Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 02/14/2019

Nplate® (romiplostim)

FDA approval: 08/22/2008
HCPCS: J2796
Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age
   b. Diagnosis of chronic immune thrombocytopenic purpura (ITP) defined by the following:
      c. Diagnosis confirmed by, or in consultation with a hematologist
      d. Persistent thrombocytopenia (platelet count < 100,000 mcL) for ≥ 3 months
         i. Current platelet count < 20,000 mcL
         OR
         ii. Current platelet count < 30,000 mcL AND symptoms of active bleeding
             AND
         iii. Inadequate response to therapy with corticosteroids, immunoglobulins, or splenectomy
      iv. Trial and failure of Promacta
      v. Dose is ≤ 10 mcg/kg/week

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: FDA approved dosing
   b. Initial Authorization Period: 3 months
   c. Renewal Criteria:
      i. Recent platelet count of 30,000-150,000 mcL
      ii. Dose is ≤ 10 mcg/kg/week

C. Nplate is considered investigational when used for all other conditions, including but not limited to:
   a. Acute thrombocytopenia
   b. Drug-induced thrombocytopenia (e.g., chemotherapy, heparin, quinidine)
   c. Thrombocytopenia secondary to:
      i. Cancer
      ii. Myelodysplastic syndrome
iii. HIV
iv. Hepatitis
v. Systemic lupus erythematosus
vi. Hemangiomas
vii. Massive bleeding
viii. Thrombotic thrombocytopenic purpura
ix. Hemolytic-uremic syndrome

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

A. FDA approved indication / Diagnosis
   a. Nplate is indicated for the treatment of thrombocytopenia in patients with chronic immune ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
   b. Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding. Nplate should not be used in an attempt to normalize platelet counts

   *Please refer to most recent prescribing information.

B. Background Information
   a. Idiopathic thrombocytopenic purpura (ITP), also known as primary immune thrombocytopenic purpura, is an autoimmune, hematologic disorder characterized by persistent thrombocytopenia due to autoantibody binding to platelet antigen(s) causing their premature destruction leading to an increase in bruising and bleeding. Risk of spontaneous bleeding increases as platelet counts drops below 20,000/mm³. There are estimated to be approximately 60,000 individuals diagnosed with chronic ITP in the U.S.
   b. First line therapy comprises oral corticosteroids, immunoglobulins, and splenectomy. These therapies may be undesirable due to the associated complications and/or failure to achieve desirable response. Nplate, administered subcutaneously, is a peptibody that binds to and activates the human thrombopoietin receptor (TPO) leading to increased platelet production.

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<th>Cross References</th>
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<tbody>
<tr>
<td>Drug Reviews and Medical Policies</td>
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<tr>
<td>Immune Globulin Replacement Therapy (IVIG, SQIG) Medication Use Guidelines</td>
<td>02/09/2017</td>
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<tr>
<td>Promacta (Eltrombopag olamine) Drug Policy</td>
<td>05/02/2013</td>
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C. Efficacy

   *Please refer to most recent prescribing information.

D. Medication Safety Considerations

   Black Box Warning: No

   *Please refer to most recent prescribing information.
E. Dosing and administration
   a. 1 mcg/kg weekly based on actual body weight
   b. Adjust the daily dose as necessary by increments of 1 mcg/kg to achieve and maintain a platelet count ≥ 50 x 10^9/L
   c. Do not exceed a dose of > 10 mcg/kg weekly

*Please refer to most recent prescribing information.

F. How supplied
   a. Single-use vials containing 250 or 500 mcg of sterile, lyophilized, solid white powder

References:

### Policy History

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*The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or [http://dailymed.nlm.nih.gov/dailymed/index.cfm](http://dailymed.nlm.nih.gov/dailymed/index.cfm)*