Nplate® (romiplostim)
(Subcutaneous)

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I. Length of Authorization [1]

Coverage will be provided for 3 months and may be renewed, unless otherwise specified.

- Coverage for use to treat Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS) cannot be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Nplate 125 mcg single-dose vial for injection: 40 vials per 28 days
- Nplate 250 mcg single-dose vial for injection: 20 vials per 28 days
- Nplate 500 mcg single-dose vial for injection: 12 vials per 28 days

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

- ITP and CIT: 1250 billable units weekly
- MDS: 1000 billable units weekly
- HS-ARS: 1250 billable units x 1 dose

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

Universal Criteria [1]

- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., lusutrombopag, eltrombopag, avatrombopag, etc.) or fostamatinib; **AND**
- Romiplostim is not being used to attempt to normalize platelet count (i.e., use is limited to decreasing the risk of bleeding from thrombocytopenia by increasing platelet levels and not normalizing them); **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 × 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:
    - Patient has failed previous therapy with corticosteroids; **OR**
    - Patient has failed previous therapy with immunoglobulins; **OR**
    - Patient has had a 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:
    - Patient has failed previous therapy with corticosteroids (i.e., patient had no response to at least a 3-month trial or is corticosteroid-dependent); **OR**
    - Patient has failed previous therapy with immunoglobulins; **OR**
    - Patient has had a splenectomy

Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS) † Φ [1]

- 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 × 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 x 10^9/L); **AND**
- Patient progressed or had no response to hypomethylating agents (e.g., azacitidine, decitabine, etc.) or immunosuppressive therapy

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

IV. Renewal Criteria [1]

Coverage 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**

- 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 × 10^9/L (not to exceed 400 x 10^9/L) as necessary to reduce the risk for bleeding

Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS) † [1]

- Coverage cannot be renewed

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 × 10^9/L (not to exceed 400 x 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 x 10^9/L), reduction in bleeding events, or reduction in platelet transfusion requirements

V. Dosage/Administration [1,3,19,21]

Indication	Dose
ITP	Adult and Pediatric patients: Initial: 1 mcg/kg subcutaneously weekly • Adjust dose weekly by increments of 1 mcg/kg to achieve and maintain platelet count of ≥ 50 × 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: – If the platelet count is < 50 × 10^9/L, increase the dose by 1 mcg/kg. – If platelet count is > 200 × 10^9/L and ≤ 400 × 10^9/L for 2 consecutive weeks, reduce the dose by 1 mcg/kg. – If platelet count is > 400 × 10^9/L, do not dose. Continue to assess the platelet count weekly. After the platelet count has fallen to < 200 × 10^9/L, resume Nplate at a dose reduced by 1 mcg/kg.

Indication	Dose
HS-ARS	Adult and Pediatric patients: • 10 mcg/kg subcutaneously x 1 dose administered as soon as possible after suspected or confirmed exposure to radiation.
CIT	Initial: 2 to 4 mcg/kg subcutaneously weekly • Increase by no more than 1 to 2 mcg/kg per week to target platelet count of 100 × 10^9/L to 150 × 10^9/L. • Do not exceed the maximum weekly dose of 10 mcg/kg.

MDS	Initial: 750 mcg subcutaneously weekly
	• Adjust dose in 250 mcg increments (from 250 mcg every other week up to 1000 mcg weekly) based on platelet counts
	  ○ If platelet count is <50 x 10^9/L for 3 consecutive weeks, then increase to the next highest dose level
	• Withhold the dose if platelet count >450 x 10^9/L
	  ○ Reinitiate at a reduced dose when platelet count is <200 x 10^9/L

VI. Billing Code/Availability Information

HCPCS Code:

- J2802 – Injection, romiplostim, 1 microgram; 1 billable unit = 1 mcg *(Effective 01/01/2025)*
- J2796 – Injection, romiplostim, 10 micrograms; 10 mcg = 1 billable unit *(Discontinue use on 01/01/2025)*

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; February 2022. Accessed January 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for romiplostim. National Comprehensive Cancer Network, 2024. 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 2024.
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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	Radiation sickness, unspecified

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):

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
15	A57160	CGS Administrators, LLC

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