CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	NPlate (romiplostim)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Nplate, approved by the FDA in 2008, is a thrombopoietin receptor agonist (TPO-RA) indicated for the treatment of thrombocytopenia in 1) Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy and 2) Pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Nplate is also indicated to increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS]).
ITP is a rare autoimmune disorder characterized by low levels of platelets due to platelet destruction and insufficient platelet production. According to the most current definitions, ITP duration of less than 3 months is referred to as newly diagnosed, 3-12 months as persistent, and greater than 12 months is considered chronic. As a TPO-RA, Nplate increases platelet production through binding and activation of the TPO receptor, a mechanism analogous to endogenous TPO.

NPlate (romiplostim) will be considered for coverage when the following criteria are met:

Immune Thrombocytopenia (ITP)

For **initial** authorization:

1. Member is at least 1 year of age; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member has a documented diagnosis of immune thrombocytopenia (ITP); AND
4. If member is less than 18 years of age, disease duration must be at least 6 months; AND
5. Member meets one of the following:
   a) Current platelet count is $<30x10^9$/L;
   b) $30x10^9$/L to $50x10^9$/L with one of the following:
      i) Active symptomatic bleeding other than minor mucocutaneous bleeding
      ii) High risk factor for bleeding (i.e., on an anticoagulant, of older age (>60 years), other clearly identified comorbidity:AND
6. Member had an inadequate response, intolerance, or contraindication to documented prior therapy with at least one of the following treatments:
   a) Corticosteroids (prednisone, prednisolone, methylprednisolone, or dexamethasone);
   b) Immunoglobulins
   c) Splenectomy; AND
7. Current weight is provided for dose calculation; AND
8. Member does NOT have any of the following:
   a) Thromboembolic condition
   b) Any cause of thrombocytopenia other than primary ITP
   c) Concurrent use with another TPO-RA or with Tavalisse.

9. **Dosage allowed/Quantity limit:** Administer 1mcg/kg subcutaneously once weekly, then adjust the weekly dose by increments of 1 mcg/kg until the patient achieves a platelet count ≥ 50 x 10^9/L. Max dose 10 mcg/kg.

   Note: Discontinue if platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks at the max dose.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Chart notes improvement in platelet count from baseline to a level sufficient to avoid clinically important bleeding; AND
2. Member's platelet count is less than 400 x 10^9/L; AND
3. Dose will be reduced if platelet count is between 200 x 10^9/L and 400 x 10^9/L.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS)

Any request related to oncology must be submitted through NantHealth/Eviti portal.

CareSource considers Nplate (romiplostim) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/04/2018	New policy for Nplate created. Platelets requirement threshold expanded.
02/08/2023	Transferred to new template. Updated and added references. Updated terminology from "chronic immune (idiopathic) thrombocytopenic purpura" to "immune thrombocytopenia." Corrected age limit from 18 years to 1 year and added 6 mo duration for peds. Modified descriptions under 30,000-50,000 platelet count to be consistent with our other TPO-RA drug policies. Added documentation of current weight. Added exclusion for thrombotic events. Added not to be used in combo with another TPO-RA or Tavalisse. Rephrased renewal criteria to be consistent with drug label to address bleeding avoidance, added dose adjustment for PC >200. Added HSARS as an Eviti diagnosis.

References:

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