Policy Title:	Nplate (romiplostim) (Subcutaneous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/20/2019		
Revision Date:	12/20/2019		

Purpose: To support safe, effective and appropriate use of Nplate (romiplostim).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Nplate (romiplostim) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Nplate (romiplostim) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Patient does not have myelodysplastic syndrome (MDS); AND

Chronic immune (idiopathic) thrombocytopenia (ITP)

- Patient aged 1 years or older; AND
- Patient has previously failed one of the following treatments for ITP:
  - Patient has failed previous therapy with corticosteroids; OR
  - Patient has failed previous therapy with immunoglobulins; OR
  - Patient has had a splenectomy; AND
- The patient is at increased risk for bleeding as indicated by platelet count (within the previous 28 days) less than 30×10^9 /L (30,000/mm^3); AND
- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., lusutrombopag, eltrombopag, avatrombopag, etc); AND
- Must not be used in an attempt to normalize platelet counts

Continuation of Therapy Criteria:

- Meets all initial criteria and is tolerating treatment; AND

- Disease response indicated by the achievement and maintenance of a platelet count (within the previous 28 days) of at least 50×10^9 /L (not to exceed 400 x 10^9 /L) as necessary to reduce the risk for bleeding; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: thrombotic/thromboembolic complications, severe hypersensitivity, risk of progression of myelodysplastic syndromes to acute myelogenous leukemia, etc.

Coverage durations:

- Initial coverage: 3 months
- Continuation of therapy coverage: 3 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = 10 mcg)
All indications	ADULT/PEDIATRIC: Initial: 1 mcg/kg subcutaneously weekly • Adjust dose weekly by increments of 1 mcg/kg to achieve and maintain platelet count of ≥ 50×10^9/L ($50,000/mm^3$) as necessary to reduce the risk for bleeding • Do not exceed the maximum weekly dose of 10 mcg/kg • Adjust the dose as follows for all patients: o If the platelet count is < 50×10^9/L, increase the dose by 1 mcg/kg. o If platelet count is > 200×10^9/L and ≤ 400×109/L for 2 consecutive weeks, reduce the dose by 1 mcg/kg. o If platelet count is > 400×10^9/L, do not dose. Continue to assess the platelet count weekly. After the platelet count has fallen to < 200×10^9/L, resume Nplate at a dose reduced by 1 mcg/kg.	125 billable units weekly

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J2796	Injection, romiplostim, 10 micrograms

References:

1. NPlate [package insert]. Thousand Oaks, CA; Amgen Inc; December 2018. Accessed December 2018.
2. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidencebased practice guideline for immune thrombocytopenia. Blood. 2011 Apr 21;117(16):4190- 207. doi: 10.1182/blood-2010-08-302984. Epub 2011 Feb 16. Review.
3. Lambert MP, Gernsheimer TB. Clinical updates in adult immune thrombocytopenia. Blood. 2017. 129:2829-2835. doi:10.1182/blood-2017-03-754119
4. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Drugs and Biologics (Non-chemotherapy) (L34741). Centers for Medicare & Medicaid Services, Inc. Updated on 5/4/2018 with effective date 6/1/2018. Accessed December 2018
5. First Coast Service Options, Inc. Local Coverage Determination (LCD): Romiplostim (Nplate®) (L33748). Centers for Medicare & Medicaid Services, Inc. Updated on 07/01/2014 with effective date 10/01/2015. Accessed December 2018.