Mass General Brigham
Health Plan

Nplate (romiplostim)
Effective 01/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

A. FDA-Approved Indications
   1. Nplate is indicated for the treatment of thrombocytopenia in:
      a. Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
      b. 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.
   2. Nplate is indicated to increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS]).

B. Compendial Uses
   1. Myelodysplastic syndromes, for lower risk disease in patients with severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents, immunosuppressive therapy, or clinical trial
   2. Chemotherapy-induced thrombocytopenia (CIT)

All other indications are considered experimental/investigational and not medically necessary.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when the following criteria is met:

1. The following diagnosis-specific criteria is met:

A. Immune thrombocytopenia (ITP)

Authorization may be granted for treatment of ITP when both of the following criteria are met:

i. Inadequate response or intolerance to prior therapy with corticosteroids, immunoglobulins, or splenectomy.
ii. Untransfused platelet count at any point prior to the initiation of the requested medication is less than $30x10^9$/L OR $30x10^9$/L to $50x10^9$/L with symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma) or risk factors for bleeding (see Section VII).

B. Hematopoietic syndrome of acute radiation syndrome (HSARS)
Authorization may be granted for treatment of hematopoietic syndrome of acute radiation syndrome (acute exposure to myelosuppressive doses of radiation).

C. Myelodysplastic Syndromes
Authorization may be granted for treatment of myelodysplastic syndromes when both of the following criteria are met:
i. Member has lower risk disease defined as Revised International Prognostic Scoring System (IPSS-R) (Very Low, Low, Intermediate), International Prognostic Scoring System (IPSS) (Low/Intermediate-1), WHO classification-based Prognostic Scoring System (WPSS) (Very Low, Low, Intermediate).
ii. Member has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents (such as azacitidine and decitabine), immunosuppressive therapy, or clinical trial.

D. Chemotherapy-induced thrombocytopenia
Authorization may be granted for treatment of chemotherapy-induced thrombocytopenia (CIT) when any of the following criteria are met:
i. The platelet count is less than $100x10^9$/L for at least 3-4 weeks following the last chemotherapy administration, or
ii. Chemotherapy administration has been delayed related to thrombocytopenia.

2. The medication is prescribed by or in consultation with a hematologist or oncologist.
3. The member will not receive concurrent treatment with other thrombopoietin receptor agonists (e.g., Promacta, Doptelet, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse).

Continuation of Therapy

A. Immune thrombocytopenia (ITP)
i. Authorization of 3 months may be granted to members with current platelet count less than $50x10^9$/L for whom the platelet count is not sufficient to prevent clinically important bleeding and who have not received a maximal Nplate dose for at least 4 weeks.
ii. Authorization of 12 months may be granted to members with current platelet count less than $50x10^9$/L for whom the current platelet count is sufficient to prevent clinically important bleeding.
iii. Authorization of 12 months may be granted to members with current platelet count of $50x10^9$/L to $200x10^9$/L.

iv. Authorization of 12 months may be granted to members with current platelet count greater than $200x10^9$/L to less than or equal to $400x10^9$/L for whom Nplate dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

B. Hematopoietic syndrome of acute radiation syndrome (HSARS)
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

C. Myelodysplastic Syndromes
Authorization may be granted for continued treatment of myelodysplastic syndromes in members who experience benefit from therapy (e.g., increased platelet counts, decreased bleeding events, reduced need for platelet transfusions).

D. Chemotherapy-induced thrombocytopenia
Authorization may be granted for continued treatment of chemotherapy-induced thrombocytopenia (CIT) in members who experience benefit from therapy (e.g., increased platelet counts, decreased bleeding events, reduced need for platelet transfusions) to maintain a target platelet count goal of $100x10^9$/L – $200x10^9$/L.

Limitations
1. For immune thrombocytopenia: initial approvals will be granted for 6 months and reauthorizations will be granted as outlined under continuation of therapy.
2. For hematopoietic syndrome of acute radiation syndrome (HSARS): initial approvals will be granted for 1 month.
3. For myelodysplastic syndromes: initial approvals and reauthorizations will be granted for 12 months
4. For chemotherapy-induced thrombocytopenia: initial approvals and reauthorizations will be granted for 6 months.

Appendix
Examples of risk factors for bleeding (not all inclusive)

- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidity (e.g., peptic ulcer disease, hypertension)
- Mandated anticoagulation therapy
- Profession (e.g., construction worker) or lifestyle (e.g., plays contact sports) that predisposes member to trauma

References

1. Nplate [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2022.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 15, 2021.
3. The NCCN Clinical Practice Guidelines in Oncology® Myelodysplastic Syndrome (Version 2.2020). © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 15, 2021.

4. Nuenert C, Terrel DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv* 2019;3(23):3829–3866.
5. Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Adv* 2019;3(22): 3780–3817.
6. Rodeghiero F, Stasi R, Gernsheimer T, et al. Standardization of terminology, definitions and outcome criteria in immune thrombocytopenic purpura of adults and children: report from an international working group. *Blood*. 2009;113(11):2386-2393.

Review History
12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024