

Clinical Policy: Romiplostim (Nplate)

Reference Number: CP.PHAR.179

Effective Date: 03.01.16

Last Review Date: 02.19

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Romiplostim (Nplate[®]) is a thrombopoietin receptor agonist.

FDA Approved Indication(s)

Nplate is indicated for the treatment of thrombocytopenia in:

- Adult patients with chronic 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.

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

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval 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 ITP;
2. Prescribed by or in consultation with a hematologist;
3. Age \geq 1 year;
4. Current (within 30 days) platelet count is $<$ 30,000/ μ L 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. Dose does not exceed 10 mcg/kg/week.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Chronic Immune Thrombocytopenia (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., increase in platelet count from baseline, reduction in bleeding events);
3. Current (within the last 90 days) platelet count is < 400,000/ μ L;
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 Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents;
- B.** Treatment of thrombocytopenia due to myelodysplastic syndrome or any cause of thrombocytopenia other than chronic ITP.

IV. 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	<p>ITP <u>Oral dosage:</u> <i>Adults:</i> Initially, 0.75 to 9 mg/day PO, given in 2 to 4 divided doses. Adjust according to patient response. <i>Children and adolescents:</i> 0.024 to 0.34 mg/kg/day PO or 0.66 to 10 mg/m²/day PO, given in 2 to 4 divided doses</p> <p><u>Intramuscular or intravenous dosage:</u> <i>Adults:</i> Initially, 0.5 to 9 mg/day IV or IM, given in 2 to 4 divided doses. Adjust according to patient response. <i>Children:</i> 0.06 to 0.3 mg/kg/day or 1.2 to 10 mg/m²/day IV or IM in divided doses every 6 to 12 hours. Adjust according to patient response.</p>	<p>Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.</p>
methylprednisolone	<p>ITP <u>Oral dosage:</u> <i>Adults:</i> 4 to 48 mg/day PO in 4 divided doses. Adjust according to patient response. <i>Children:</i> 0.5 to 1.7 mg/kg/day PO in divided doses every 6 to 12 hrs</p> <p><u>Intravenous dosage:</u> <i>Adults:</i> 10 to 40 mg IV every 4 to 6 hours for up to 72 hours <i>Children:</i> 0.11 to 1.6 mg/kg/day IV in 3 or 4 divided doses.</p>	<p>Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.</p>
prednisone	<p>ITP <i>Adults:</i> 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.</p>	<p>Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.</p>

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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*

V. 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 \geq 50,000/ μ L as necessary to reduce the risk for bleeding. Do not dose if platelet count is $>$ 400,000/ μ L.	10 mcg/kg/week

VI. Product Availability

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

VII. References

1. Nplate Prescribing Information. Thousand Oaks, CA: Amgen Inc.; December 2018. Available at <https://www.nplate.com/>. Accessed December 18, 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/>.

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	P&T Approval Date
<p>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.</p>	03.16	03.16
<p>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 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</p>	03.17	03.17
<p>Added requirement for splenectomy unless member has contraindications to surgery; modified requirement related to platelet count to also include active bleed.</p>	07.17	08.17
<p>1Q18 annual review: Policies combined for Centene Medicaid and Commercial lines of business. New policy for Marketplace line of business; No significant changes from previous corporate approved policy; Added age restriction per PI as safety and effectiveness in pediatric patients (< 18 years) have not been established; Commercial: added requirements related to specialist involvement, insufficient response to corticosteroids and immunoglobulins, splenectomy (unless member has contraindications to surgery), and platelet count or active bleed; re-auth: added platelet count < 400 x 10⁹/L within the last 90 days; modified initial/continued approval duration from 6 months or to member’s renewal period (whichever is longer)/LOB to 6/12 months; Medicaid: Removed “other causes (e.g., myelodysplastic syndrome) of thrombocytopenia has been ruled out with documentation supporting that ITP is not due to any other causes” since specialist is involved in care; References reviewed and updated.</p>	11.15.17	02.18
<p>Removed requirement related to splenectomy based on specialist feedback</p>	08.20.18	11.18
<p>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.</p>	10.30.18	02.19

Reviews, Revisions, and Approvals	Date	P&T Approval Date
No significant changes: updated FDA approved indication to include use in children one year of age and older (was previously labeled for adults only)	12.19.18	

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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy; HIM.PA.103.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene[®] and Centene Corporation[®] are registered trademarks exclusively owned by Centene Corporation.