

Nplate™ (romiplostim) (Subcutaneous)

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I. Length of Authorization

Coverage will be provided for 3 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 250 mcg injection: 20 vials per 28 days
- 500 mcg injection: 12 vials per 28 days

B. Max Units (per dose and over time) [Medical Benefit]:

- 125 billable units weekly

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient does not have myelodysplastic syndrome (MDS); **AND**

Chronic immune (idiopathic) thrombocytopenia (ITP) †

- Patient aged 1 years or older; **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; **AND**
- 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**
- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., lusutrombopag, eltrombopag, avatrombopag, etc); **AND**
- Must not be used in an attempt to normalize platelet counts; **AND**

- Patient has tried and failed to tolerate or respond to a trial of Promacta® therapy (or a documented contraindication exists)

† FDA-labeled indication(s)

IV. Renewal Criteria

- Patient continues to meet the criteria identified in section III; **AND**
- Disease response indicated by the achievement and maintenance of a platelet count (within the previous 28 days) of at least $50 \times 10^9/L$ (not to exceed $400 \times 10^9/L$) as necessary to reduce the risk for bleeding; **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.

V. Dosage/Administration

Indication	Dose
All indications	<p>ADULT/PEDIATRIC</p> <p>Initial: 1 mcg/kg subcutaneously weekly</p> <ul style="list-style-type: none"> • Adjust dose weekly by increments of 1 mcg/kg to achieve and maintain platelet count of $\geq 50 \times 10^9/L$ ($50,000/mm^3$) as necessary to reduce the risk for bleeding • Do not exceed the maximum weekly dose of 10 mcg/kg • Adjust the dose as follows for all patients: <ul style="list-style-type: none"> – If the platelet count is $< 50 \times 10^9/L$, increase the 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 the dose by 1 mcg/kg. – If platelet count is $> 400 \times 10^9/L$, do not dose. Continue to assess the platelet count weekly. After the platelet count has fallen to $< 200 \times 10^9/L$, resume Nplate at a dose reduced by 1 mcg/kg.

VI. Billing Code/Availability Information

JCode:

- J2796 – Injection, romiplostim, 10 micrograms: 10 mcg = 1 billable unit

NDC(s):

- Nplate 250 mcg single-dose vial: 55513-0221-xx
- Nplate 500 mcg single-dose vial: 55513-0222-xx

VII. References

1. NPlate [package insert]. Thousand Oaks, CA; Amgen Inc; December 2018. Accessed December 2018.

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 December 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 December 2018.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D69.3	Immune thrombocytopenic purpura

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologics. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5,8	NCD/LCD Document (s): L34741
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34741&bc=gAAAAAAAAAAAA	

Jurisdiction(s): N	NCD/LCD Document (s): L33748
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33748&bc=gAAAAAAAAAAAA	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC