

Medical Affairs Policy & Procedure

Title/Service: Nplate (romiplostim)

Revised	09/16/2011
Reviewed	04/24/09; 02/05/10
Developed	04/24/09
Policy Committee Approval	09/16/2011

Description:

Nplate (romiplostim) is a thrombopoietin receptor agonist which stimulates platelet production. Nplate works similarly to thrombopoietin (TPO), a natural protein in the body. Nplate stimulates the TPO receptor, which is necessary for growth and maturation of bone marrow cells that produce platelets.

Indications of Coverage:

Nplate is considered medically necessary in individuals over the age of eighteen for the treatment of thrombocytopenia when **all** of the following criteria are met:

- A. The individual has been diagnosed with chronic immune (idiopathic) thrombocytopenic purpura (ITP) by a hematologist
 - B. The individual has had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
 - C. The degree of thrombocytopenia (platelet count less than 30,000/microliter) and clinical condition increase the risk for bleeding. Nplate should not be used in an attempt to normalize platelet counts.
- If criteria are met, treatment may be approved for three months and may be provided by the physician's office or outpatient clinic for initiation of therapy and dosage adjustment, if allowed by the individual's health plan or policy language. Subsequent treatment may be approved in six month increments with review of continued therapeutic response and consistent prescription medication use.

Dosage and Administration:

Only prescribers enrolled in the Nplate NEXUS (Network of Experts Understanding and Supporting Nplate and Patients) Program may prescribe Nplate. The initial dose is 1 mcg/kg based on actual body weight (ABW). The ABW is used at initiation of therapy, and with adjustments of the weekly dose by

increments of 1 mcg/kg until the patient achieves a platelet count greater than or equal to 50,000/ microliter as necessary to reduce the risk for bleeding. The maximum weekly dose is 10 mcg/kg.

Dose Adjustment:

If the platelet count is less than 50,000/ microliter, the dose is increased by 1 mcg/kg. If the platelet count is greater than 200,000/ microliter for two consecutive weeks, the dose is reduced by 1 mcg/kg. If the platelet count is greater than 400,000/ microliter, no dose is given. The platelet count continues to be assessed weekly. After the platelet count has fallen to less than 200,000/ microliter, therapy may be resumed.

- Romiplostim should be discontinued after four weeks of therapy if the platelet count does not increase to a level sufficient to avoid clinically important bleeding despite using the maximum weekly dose of 10 mcg/kg.

Limitations of Coverage:

- A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.
- B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.
- C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

Documentation Required:

- Office notes
- Laboratory results
- Prescription medication use data

Rationale:

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. Romiplostim (Nplate) is a protein that increases platelet production. This guideline is based on the Food and Drug Administration (FDA) approved Medication Guide.

References:

1. Nplate (romiplostim). Thousand Oaks, CA: Amgen Inc. Revised: 07/2011. Available at: pi.amgen.com/united_states/nplate/nplate_pi_hcp_english.pdf. Accessed: 25 Aug 11.

Approved by the Medical Director