

Medical Policy:

Nplate™ (romiplostim) Subcutaneous

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 $30 \times 10^9/L$ ($30,000/mm^3$); **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. Hematopoietic Syndrome of Acute Radiation Syndrome†

- 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. Immune thrombocytopenia (ITP)

- 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 $50 \times 10^9/L$ (not to exceed $400 \times 10^9/L$) as necessary to reduce the risk for bleeding

2. Hematopoietic Syndrome of Acute Radiation Syndrome

- 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: <u>Immune thrombocytopenia (ITP) †</u> 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: “ <u>Pediatric Immune thrombocytopenia (ITP) †</u> 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” <u>Hematopoietic Syndrome of Acute Radiation Syndrome†</u> Added: “ (radiation levels greater than 2 gray (Gy))” <u>Renewal Criteria: Immune thrombocytopenia (ITP)</u> 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 $50 \times 10^9/L$ (not to exceed $400 \times 10^9/L$) 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/mm ³ and 400,000/mm ³) 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 $\geq 50 \times 10^9 /L$
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.