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**Effective Date: 04/14/2022**

**Nplate® (romiplostim)**

**HCPCS: J2796**

**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 confirmed by, or in consultation with a hematologist
  - c. Diagnosis of immune thrombocytopenic purpura (ITP) defined by the following:
    - i. Thrombocytopenia (platelet count < 100,000 mcL)
      - 1. Current platelet count < 20,000 mcL
      - OR
      - 2. Current platelet count < 30,000 mcL AND symptoms of active bleeding
      - AND
    - ii. Inadequate response to therapy with corticosteroids, immunoglobulins, or splenectomy
    - iii. Dose is  $\leq$  10 mcg/kg/week
    - OR
  - d. A diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS)
  - e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in Wellmark Advantage Health Plan's utilization management medical drug list.
- B. Quantity Limitations, Authorization Period and Renewal Criteria
  - a. Quantity Limits: Align with FDA recommended dosing
  - b. Authorization Period:
    - i. For ITP: Three months initially. Continuation of therapy to be reviewed annually
    - ii. For HS-ARS: One month approval to allow for one time administration
  - c. Renewal Criteria:
    - i. For ITP:
      - 1. Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit.
      - 2. Recent platelet count of 30,000-150,000
      - 3. Dose is  $\leq$  10 mcg/kg/week
    - ii. For HS-ARS:
      - 1. Not applicable as no further authorization will be provided.

\*\*\*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

This policy and any information contained herein is the property of Wellmark Advantage Health Plan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and Wellmark Advantage Health Plan employees for the purpose of coverage determinations.

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.

## Background Information

- Nplate is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy and 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 (HS-ARS).
- Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP. 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.
- 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/mm<sup>3</sup>. There are estimated to be approximately 60,000 individuals diagnosed with chronic ITP in the U.S.
  - For all patients with severe bleeding (eg, intracranial, gastrointestinal) and a platelet count < 30,000/microL, it is recommended that immediate platelet transfusion along with ITP-specific therapy with intravenous immune globulin (IVIG) and high-dose glucocorticoids. Recommendations also suggest ITP-specific therapy for patients with a new diagnosis of ITP and a platelet count < 20,000/microL, even in the absence of bleeding symptoms, because the thrombocytopenia may be persistent and become more severe. Some patients with platelet counts > 30,000/microL may require treatment if they have an increased risk of bleeding (eg, peptic ulcer disease, high risk of falling), other hemostatic defects (eg, use of antiplatelet agents or anticoagulants), a history of bleeding at a higher platelet count, or a need for surgery/invasive procedures.
  - 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.
- Hematopoietic syndrome of acute radiation syndrome
  - Acute Radiation Syndrome (ARS) (sometimes known as radiation toxicity or radiation sickness) is an acute illness caused by irradiation of the entire body (or most of the body) by a high dose of penetrating radiation in a very short period of time (usually a matter of minutes).
  - The type of radiation exposure event influences the nature of the exposure (i.e., nonionizing versus ionizing radiation), types of ionizing particles (eg, alpha particles, beta particles, neutrons) and/or x-ray/gamma rays, the amount and duration of radiation exposure, and the consequent biologic effects.
  - Hematopoietic syndrome (sometimes referred to as bone marrow syndrome) will usually occur with a dose between 0.7 and 10 Gray (Gy: derived unit of ionizing radiation dose in the International System of Units (SI). It is defined as the absorption of one joule of radiation energy per kilogram of matter.)

- Prodromal symptoms include anorexia, nausea and vomiting. Latent stage includes death of stem cells in bone marrow which can manifest symptoms of anorexia, fever, and malaise with a drop in all blood cell counts causing infection and hemorrhage.
- The recommended dose of Nplate is 10 mcg/kg administered once as a subcutaneous injection, and the dose should be administered as soon as possible after suspected or confirmed exposure to radiation levels greater than 2 Gy. Nplate should be administered regardless of whether a complete blood count can be obtained. The patient's absorbed whole body radiation dose should be estimated based on information from public health authorities, biodosimetry if available, or clinical findings such as time to onset of vomiting or lymphocyte depletion kinetics.
- Efficacy studies of Nplate could not be conducted in humans with acute radiation syndrome for ethical and feasibility reasons. Efficacy studies conducted in animals, Nplate's effect on platelet count in healthy human volunteers and its effect on thrombocytopenia in patients with ITP lead to its approval. Nplate significantly increased 60-day survival in irradiated animals. 72.5% survival in the Nplate group compared to 32.5% survival in the control group after total body irradiation of 6.8 Gy.

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Policy History		
#	Date	Change Description
1.1	Effective Date: 04/14/2022	Annual review of criteria was performed, no changes were made.
1.0	Effective Date: 01/1/2022	Effective as of date on policy

\* 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>