
D69.6	Thrombocytopenia, unspecified
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela
T66.XXXA	Radiation sickness, unspecified, initial encounter
T66.XXXD	Radiation sickness, unspecified, subsequent encounter
T66.XXXS	Radiation sickness, unspecified, sequela

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC