

Clinical Policy: Romiplostim (Nplate)

Reference Number: PA.CP.PHAR.179

Effective Date: 01/18

Last Review Date: 07/18

[Coding Implications](#)

[Revision Log](#)

Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness[®] clinical policy for romiplostim (Nplate[®]).

FDA Approved Indication(s)

Nplate is indicated for the treatment of thrombocytopenia in patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Limitation(s) of use:

- Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome or any cause of thrombocytopenia other than chronic 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.

Policy/Criteria

It is the policy of Pennsylvania Health and Wellness[®] that Nplate is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Immune Thrombocytopenia (must meet all):

1. Diagnosis of chronic immune thrombocytopenia (ITP);
2. Prescribed by or in consultation with a hematologist;
3. Age \geq 18 years;
4. Member has had an insufficient response to the following first line agents: corticosteroids and immunoglobulins;
5. Member has relapsed after splenectomy, or has a contraindication to splenectomy;
6. Platelet count is $< 30 \times 10^9/L$ or member has an active bleed;
7. Prescribed dose of Nplate does not exceed a maximum weekly dose of 10 mcg/kg.

Approval Duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53 Policy.

II. Continued Approval

A. Chronic Immune Thrombocytopenia (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;

2. Documentation of positive response to therapy (e.g.: increase in platelet count from baseline levels);
3. Current platelet count (dated within that last 90 days) is < 400 x 10⁹/L;
4. Prescribed dose of Nplate does not exceed a maximum weekly dose of 10 mcg/kg.

Approval Duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:

Nplate contains romiplostim, a protein produced by recombinant DNA technology in Escherichia coli. Romiplostim increases platelet production through binding and activation of the thrombopoietin (TPO) receptor, a mechanism analogous to endogenous TPO.

Formulations:

Nplate is supplied in single-dose vials that deliver 250 mcg and 500 mcg of romiplostim.

Appendices

Appendix A: Abbreviation Key

ITP: immune thrombocytopenia

TPO: thrombopoietin

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2796	Injection, romiplostim, 10 mcg

Reviews, Revisions, and Approvals	Date	Approval Date
Added age restriction per PI as safety and effectiveness in pediatric patients (< 18 years) have not been established. References reviewed.	02/18	

References

1. Nplate Prescribing Information. Thousand Oaks, CA: Amgen Inc.; October 2017. Available at <https://www.nplate.com/>. Accessed November 15, 2017.
2. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. *Blood*. 2011; 117(16): 4190-4207.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: <http://www.clinicalpharmacology-ip.com/>.