

Nplate (romiplostim)

Nplate is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in:

- Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- 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 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]).

I. Criteria for Initial Approval

Limitations of Use:

- Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP.
- Nplate should only be used 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.

Nplate will be considered for coverage when all of the criteria below are met, confirmed with supporting medical documentation:

New Onset - Acute ITP

- Patient is at least 18 years of age.
- Patient has acute ITP.
- Prescribed by a hematologist or provider familiar with ITP.
- Immune (idiopathic) thrombocytopenia (ITP):
 - The patient is at increased risk for bleeding as indicated by platelet count less than $30 \times 10^9/L$ ($30,000/mm^3$); AND
 - Laboratory value for platelet count is current (e.g., drawn within the previous 28 days).
- Patient has previously failed one of the following treatments for ITP:
 - Therapy with corticosteroids;

- Therapy with immunoglobulins; OR
- Patient has had a splenectomy.
- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., lusutrombopag, eltrombopag, avatrombopag, etc.) or fostamatinib.

Chronic ITP - Greater than 6 months

- Patient is 1 year of age or older.
- Patient has had chronic ITP for at least 6 months.
- Prescribed by a hematologist or provider familiar with ITP.
- Immune (idiopathic) thrombocytopenia (ITP)
 - The patient is at increased risk for bleeding as indicated by platelet count less than $30 \times 10^9/L$ ($30,000/mm^3$); AND
 - Laboratory value for platelet count is current (e.g., drawn within the previous 28 days).
- Patient has previously failed one of the following treatments for ITP:
 - Therapy with corticosteroids (e.g., patient had no response to at least a 3-month trial or is corticosteroid dependent); OR
 - Therapy with immunoglobulins.
- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., lusutrombopag, eltrombopag, avatrombopag, etc.) or fostamatinib.

Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)

- Patient is at least 18 years of age.
- Prescribed by a hematologist or specialist familiar with HS-ARS.
- Patient has suspected or confirmed exposure to radiation levels greater than 2 gray (Gy).
 - Patient has lower risk disease (e.g., IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]).
 - Patient has severe or refractory thrombocytopenia (e.g., platelet count $<20 \times 10^9/L$ or higher with a history of bleeding).
 - Patient progressed or had no response to hypomethylating agents (e.g., azacitidine, decitabine, etc.), immunosuppressive therapy, or clinical trial.

II. Criteria for Continuation of Therapy

Nplate coverage can be renewed based upon the following criteria:

ITP

- Disease response indicated by the achievement and maintenance of a platelet count of at least $50 \times 10^9/L$ (not to exceed $400 \times 10^9/L$) as necessary to reduce the risk for bleeding;

- Patient continues to meet universal and other indication-specific relevant criteria, such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc., identified in **Section I**; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: thrombotic/thromboembolic complications, risk of progression of myelodysplastic syndromes to acute myelogenous leukemia, etc.

HS-ARS

- Coverage cannot be renewed for this indication.

III. Dosing/Administration

Nplate must be administered according to the current FDA labeling guidelines for dosage and timing. The recommended dosing is as follows:

- Patients with Immune Thrombocytopenia (ITP):
 - Recommended initial dose: 1 mcg/kg once weekly as a subcutaneous injection. Adjust dose based on platelet response.
- Patients acutely exposed to myelosuppressive doses of radiation (HS-ARS):
 - Recommended dose: 10 mcg/kg administered once as a subcutaneous injection. Administer the dose as soon as possible after suspected or confirmed exposure to myelosuppressive doses of radiation.

IV. Length of Authorization for Initial Therapy

Nplate will be authorized for 6 months when criteria for initial approval are met.

V. Billing Code/Information

J2796 Injection, Nplate (romiplostim) 10mcg; 1mcg = 1 billable unit.

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 10/26/2021

Last Reviewed Date: 10/26/2021