NPlate® (romiplostim)

Effective: 9/1/15

Clinical documentation and prior authorization required ✔ Type of review – case management
Not covered Type of review – clinical review Fax: 617-673-0988 ✓
Pharmacy (RX) or medical (MED) benefit MED / RX Department to review RxUM

OVERVIEW

FDA-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.

PHARMACY COVERAGE GUIDELINES
Tufts Health Plan – Network Health may authorize coverage of NPlate (romiplostim) for members when all the following criteria are met and the limitations do not apply:

1. The member has been evaluated by a specialist AND
2. The member is at least 18 years of age or older AND
3. The member has a diagnosis of thrombocytopenia associated with chronic immune (idiopathic) thrombocytopenia purpura (ITP) or another type of thrombocytopenic condition AND
4. The member has previously tried and failed treatment with or does the member have a contraindication to both glucocorticoids (e.g. prednisone, dexamethasone) and Intravenous Immunoglobulin (IVIG).
LIMITATIONS
1. Initial authorization for thrombocytopenia associated with chronic immune (idiopathic) thrombocytopenia purpura (ITP) or another type of thrombocytopenic condition will be limited to 6 months. Subsequent authorization may be given in 12-month intervals based on submission of current progress notes from the physician documenting efficacy.

CODES
The following HCPCS/CPT code(s) are:

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<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
- April 16, 2009: Reviewed by the Pharmacy and Therapeutics Committee.
- June 13, 2013: Reviewed by the Pharmacy and Therapeutics Committee.
- November 9, 2014: Reviewed by the Pharmacy and Therapeutics Committee.
- August 11, 2015: No changes.

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION
Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews
Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

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.