

PHARMACY POLICY STATEMENT

Marketplace

| | |
|---------------------|------------------------------|
| DRUG NAME | NPlate (romiplostim) |
| BENEFIT TYPE | Medical |
| STATUS | Prior Authorization Required |

Nplate, approved by the FDA in 2008, is a thrombopoietin receptor agonist (TPO-RA) indicated for the treatment of thrombocytopenia in 1) Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy and 2) Pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Nplate is also indicated to increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS]).

ITP is a rare autoimmune disorder characterized by low levels of platelets due to platelet destruction and insufficient platelet production. ITP duration of less than 3 months is referred to as newly diagnosed, 3-12 months as persistent, and greater than 12 months is considered chronic. As a TPO-RA, Nplate increases platelet production through binding and activation of the TPO receptor, a mechanism analogous to endogenous TPO.

NPlate (romiplostim) will be considered for coverage when the following criteria are met:

Immune Thrombocytopenia (ITP)

For **initial** authorization:

1. Member is at least 1 year of age; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member has a documented diagnosis of immune thrombocytopenia (ITP); AND
4. If member is less than 18 years of age, disease duration must be at least 6 months; AND
5. Member meets one of the following:
 - a) Current platelet count is $<30 \times 10^9/L$
 - b) $30 \times 10^9/L$ to $50 \times 10^9/L$ with one of the following:
 - i) Active symptomatic bleeding other than minor mucocutaneous bleeding
 - ii) High risk factor for bleeding (i.e., on an anticoagulant, of older age (>60 years), other clearly identified comorbidity; AND
6. Member had an inadequate response, intolerance, or contraindication to documented prior therapy with at least one of the following treatments:
 - a) Corticosteroids (prednisone, prednisolone, methylprednisolone, or dexamethasone)
 - b) Immunoglobulins
 - c) Splenectomy; AND
7. Current weight is provided for dose calculation; AND
8. Member does NOT have any of the following:
 - a) Any cause of thrombocytopenia other than primary ITP
 - b) Concurrent use with another TPO-RA.
9. **Dosage allowed/Quantity limit:** Administer 1 mcg/kg subcutaneously once weekly, then adjust the weekly dose by increments of 1 mcg/kg until the patient achieves a platelet count $\geq 50 \times 10^9/L$ as necessary to reduce the risk for bleeding, per prescribing information. Max dose 10 mcg/kg.

Note: Discontinue if platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks at the max dose.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes show achievement of a platelet count $\geq 50 \times 10^9 /L$ as necessary to reduce the risk for bleeding; AND
2. Member's platelet count is less than $400 \times 10^9/L$; AND
3. Dose will be reduced if platelet count is between $200 \times 10^9/L$ and $400 \times 10^9/L$.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS)

Any request related to oncology must be submitted through [NantHealth/Eviti](#) portal.

CareSource considers Nplate (romiplostim) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|------------|--|
| 10/04/2018 | New policy for Nplate created. Platelets requirement threshold expanded. |
| 02/08/2023 | Transferred to new template. Updated and added references. Updated terminology from "chronic immune (idiopathic) thrombocytopenic purpura" to "immune thrombocytopenia." Corrected age limit from 18 years to 1 year and added 6 mo duration for peds. Modified descriptions under 30,000-50,000 platelet count to be consistent with our other TPO-RA drug policies. Added documentation of current weight. Added exclusion for thrombotic events. Added not to be used in combo with another TPO-RA or Tavalisse. Rephrased renewal criteria to be consistent with drug label to address bleeding avoidance, added dose adjustment for PC >200. Added HSARS as an Eviti diagnosis. |
| 08/12/2025 | Added references. Changed initial auth duration from 3 months to 6 months. Modified concurrent med use criterion. Removed exclusion criterion for thromboembolic disease (not an absolute contraindication; must monitor). Clarified dosing and to refer to PI. Added plt >50 to reauth criteria 1 (label). |

References:

1. Nplate [Package Insert]. Thousand Oaks, CA: Amgen, Inc.; 2025.
2. Cooper N, Terrinoni I, Newland A. The efficacy and safety of romiplostim in adult patients with chronic immune thrombocytopenia. *Ther Adv Hematol*. 2012 Oct; 3(5): 291–298.
3. Kuter DJ, et al. Romiplostim or standard of care in patients with immune thrombocytopenia. *N Engl J Med*. 2010 Nov 11;363(20):1889-99.
4. Kuter DJ, et al. Efficacy of romiplostim in patients with chronic immune thrombocytopenic purpura: a double-blind randomised controlled trial. *Lancet*. 2008 Feb 2;371(9610):395-403.
5. Kuter DJ, 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.
6. Tarantino MD, Despotovic J, Roy J, et al. Romiplostim treatment for children with immune thrombocytopenia: Results of an integrated database of five clinical trials. *Pediatr Blood Cancer*. 2020;67(11):e28630. doi:10.1002/pbc.28630
7. Grainger J, Bussel J, Tarantino M, et al. A single-arm, long-term efficacy and safety study of subcutaneous romiplostim in children with immune thrombocytopenia. *Blood Adv*. 2023;7(3):396-405. doi:10.1182/bloodadvances.2021006014

8. Grainger JD, Kühne T, Hippenmeyer J, Cooper N. Romiplostim in children with newly diagnosed or persistent primary immune thrombocytopenia. *Ann Hematol.* 2021;100(9):2143-2154. doi:10.1007/s00277-021-04590-0
9. Kuter DJ, Newland A, Chong BH, et al. Romiplostim in adult patients with newly diagnosed or persistent immune thrombocytopenia (ITP) for up to 1 year and in those with chronic ITP for more than 1 year: a subgroup analysis of integrated data from completed romiplostim studies. *Br J Haematol.* 2019;185(3):503-513. doi:10.1111/bjh.15803
10. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia [published correction appears in *Blood Adv.* 2020 Jan 28;4(2):252]. *Blood Adv.* 2019;3(23):3829-3866. doi:10.1182/bloodadvances.2019000966
11. Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Adv.* 2019;3(22):3780-3817. doi:10.1182/bloodadvances.2019000812
12. Neunert CE, Arnold DM, Grace RF, Kuhne T, McCrae KR, Terrell DR. The 2022 review of the 2019 American Society of Hematology guidelines on immune thrombocytopenia. *Blood Adv.* 2024;8(13):3578-3582. doi:10.1182/bloodadvances.2023012541
13. Cuker A, Despotovic JM, Grace RF, et al. Tapering thrombopoietin receptor agonists in primary immune thrombocytopenia: Expert consensus based on the RAND/UCLA modified Delphi panel method. *Res Pract Thromb Haemost.* 2020;5(1):69-80. Published 2020 Dec 8. doi:10.1002/rth2.12457

Effective date: 01/01/2026

Revised date: 08/12/2025