Nplate® (romiplostim)
(Subcutaneous)

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I. Length of Authorization

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 SDV for injection: 4 vials per 28 days
- Nplate 250 mcg SDV for injection: 20 vials per 28 days
- Nplate 500 mcg SDV for injection: 12 vials per 28 days

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

- ITP: 125 billable units weekly
- MDS: 100 billable units weekly
- HS-ARS: 125 billable units x 1 dose

III. Initial Approval Criteria [1,3,13,14]

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**
- Must not be used in an attempt to normalize platelet counts; **AND**
- Laboratory value for platelet count is current (i.e., drawn within the previous 28 days); **AND**

Immune (idiopathic) thrombocytopenia (ITP) † Φ [1,4-12]

- 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 one 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 with chronic ITP for at least 6 months (or meets the corticosteroid requirement below); **AND**
        - Patient is 1 year of age or older; **AND**
        - Patient has previously failed one 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

- Patient has tried and failed to tolerate or respond to a trial of Promacta® therapy or a documented contraindication exists

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

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

Myelodysplastic Syndromes (MDS) ‡ [2,3,13,14]

- Patient is at least 18 years of age; **AND**
- Patient has lower risk disease [i.e., IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate)]; **AND**
- Patient has severe or refractory thrombocytopenia (i.e., platelet count <20 x 10^9/L or higher with a history of bleeding); **AND**
- Patient progressed or had no response to hypomethylating agents (e.g., azacitidine, decitabine, etc.), immunosuppressive therapy, or clinical trial

† FDA-labeled 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 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 the following: thrombotic/thromboembolic complications, risk of progression of myelodysplastic syndromes to acute myelogenous leukemia, etc.; **AND**

ITP

- Disease response 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

HS-ARS

- Coverage cannot be renewed

MDS [2,3]

- 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 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 [1,3,13]

Indication	Dose
ITP	ADULT/PEDIATRIC 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.
Hematopoietic Syndrome of Acute Radiation Syndrome	ADULT/PEDIATRIC 10 mcg/kg subcutaneously x 1 dose administered as soon as possible after suspected or confirmed exposure to radiation.
MDS	Initial: 750 mcg weekly • Adjust dose in 250 mcg increments (from 250 mcg every other week up to 1000 mcg weekly) based on platelet counts o If platelet count is <50 x 10^9/L for 3 consecutive weeks, then increase to the next highest dose level

Indication	Dose
	• Withhold the dose if platelet count >450 x 10^9/L o Reinitiate at a reduced dose when platelet count is <200 x 10^9/L

VI. Billing Code/Availability Information

HCPCS Code:

- J2796 – Injection, romiplostim, 10 micrograms; 10 mcg = 1 billable unit

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; January 2021. Accessed January 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for romiplostim. National Comprehensive Cancer Network, 2021. 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 2021.
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11. Kuter DJ, Bussel JB, Newland A, et al. Long-term treatment with romiplostim in patients with chronic immune thrombocytopenia: safety and efficacy. Br J Haematol. 2013 May;161(3):411-23. doi: 10.1111/bjh.12260.
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13. Kantarjian H, Fenaux P, Sekeres MA, et al. Safety and efficacy of romiplostim in patients with lower-risk myelodysplastic syndrome and thrombocytopenia. J Clin Oncol. 2010 Jan 20;28(3):437-44.
14. Kantarjian HM, Giles FJ, Greenberg PL, et al. Phase 2 study of romiplostim in patients with low- or intermediate-risk myelodysplastic syndrome receiving azacitidine therapy. Blood. 2010 Oct 28;116(17):3163-70.
15. CGS Administrators, LLC. Local Coverage Article: Billing and Coding: Immune Thrombocytopenia (ITP) Therapy (A57160). Centers for Medicare & Medicaid Services, Inc. Updated on 02/14/2020 with effective date 04/01/2020. Accessed January 2021.

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
T66	Radiation sickness, unspecified

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

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

Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

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

Jurisdiction(s): 15	**NCD/LCD/Article Document (s):** A57160
https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57160&bc=gAAAAAAAAAAA&	

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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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