Nplate™ (romiplostim)  (Subcutaneous)

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:
   - 250 mcg injection: 20 vials per 28 days
   - 500 mcg injection: 12 vials per 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:
   - 125 billable units weekly

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient does not have myelodysplastic syndrome (MDS): 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., lusutrombopag, eltrombopag, avatrombopag, etc): AND
- Must not be used in an attempt to normalize platelet counts: AND

Immune (idiopathic) thrombocytopenia (ITP) †

- Patient has acute ITP: AND
  - Patient is at least 18 years of age: 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 a splenectomy; **OR**

• Patient with chronic ITP for at least 6 months; **AND**
  o Patient is 1 year of age or older; **AND**
  o 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**

• 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 × 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, risk of progression of myelodysplastic syndromes to acute myelogenous leukemia, etc.

### V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>All indications</td>
<td>ADULT/PEDIATRIC</td>
</tr>
<tr>
<td>Initial</td>
<td>1 mcg/kg subcutaneously weekly</td>
</tr>
</tbody>
</table>

- Adjust dose weekly by increments of 1 mcg/kg to achieve and maintain platelet count of ≥ 50 × 10⁹/L (50,000/mm³) 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:
  - If the platelet count is < 50 × 10⁹/L, increase the dose by 1 mcg/kg.
  - If platelet count is > 200 × 10⁹/L and ≤ 400 × 10⁹/L for 2 consecutive weeks, reduce the dose by 1 mcg/kg.
  - If platelet count is > 400 × 10⁹/L, do not dose. Continue to assess the platelet count weekly. After the platelet count has fallen to < 200 × 10⁹/L, resume Nplate at a dose reduced by 1 mcg/kg.

### VI. Billing Code/Availability Information

**HCPCS Code:**

- J2796 – Injection, romiplostim, 10 micrograms: 10 mcg = 1 billable unit
NDC(s):
• Nplate 125 mcg single-dose vial: 55513-0223-xx
• Nplate 250 mcg single-dose vial: 55513-0221-xx
• Nplate 500 mcg single-dose vial: 55513-0222-xx

VII. References


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D69.3</td>
<td>Immune thrombocytopenic purpura</td>
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</table>

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 Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Articles 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/Article):

<table>
<thead>
<tr>
<th>Jurisdiction(s): N</th>
<th>NCD/LCD/Article Document (a): L33748</th>
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# Medicare Part B Administrative Contractor (MAC) Jurisdictions

<table>
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<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
</tr>
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<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
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<td>H (4 &amp; 7)</td>
<td>LA, AR, MS, TX, OK, CO, NM</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>8</td>
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<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
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<td>First Coast Service Options, Inc.</td>
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<td>M (11)</td>
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<td>L (12)</td>
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<td>Novitas Solutions, Inc.</td>
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<tr>
<td>K (13 &amp; 14)</td>
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<td>CGS Administrators, LLC</td>
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