Nplate™ (romiplostim)  
(Subcutaneous)  

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

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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:  
  o Patient has failed previous therapy with corticosteroids; OR  
  o Patient has failed previous therapy with immunoglobulins; OR  
  o 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/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 × 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**

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J2796</td>
<td>Injection, romiplostim, 10 micrograms: 10 mcg = 1 billable unit</td>
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**Applicable NDCs**

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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>55513-0221-xx</td>
<td>Nplate 250 mcg single-dose vial</td>
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<tr>
<td>55513-0222-xx</td>
<td>Nplate 500 mcg single-dose vial</td>
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**Applicable Diagnosis Codes**

<table>
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<th>Code</th>
<th>Description</th>
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<tr>
<td>D69.3</td>
<td>Immune thrombocytopenic purpura</td>
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**Revision History**

<table>
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<th>Date</th>
<th>Description</th>
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<tr>
<td>01/01/2020</td>
<td>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.</td>
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References


