Clinical Policy: Romiplostim (Nplate)

Reference Number: PA.CP.PHAR.179
Effective Date: 01/18
Last Review Date: 01/19

Coding Implications
Revision Log

Description
Romiplostim (Nplate®) is a thrombopoietin receptor agonist.

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 ≥ 18 years;
4. Current (within 30 days) platelet count is < 30,000/µL or member has an active bleed;
5. Failure of systemic corticosteroids and immune globulins unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B*);

**Prior authorization may be required for immune globulins*

6. Member has relapsed after splenectomy, or has a contraindication to splenectomy;
7. Prescribed dose does not exceed 10 mcg/kg/week.

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, reduction in bleeding events);
3. Current (within that last 90 days) platelet count is < 400,000/µL;
4. If request is for a dose increase, new dose does not exceed 10 mcg/kg/week.

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.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
ITP: chronic immune thrombocytopenia

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Corticosteroids*		
dexamethasone	**ITP** <u>Oral dosage:</u> *Adults*: Initially, 0.75 to 9 mg/day PO, given in 2 to 4 divided doses. Adjust according to patient response. *Children and adolescents*: 0.024 to 0.34 mg/kg/day PO or 0.66 to 10 mg/m^2/day PO, given in 2 to 4 divided doses <u>Intramuscular or intravenous dosage:</u> *Adults:* Initially, 0.5 to 9 mg/day IV or IM, given in 2 to 4 divided doses. Adjust according to patient response. *Children:* 0.06 to 0.3 mg/kg/day or 1.2 to	Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	10 mg/m^2/day IV or IM in divided doses every 6 to 12 hours. Adjust according to patient response.	
methylprednisolone	**ITP** Oral dosage: *Adults:* 4 to 48 mg/day PO in 4 divided doses. Adjust according to patient response. *Children:* 0.5 to 1.7 mg/kg/day PO in divided doses every 6 to 12 hrs Intravenous dosage: *Adults:* 10 to 40 mg IV every 4 to 6 hours for up to 72 hours *Children:* 0.11 to 1.6 mg/kg/day IV in 3 or 4 divided doses.	Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.
prednisone	**ITP** *Adults:* Initially, 1 mg/kg PO once daily; however, lower doses of 5 mg/day to 10 mg/day PO are preferable for long-term treatment.	Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.
Immune globulins		
immune globulins (Carimune® NF, Flebogamma® DIF 10%, Gammagard® S/D, Gammaked™, Gamunex®-C, Gammaplex®, Octagam® 10%, Privigen®)	**ITP** Refer to prescribing information	Refer to prescribing information

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
Examples of corticosteroids provided are not all inclusive

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ITP	The initial dose is 1 mcg/kg SC based on actual body weight. Adjust weekly dose by increments of 1 mcg/kg to achieve and maintain a platelet count ≥	10 mcg/kg/week

Indication	Dosing Regimen	Maximum Dose
	50,000/µL as necessary to reduce the risk for bleeding. Do not dose if platelet count is > 400,000/µL.	

V. Product Availability

Lyophilized powder in single-dose vials for injection: 250 mcg, 500 mcg

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	
1Q 2019 annual review: added requirement that initial platelet counts be current (within 30 days); for cont tx approval, clarified that member must be continuing on interferon-based therapy; added MDS and other causes of thrombocytopenia other than chronic ITP as diagnoses not covered per package insert; no significant changes; references reviewed and updated.	01/19	

References

1. Nplate Prescribing Information. Thousand Oaks, CA: Amgen Inc.; October 2017. Available at https://www.nplate.com/. Accessed October 30, 2018.
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.; 2018. Available at: http://www.clinicalpharmacology-ip.com/.