Pharmacy Medical Necessity Guidelines: Nplate® (romiplostim)

Effective: July 11, 2017

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
<th>Type of Review – Clinical Review</th>
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<tbody>
<tr>
<td>Not Covered</td>
<td>MED</td>
<td>PRECERT/MM</td>
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<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>Department to Review</td>
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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

**Fax Numbers:**
All plans except Tufts Health Public Plans: PRECERT: 617.972.9409
Tufts Health Public Plans: MM: 888.415.9055

**Note:** For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Nplate (romiplostim) is indicated for the treatment of thrombocytopenia in patients with chronic immune thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.

Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than chronic ITP. Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Nplate should not be used in an attempt to normalize platelet counts.

Nplate (romiplostim) is a recombinant thrombopoietin (TPO) receptor agonist that stimulates bone marrow megakaryocytes to produce platelets. Romiplostim, a Member of the TPO mimetic class, is an Fc-peptide fusion protein (peptibody) that activates intracellular transcriptional pathways leading to increased platelet production via the TPO receptor (also known as cMpl).

As defined by the American Society of Hematology, ITP is defined as isolated thrombocytopenia (low platelet count with otherwise normal results on complete blood count and peripheral blood smear) in a patient with no clinically apparent associated conditions or factors that can cause thrombocytopenia (such as infection with the human immunodeficiency virus [HIV], systemic lupus erythematosus, lymphoproliferative disorders, myelodysplasia, agammaglobulinemia, therapy with certain drugs, alloimmune thrombocytopenia, and congenital or hereditary thrombocytopenia). An abnormal blood count or peripheral blood smear due to a coexisting nonimmune condition (such as iron deficiency or thalassemia minor) does not, in itself, exclude the diagnosis of ITP.

Primarily a disorder of increased platelet destruction, ITP is probably caused by the development of autoantibodies to platelet-membrane antigens. The reported prevalence of ITP in adults and children is 1 to 13 per 100 000 persons; the clinical presentation and course of ITP differ in children and adults. In children, ITP is usually an acute, self-limited disorder that resolves spontaneously; in adults, it is typically a chronic disorder with a more insidious onset. In about one third of adults with ITP, the condition is persistent and relatively resistant to most treatments. Because adult patients with moderate to severe thrombocytopenia generally begin treatment immediately after diagnosis, data on the natural history of untreated disease are lacking. Data are also lacking on the natural history of adult patients who are incidentally discovered to have mild thrombocytopenia and are not treated. Available evidence suggests that only about 5% of adults with chronic ITP have spontaneous remission.
**COVERAGE GUIDELINES**

The plan may authorize coverage of Nplate (romiplostim) for Members when **all** of the following criteria are met:

1. The Member is at least 18 years of age  **AND**
2. Documented diagnosis of chronic immune (idiopathic) thrombocytopenic purpura  **AND**
3. Documentation of one of the following:
   a. The Member has had an insufficient response or intolerance to corticosteroids and/or immunoglobulins **OR**
   b. The Member has not responded to splenectomy

**Dosing Recommendations**

**Initial:**
- 1 mcg/kg subcutaneously once weekly

**Dose Adjustments:**
- Adjust weekly dose by increments of 1 mcg/kg to achieve and maintain a platelet count ≥ 50 x 10^9/L as necessary to reduce the risk for bleeding.
- If the platelet count is < 50 x 10^9/L, increase the dose by 1 mcg/kg.
- If platelet count is > 200 x 10^9/L for 2 consecutive weeks, reduce the dose by 1 mcg/kg.
- If platelet count is > 400 x 10^9/L, do not dose. Continue to assess the platelet count weekly. After the platelet count has fallen to < 200 x 10^9/L, resume Nplate at a dose reduced by 1 mcg/kg.
- Discontinue Nplate if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks of Nplate therapy at the maximum weekly dose of 10 mcg/kg.

**LIMITATIONS**

None

**CODES**

The following HCPCS/CPT code(s) are:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>J2796</td>
<td>Injection, romiplostim, 10 micrograms</td>
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**REFERENCES**


**APPROVAL HISTORY**

November 11, 2008: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- November 10, 2009: No changes.
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
- November 9, 2010: No changes
- November 15, 2011: No changes
- November 6, 2012: No changes
- October 15, 2013: No changes
- October 7, 2014: No changes
- August 11, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- July 11, 2017: No changes

**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.
For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.