Nplate™ (romiplostim)  
(Subcutaneous)  

Last Review Date: January 1, 2019  
Number: MG.MM.PH.96

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:
  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 × 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
† FDA-labeled indication(s)
II. **RENEWAL CRITERIA**

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria identified in section I; **AND**
- Disease response indicated by the achievement and maintenance of a platelet count (within the previous 28 days) of at least 50 × 10^9/L (not to exceed 400 × 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**

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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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<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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<tr>
<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**

N/A

**References**