

Romiplostim (Nplate®)

Place of Service
Office Administration
Outpatient Facility Infusion
Administration
Infusion Center Administration

HCPCS: J2796 per 10 mcg

Condition listed in policy (*see criteria for details*)

- [Chemotherapy-induced thrombocytopenia](#)
- [Primary immune thrombocytopenia \(ITP\)](#)
- [Myelodysplastic syndrome \(MDS\) – related thrombocytopenia](#)

AHFS therapeutic class: Other miscellaneous therapeutic agent

Mechanism of action: thrombopoietin receptor agonist

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Nplate® (romiplostim) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Chemotherapy-induced thrombocytopenia

1. Platelet count is $<100,000/\text{mcl}$ (i.e. $<100 \times 10^9/\text{L}$), **AND**
2. Meets either of the following:
 - a. Being used following a delay (of at least one week) in chemotherapy related to thrombocytopenia, or
 - b. Thrombocytopenia is ≥ 3 -4 weeks following last chemotherapy administration

Covered Doses

Up to 10 mcg/kg SC weekly

Coverage Period

3 months

ICD-10:

D69.5, D69.6, T45.1X5A, T45.1X5D, T45.1X5S

Primary immune thrombocytopenia (ITP)

1. Patient has refractory ITP, **AND**
2. Platelet count $<30,000/\text{mcl}$ (i.e. $<30 \times 10^9/\text{L}$), **AND**
3. Not being used in combination with thrombopoietin receptor agonists (Promacta, Doptelet), **AND**
4. Inadequate response or intolerable side effect to one of the following treatments: corticosteroids, IVIG, anti-D antibody, or splenectomy, or contraindication to all these treatments cannot be used

Covered Doses

Up to 10 mcg/kg SC weekly

Coverage Period

Initial authorization: 3 months

Maintenance: Indefinite

ICD-10:

D69.3

Myelodysplastic syndrome (MDS)-related thrombocytopenia

1. Patient has **very low, low, or intermediate risk MDS** (See Table 1A below), **AND**
2. Inadequate response or intolerable side effect to one NCCN-supported first-line therapy for low risk MDS OR medical rationale why patient is unable to use all NCCN supported first-line therapies for low risk MDS. (See Table 2A below)

Covered Doses

Up to 1500 mcg weekly

Coverage Period

Initial: 6 months

Reauthorization for 6 months if meets the following:

1. Patient disease has not progressed to acute leukemia, **AND**
2. Increased platelet level from baseline

ICD-10:

C93.10, D46.0, D46.1, D46.20, D46.21, D46.4, D46.9, D46.A, D46.B, D46.Z

Table 1A: MDS Foundation International Prognostic Scoring System (IPSS-R) Factors

- Hemoglobin
- Absolute Neutrophil Count (ANC)
- Platelets
- Bone Marrow Blasts
- Cytogenetic Category

<https://www.mds-foundation.org/ipss-r-calculator/>

Table 2A: NCCN Supported First-line Agents for Severe or Refractory Thrombocytopenia

Hypomethylating agents

- Decitabine
- Azacitidine

Immunosuppressive therapy (IST)

- Equine ATG (antithymocyte globulin)
- Cyclosporine A
- Lenalidomide

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Nplate® (romiplostim) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

125 mcg, 250 mcg, 500 mcg (single-use vials)

(6) References

- AHFS®. Available at: www.lexi.com
- Drugdex®. Available at: <http://www.micromedexsolutions.com>
- George JN, Woolf SH, Raskob GE, et al. Idiopathic Thrombocytopenic Purpura: A Practice Guideline Developed by Explicit Methods for The American Society of Hematology. Blood. 1996 Jul 1;88(1):3-40.
- National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 1.2022). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 1.2023). Available by subscription at: www.nccn.org.

- Neunert C, Lim W, Crowther M. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia . Blood 2011;117(16): 4190-4207.
- Nplate® (romiplostim) [Prescribing information]. Thousand Oaks, CA: Amgen. 2/2022.

(7) Policy Update

Date of last review: 4Q2023

Date of next review: 4Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*