

## Pharmacy Policy

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# Nplate

**Policy Number:** 9.106

**Version Number:** 2

**Version Effective Date:** 1/1/2022

### Product Applicability All Plan+ Products

#### Well Sense Health Plan

New Hampshire Medicaid

#### Boston Medical Center HealthNet Plan

MassHealth- MCO

MassHealth- ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

## Prior Authorization Policy

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### Products Affected:

- **Nplate (romiplostim)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

<b>Covered Use</b>	All FDA approved and medically accepted indications unless otherwise excluded
<b>Required Medical Information</b>	<ol style="list-style-type: none"> <li>1. Diagnosis of chronic, relapsed or refractory ITP, and platelet count is less than 20,000/microL (lab documentation included) with bleeding symptoms present <b>OR</b> Medical necessity for platelet elevation (upcoming surgery, peptic ulcer disease or condition that may predispose member to bleeding); <b>AND</b> <ol style="list-style-type: none"> <li>a. Baseline serum ALT, AST, and bilirubin levels have been obtained prior to initiation of therapy; <b>AND</b></li> <li>b. An inadequate response or intolerance to a trial of corticosteroids, immune globulin,</li> </ol> </li> </ol>

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	<p>rituximab or splenectomy;<b>AND</b></p> <p>c. Age greater than or equal to 1 year</p> <p>2. Diagnosis of Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)</p> <p>a. Suspected or confirmed presence of greater than or equal to grade 3 hematologic toxicity or exposure to greater than or equal to 2 gray (Gy); <b>AND</b></p> <p>b. Prescribed by or in consultation with a hematologist or oncologist</p>
<b>Coverage Duration</b>	ITP or medical necessity for platelet elevation: 12 months HS-ARS: 4 weeks
<b>Quantity Limit</b>	None
<b>Other criteria</b>	<p>Reauthorization for diagnosis of ITP: Documentation of the following:</p> <p>1. Platelet levels related to ITP have improved and stabilized;</p> <p>*For all other diagnoses initial criteria must be met</p>

#### Applicable Coding:

Code	Medication
J2796	NPlate (romiplostim)

#### Clinical Background Information and References

1. Allen JY, et al. Management of radiation injury. In UpToDate. Last updated: April 2021. Accessed July 2021.
2. Crowther MA, et al. The American Society of Hematology 2011 Evidence-Based Practice Guideline For Immune Thrombocytopenia. Blood 2011; 117(16):4190-4207.
3. George, JN. Treatment and prognosis of immune (idiopathic) thrombocytopenia purpura in adults. In UpToDate. Accessed June 2017.
4. George, JN. Immune thrombocytopenia (ITP) in adults: Treatment of chronic refractory disease. In UpToDate. Accessed June 2017.
5. George, J, Arnold, D. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. UpToDate. Last updated: May 29,2018. Accessed June 18, 2018.
6. Nplate® (romiplostim) Prescribing Information. Amgen Inc.; Thousand Oaks, CA 91320-1799. February 2021.
7. Rodeghiero F, Stasi R, Gernsheimer T, et al. Standardization of terminology, definitions, and outcome criteria in immune thrombocytopenia purpura of adults and children: a report from an international

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working group. Blood 2009;113(11):2386-2393. Available at:  
<http://bloodjournal.hematologylibrary.org/content/113/11/2386.full.pdf+html>

8. Schrier, S. Treatment of aplastic anemia in adults. In UpToDate. Topic last updated May 16, 2017. Accessed June 2017.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.086 Nplate and Tavalisse Policy policy retired, new policy created: split Nplate and Tavalisse into 2 separate policies	1/1/2021	P&T Committee
8/12/2021	Annual P&T Review: Added indication of HS-ARS, rearranged policy for clarity	1/1/2022	P&T Committee

### Next Review Date

8/2022

### Other Applicable Policies

### Reference to Applicable Laws and Regulations, If Any

### Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

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Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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