**Nplate™ (romiplostim)**
(Subcutaneous)

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

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**Medical Guideline Disclaimer**

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**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 $30 \times 10^9/L$ (30,000/mm$^3$); **AND**
- Patient is not on any other thrombopoietin receptor agonist or mimic (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 $50 \times 10^9/L$ (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.

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 thrombocyticpurpura |

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


