# 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: 125 billable units weekly
- MDS: 100 billable units weekly
- HS-ARS: 125 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**

**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]**

- 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 <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.) or immunosuppressive therapy

† 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 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]**

- 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]

| Indication | Dose |
|---|---|
| ITP | Adult and Pediatric patients:<br>Initial: 1 mcg/kg subcutaneously weekly<br>• 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<br>• Do not exceed the maximum weekly dose of 10 mcg/kg<br>• Adjust the dose as follows for all patients:<br>– If the platelet count is < 50 × $10^9$/L, increase the dose by 1 mcg/kg. |

| Indication | Dose |
|---|---|
| | – If platelet count is > 200 × $10^9$/L and ≤ 400 × $10^9$/L for 2 consecutive weeks, reduce the dose by 1 mcg/kg.<br>– 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. |
| HS-ARS | Adult and Pediatric patients:<br>• 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<br>• 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.<br>• Do not exceed the maximum weekly dose of 10 mcg/kg. |
| MDS | Initial: 750 mcg subcutaneously weekly<br>• Adjust dose in 250 mcg increments (from 250 mcg every other week up to 1000 mcg weekly) based on platelet counts<br>o If platelet count is <50 x $10^9$/L for 3 consecutive weeks, then increase to the next highest dose level<br>• Withhold the dose if platelet count >450 x $10^9$/L<br>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; February 2022. Accessed December 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for romiplostim. National Comprehensive Cancer Network, 2022. 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 December 2022.

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19. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hematopoietic Growth Factors 1.2023. National Comprehensive Cancer Network, 2023. 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 Guidelines, go online to NCCN.org. Accessed December 2022.
20. CGS Administrators, LLC. Local Coverage Article: Billing and Coding: Immune Thrombocytopenia (ITP) Therapy (A57160). Centers for Medicare & Medicaid Services, Inc. Updated on 02/23/2022 with effective date 03/03/2022. Accessed December 2022.

## 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)

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:

https://www.cms.gov/medicare-coverage-database/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/new-search/search-results.aspx?keyword=a57160&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP | |

| 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 |

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PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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Room 509F, HHH Building
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ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው: 763.847.4013 ).

ဟသူဉ်ဟ်သး– နမ့ါကတိၤ ကညီ ကျိာ်အယိ, နမၤန့ါ ကျိာ်အတ၊်မၤစၢၤလၢ တလၢာ်ဘူဉ်လၢာ်စ့ၤ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).