

Corporate Medical Policy: Romiplostim (Nplate®) “Notification”

POLICY EFFECTIVE APRIL 1, 2026

Restricted Product(s):

- romiplostim (Nplate®) subcutaneous injection for administration by a healthcare professional

FDA Approved Use:

- For the treatment of immune thrombocytopenia (ITP) in:
 - Adults with ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
 - 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
- 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])
- Limitations of use:
 - Not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP
 - Use should be only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding
 - Use should not be in an attempt to normalize platelet counts

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

Initial Criteria for Approval:

1. The patient has a diagnosis of **chronic immune (idiopathic) thrombocytopenia (ITP); AND**
 - a. ONE of the following:
 - i. The patient is 18 years of age or older; **OR**
 - ii. The patient is 1 year of age or older AND has had a diagnosis of ITP for at least 6 months [**medical record documentation required**]; **AND**
 - b. ONE of the following [**medical record documentation required**]:
 - i. The patient has a platelet count $\leq 30 \times 10^9/L$; **OR**

- ii. The patient has a platelet count $< 50 \times 10^9/L$ AND has symptomatic bleeding and/or an increased risk for bleeding (e.g., ≥ 60 years old, on anticoagulant or antiplatelet medications, history of bleeding, comorbidities for bleeding [e.g., peptic ulcer disease, uncontrolled hypertension, anemia or low hemoglobin], etc.); **AND**
 - c. ONE of the following:
 - i. The patient has tried and had an inadequate response to a prior ITP treatment (i.e., corticosteroids [prednisone, dexamethasone], immunoglobulins [IVIG or anti-D], anti-CD20 monoclonal antibody [rituximab], or splenectomy); **OR**
 - ii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL other ITP treatment (i.e., corticosteroids [prednisone, dexamethasone], immunoglobulins [IVIG or anti-D], anti-CD20 monoclonal antibody [rituximab], and splenectomy); **OR**
 2. The patient has a diagnosis of **Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS)** (i.e., acute exposure to myelosuppressive doses of radiation [radiation levels > 2 gray (Gy)]); **AND**
 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, oncologist) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
 4. The patient will NOT be using the requested agent in combination with another thrombopoietin receptor agonist or mimetic (e.g., avatrombopag [Doptelet], eltrombopag [Alvaiz, Promacta], lusutrombopag [Mupleta], romiplostim [Nplate], etc.); **AND**
 5. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
 6. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting**, Site of Care Criteria applies (outlined below)*

Duration of Approval:

ITP: 90 days (3 months)

HSARS: 30 days (1 dose)

Continuation Criteria for Approval:

1. The patient was approved through Blue Cross NC initial criteria for approval; **OR**
2. The patient would have met initial criteria for approval at the time they started therapy; **AND**
3. ONE of the following:
 - a. The patient has a diagnosis of **Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS)** (i.e., acute exposure to myelosuppressive doses of radiation [radiation levels > 2 gray (Gy)]) – **please refer to initial criteria for approval**; **OR**
 - b. The patient has a diagnosis of **chronic immune (idiopathic) thrombocytopenia (ITP)**; **AND**
 - i. ONE of the following [**medical record documentation required**]:
 1. The patient's platelet count has increased and stabilized to $> 50 \times 10^9/L$; **OR**
 2. The patient's platelet count has doubled from baseline; **OR**

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3. The patient's platelet count has increased sufficiently to avoid clinically important bleeding; **AND**
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, oncologist) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
5. The patient will NOT be using the requested agent in combination with another thrombopoietin receptor agonist or mimetic (e.g., avatrombopag [Doptelet], eltrombopag [Alvaiz, Promacta], lusutrombopag [Mulpleta], romiplostim [Nplate], etc.); **AND**
6. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
7. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting**, Site of Care Criteria applies (outlined below)*

Duration of Approval:

ITP: 365 days (1 year)

FDA Label Reference				
Medication	Indication	Dosing	HCP/CS	Maximum Units*
romiplostim (Nplate®) subcutaneous (SC) injection	Immune thrombocytopenia (ITP)	<ul style="list-style-type: none"> • Initial dose: 1 mcg/kg SC once weekly; adjust dose based on platelet count response • Adjust weekly dose by increments of 1 mcg/kg to achieve and maintain platelet count of $\geq 50 \times 10^9/L$ as necessary to reduce the risk for bleeding • Do not exceed a maximum weekly dose of 10 mcg/kg • Adjust dose as follows for all patients: <ul style="list-style-type: none"> ○ If platelet count is $< 50 \times 10^9/L$, increase dose by 1 mcg/kg ○ If platelet count is $> 200 \times 10^9/L$ and $\leq 400 \times 10^9/L$ for 2 consecutive weeks, reduce dose by 1 mcg/kg ○ If platelet count is $> 400 \times 10^9/L$, do not dose; continue to assess platelet count weekly, and after platelet count has fallen to $< 200 \times 10^9/L$, 	J2802	Initial: 7,500 Continuation: 52,000

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FDA Label Reference				
Medication	Indication	Dosing	HCPCS	Maximum Units*
		resume treatment at a dose reduced by 1 mcg/kg <ul style="list-style-type: none"> Discontinue use if platelet count does not increase to a sufficient level to avoid clinically important bleeding after 4 weeks of treatment at the maximum weekly dose of 10 mcg/kg 		
	Acute exposure to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS])	10 mcg/kg SC one-time dose; administer dose as soon as possible after suspected or confirmed exposure to myelosuppressive doses of radiation		1,000

***Maximum units allowed for duration of approval**

***Site of Care Medical Necessity Criteria**

1. For requests for injection or infusion administration in an **inpatient setting**, the injection or infusion may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the injection or infusion; **OR**
2. For requests for injection or infusion administration in an **outpatient hospital setting**, the injection or infusion may be given if the above medical necessity criteria are met AND ONE of the following must be met:
 - a. History of a severe adverse event following the injection or infusion of the requested medication (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); **OR**
 - b. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access); **OR**
 - c. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
 - d. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
 - e. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**

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- f. Re-initiation of therapy, defined as ONE of the following:
 - i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; **OR**
 - ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**
 - g. Requirement of a change in the requested restricted product formulation; **AND**
3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv.* Dec 10 2019;3(23):3829-66.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q2 annually.

April 2026: Criteria change: For chronic ITP indication, reformatted criteria to allow for either a platelet count $\leq 30 \times 10^9/L$ OR a platelet count $< 50 \times 10^9/L$ with symptomatic bleeding and/or an increased risk for bleeding (with listed examples); adjusted trial and failure requirements to include trial of a prior ITP treatment or intolerance/FDA labeled contraindication/hypersensitivity to all other ITP treatment, and listed additional examples of ITP treatments; removed allowance for insufficient response to or not a candidate for splenectomy, and included splenectomy as an option within prior ITP trial agents; extended ITP duration of approval to 90 days (3 months); and updated ITP disease state terminology for clarity. Updated continuation criteria to differentiate between diagnoses and added redirection to initial criteria for HSARS indication. Within continuation criteria for ITP indication, added allowance for doubled platelet count from baseline, and made other minor adjustments to criteria verbiage. Added requirement to be prescribed by or in consultation with a specialist within initial and continuation sections. Added requirement within initial and continuation sections that Nplate will not be used in combination with another thrombopoietin receptor agonist or mimetic (with listed examples). Adjusted maximum units. Reference added. **Policy notification given 2/1/2026 for effective date 4/1/2026.**

November 2025: Criteria change: Updated Site of Care medical necessity criteria to add additional bypass for patients with a history of severe adverse events or conditions that cause an increased risk for severe adverse event to align with the Place of Service for Medical Infusions policy for clarity of intent.

January 2025: Coding change: Added HCPCS code J2802 to dosing reference table effective 1/1/2025; deleted J2796 termed 12/31/2024. Adjusted maximum units according to coding unit definition for clarity.

October 2021: Criteria change: Added Site of Care medical necessity criteria. **Policy notification given 8/2/2021 for effective date 10/1/2021.**

August 2021: Criteria update: Reformatted age and diagnosis criteria for clarity, no change to policy intent.

June 2021: Criteria change: Added new indication for HSARS; added maximum units; medical policy formatting change. **Policy notification given 4/16/2021 for effective date 6/16/2021.**

*Further historical criteria changes and updates available upon request from Medical Policy and/or Corporate Pharmacy.