Medical Policy:

Nplate™ (romiplostim) Subcutaneous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.96	March 14, 2025	

Length of Authorization

Immune thrombocytopenia: Coverage will be provided for 3 months and may be renewed

Hematopoietic Syndrome of Acute Radiation Syndrome: Coverage will be provided for one dose and is not applicable for renewal

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

ITP-1250 billable units weekly

HS-ARS: 1250 billable units x 1 dose

Guideline

I. Initial Approval Criteria

Coverage is provided in the following conditions:

1. **Immune thrombocytopenia (ITP)** †

A. The patient is at increased risk for bleeding as indicated by platelet count (within the previous 28 days) less than 30×10^9/L (30,000/mm³); **AND**
B. Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., lustrombopag, eltrombopag, avatrombopag, etc); **AND**
C. Must not be used in an attempt to normalize platelet counts
    i. Patient has acute ITP; **AND**
        a. Patient aged 18 years or older; **AND**
        b. Patient has previously failed **ONE** of the following treatments for ITP:
            1.)Patient has failed previous therapy with corticosteroids; **OR**
            2.)Patient has failed previous therapy with immunoglobulins; **OR**
            3.)Patient has had a splenectomy; **OR**
    ii. Patient has had chronic ITP for at least 6 months (or meets the corticosteroid requirement below); **AND**
        a. Patient is at least 1 year of age; **AND**
        b. Patient has previously failed any of the following treatments for ITP:
            1.) 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**
            2.) Patient has failed previous therapy with immunoglobulins; **OR**
            3.) Patient has had a splenectomy

2. <u>Hematopoietic Syndrome of Acute Radiation Syndrome†</u>
A. Patient has been acutely exposed to myelosuppressive doses of radiation (radiation levels greater than 2 gray (Gy))

† FDA-labeled indication(s)

II. Renewal Criteria

Authorizations can be renewed for **ITP** based on the following criteria:

1. **<u>Immune thrombocytopenia (ITP)</u>**
    A. 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 Initial Criteria; **AND**
    B. 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**
    C. Disease response as indicated by the achievement and maintenance of a platelet count of at least 50×10^9/L (not to exceed 400×10^9/L) as necessary to reduce the risk for bleeding

2. **<u>Hematopoietic Syndrome of Acute Radiation Syndrome</u>**
    A. Not applicable for renewal beyond initial approval

Limitations/Exclusions

NPlate is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

Discontinue Nplate if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks of Nplate therapy at the maximum weekly dose of 10 mcg/kg

Applicable Procedure Codes

Code	Description
J2802	Injection romiplostim, 1 microgram: 1mcg = 1 billable unit

Applicable NDCs

Code	Description
55513-0221-xx	Nplate 250 mcg single-dose vial
55513-0222-xx	Nplate 500 mcg single-dose vial
55513-0223-xx	Nplate 125 mcg single-dose vial

ICD-10 Diagnoses

Code	Description
D69.3	Immune thrombocytopenic purpura
T66	Radiation sickness, unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	03/14/2025	Annual Review: Updated dosing limits, Initial Criteria: Immune thrombocytopenia (ITP) † Added: "Patient has acute ITP; AND" to current criteria Added pediatric section under ITP to combine: "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" Removed the following when combined: "Pediatric Immune thrombocytopenia (ITP) † Pediatric patient aged 1 year or older with ITP for at least 6 months; 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" Hematopoietic Syndrome of Acute Radiation Syndrome† Added: " (radiation levels greater than 2 gray (Gy))" Renewal Criteria: Immune thrombocytopenia (ITP) Removed and reworded the following: "The member has sufficient response after 4 weeks of therapy (Response is defined as a platelet count between 50,000/mm3 and 400,000/mm3) OR Appropriate dosage adjustment was made based on platelet count AND Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: thrombotic/thromboembolic complications, severe hypersensitivity, risk of progression of myelodysplastic syndromes to acute myelogenous leukemia, etc." Replaced with: "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 Initial Criteria; 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 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"
EmblemHealth & ConnectiCare	2/1/2024	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	5/30/2023	Annual Review: added code: T66, no criteria changes
EmblemHealth & ConnectiCare	09/13/2022	Transferred policy to new template.
EmblemHealth & ConnectiCare	03/01/2022	Added NDC 125mcg single-dose vial Added Indication for Hematopoietic Syndrome of Acute Radiation Syndrome to Criteria Removed "Patient continues to meet criteria identified above" from renewal criteria Added "The member has sufficient response after 4 weeks of therapy (Response is defined as a platelet count between 50,000/mm3 and 400,000/mm3) OR Appropriate dosage adjustment was made based on platelet count" Added Exclusion Criteria - The member has not received 4 weeks of Nplate therapy at the maximum weekly dose of 10 mcg/kg and the platelet count did not increase to a sufficient level ≥ 50 × 109 /L
EmblemHealth & ConnectiCare	01/01/2020	Under Guideline, Immune thrombocytopenia (ITP), added 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.

References

1. NPlate [package insert]. Thousand Oaks, CA; Amgen Inc; October 2019. Accessed March 2022.
2. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. Blood. 2011 Apr 21;117(16):4190-207. doi: 10.1182/blood-2010-08-302984. Epub 2011 Feb 16. Review.
3. Lambert MP, Gernsheimer TB. Clinical updates in adult immune thrombocytopenia. Blood. 2017. 129:2829-2835. doi:10.1182/blood-2017-03-754119
4. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Drugs and Biologics (Non-chemotherapy) (L34741). Centers for Medicare & Medicaid Services, Inc. Updated on 5/4/2018 with effective date 6/1/2018. Accessed August 2018.
5. First Coast Service Options, Inc. Local Coverage Determination (LCD): Romiplostim (Nplate®) (L33748). Centers for Medicare & Medicaid Services, Inc. Updated on 07/01/2014 with effective date 10/01/2015. Accessed August 2018.