Clinical Policy: Romiplostim (Nplate)

Reference Number: CP.PHAR.179
Effective Date: 03/16
Last Review Date: 03/17

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for romiplostim (Nplate®).

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® 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. Other causes (e.g.,: myelodysplastic syndrome) of thrombocytopenia has been ruled out; **documentation must support that ITP is not due to any other causes*
4. Member has had an insufficient response to the following first line agents: corticosteroids and immunoglobulins;
5. Platelet count is $< 30 \times 10^9$/L;
6. 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 CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. Chronic Immune Thrombocytopenia (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
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 $< 400 \times 10^9$/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 Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

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.

FDA Approved Indications:
Nplate (romiplostim) is a TPO receptor agonist/subcutaneous injectable indicated for:

- Treatment of thrombocytopenia in patients with chronic immune thrombocytopenia (ITP) who have had insufficient response to corticosteroids, immunoglobulins or splenectomy.

Limitations 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.

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
Policy converted to new template and split from CP.PHAR.53. TPO RAs. Criteria: age added per PI; documentation requests removed; changed all approval periods to 3 and 6 months; changed platelet criteria from <30,000 platelets at time of diagnosis to current platelet count <50,000.	03/16	03/16
Criteria: initial-removed age restriction. Added requirement for a hematologist to be involved in care. For Chronic ITP, changed platelet criteria to <30, and modified trial to require the use of the 2 first line agents: corticosteroid and IVIG. Certain conditions representing safety criteria	03/17	03/17

Reviews, Revisions, and Approvals	Date	Approval Date
removed as the PI does not specify a test/ objective method by which they should be evaluated. Retained verifiable lab finding useful to assess need for therapy and continuation of therapy		

References

1. Nplate Prescribing Information. Thousand Oaks, CA: Amgen Inc.; April 2016. Available at http://www.nplate.com. Accessed March 3, 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.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Guidelines should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.