EmblemHealth

Nplate™ (romiplostim) (Subcutaneous)

Last Review Date: January 1, 2020	Number: MG.MM.PH.96

LENGTH OF AUTHORIZATION

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

DOSING LIMITS

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

- 125 billable units weekly

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

Chronic immune (idiopathic) thrombocytopenia (ITP) †

- Patient aged 18 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 30×10^9/L (30,000/mm³); **AND**
- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., lustrombopag, eltrombopag, avatrombopag, etc); **AND**
- Must not be used in an attempt to normalize platelet counts

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

† FDA-labeled indication(s)

II. RENEWAL CRITERIA

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria identified above; **AND**
- Disease response indicated by the achievement and maintenance of a platelet count (within the previous 28 days) of at least 50 × 109/L (not to exceed 400 x 109/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.

Limitations/Exclusions

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

Applicable Procedure Codes

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

Applicable NDCs

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

Applicable Diagnosis Codes

D69.3	Immune thrombocytopenic purpura

Revision History

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 December 2019.
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.