blue california
Promise Health Plan

romiplostim (Nplate)

Medical Benefit Drug Policy

For oncology-related indications, coverage will be made based on medical necessity. Medical necessity determinations are made based on U.S. Food and Drug Administration (FDA) labeling, peer-reviewed medical literature, Medi-Cal coverage guidelines, and Centers for Medicare & Medicaid Services (CMS) approved compendia support (i.e., Clinical Pharmacology, National Comprehensive Cancer Network® (NCCN), American Hospital Formulary Service Drug Information, Thomson Micromedex DrugDex,® and Lexicomp®).

Place of Service

Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: BLOOD PRODUCTS AND MODIFIERS
Mechanism of Action: thrombopoietin receptor agonist
HCPCS:
J2802:Injection, romiplostim, 1 microgram
How Supplied:
125 mcg, 250 mcg, 500 mcg (single-use vials)

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

- Acute Exposure to Myelosuppressive Doses of Radiation
- Chemotherapy-Induced Thrombocytopenia
- Immunotherapy-Related Thrombocytopenia
- Primary Immune Thrombocytopenia (ITP)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Acute Exposure to Myelosuppressive Doses of Radiation

Meets medical necessity if all the following are met:

1. Diagnosis only

Covered Doses:

10 mcg/kg given subcutaneously

Coverage Period:

one dose

ICD-10:

T66.X (X = any number)

Chemotherapy-Induced Thrombocytopenia

Meets medical necessity if all the following are met:

1. Platelet count is <100, 000/mcl (i.e. <100 x10^9/L)
2. Meets either of the following:
   a. Being used following a delay (of at least one week) in chemotherapy related to thrombocytopenia
   b. Thrombocytopenia is ≥ 3-4 weeks following last chemotherapy administration

Covered Doses:

Up to 10 mcg/kg given subcutaneously weekly

Coverage Period:

Initial: 6 months

Reauthorization 6 months if meets ALL the following:

1. Patient is experiencing benefit from treatment
2. Continuation of treatment is being used to maintain chemotherapy treatment plan

ICD-10:

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

Immunotherapy-Related Thrombocytopenia

Meets medical necessity if all the following are met:

Initial

1. Patient has immunotherapy-related Grade 3 (platelet count 50,000 cells/mcl-25,000 cells/mcl) or Grade 4 (platelet count < 25,000 cells/mcl) thrombocytopenia
2. Patient has had no response to at least 1 week of corticosteroids (i.e., prednisone/IV methylprednisolone 1-2 mg/kg daily)

Reauthorization

1. Platelet count has increased from baseline and ≤ 400,000 cells/mcl

Covered Doses:
Up to 10 mcg/kg given subcutaneously weekly

Coverage Period:
6 months

ICD-10:
D69.59

Primary Immune Thrombocytopenia (ITP)
Meets medical necessity if all the following are met:
1. Platelet count <30, 000/mcl (i.e. <30 x10^9/L)
2. Not being used in combination with another medication for ITP (e.g., Doptelet, Promacta, Tavalisse, Wayrilz)
3. 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 given subcutaneously weekly

Coverage Period:
Initial: 3 months
Maintenance: Yearly, based on continued response to therapy

Effective 2/1/2026 and after: Yearly, if meets ALL the following:
1. Platelet count has increased or stabilized from baseline and ≤ 400,000 cells/mcl
2. Not being used in combination with another medication for ITP (e.g., Doptelet, Promacta, Tavalisse, Wayrilz)

ICD-10:
D69.3

References

1. AHFS. Available at: www.lexi.com
2. Drugdex. Available at: http://www.micromedexsolutions.com
3. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 3.2024). Available by subscription at: www.nccn.org.
4. National Comprehensive Cancer Network. Management of Immune Checkpoint Inhibitor-Related Toxicities (Version 1.2025). Available by subscription at: www.nccn.org.
5. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Adv 2019;3(23):3829-3866.
6. Nplate (romiplostim) Prescribing Information. Amgen, Thousand Oaks, CA. 3/2025.

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- For oncology-related indications, coverage will be made based on medical necessity

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee