RX.PA.023.MPC Nplate® (romiplostim)

The purpose of this policy is to define the prior authorization process for Nplate® (romiplostim).

Nplate® (romiplostim) is indicated for the treatment of thrombocytopenia in patients with immune thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Nplate® (romiplostim) should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding. Nplate® (romiplostim) should not be used in an attempt to normalize platelet counts.

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]).

PROCEDURE

A. Initial Authorization Criteria:

Must meet all of the criteria listed below:

1. Immune Thrombocytopenia
   - Must be prescribed by a hematologist or oncologist
   - Must be administered by or under the direction of the prescriber or a healthcare provider
   - Member is being treated for thrombocytopenia associated with one of the following conditions:
     - Acute immune thrombocytopenia (ITP) in members age 18 years or older
     - Chronic ITP for at least 6 months in members age 1 year or older
   - Must have a previous inadequate response or intolerance to corticosteroids and immunoglobulins as documented through platelet response, or a splenectomy
   - Member is not receiving any other thrombopoietin receptor agonists or mimetic ((e.g., lusutrombopag, eltrombopag, avatrombopag, etc.) or fostamatinib.)
   - Must not be concurrently receiving a rituximab product
   - Must have a platelet count <30 x 10^9/L within the past month prior to initiation
   - Provider attests to utilizing the lowest dose of Nplate to achieve and maintain platelet count ≥50 x 10^9/L

2. Hematopoietic Syndrome of Acute Radiation Syndrome

- Member is age 39 weeks (term neonate) or older
- Must be prescribed by a hematologist or oncologist
- Must be administered by or under the direction of the prescriber or a healthcare provider
- Member has suspected or confirmed exposure to radiation levels greater than 2 gray (Gy).
    - Patient has lower risk disease (e.g., IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]).
    - Patient has severe or refractory thrombocytopenia (e.g., platelet count <20 x 10^9/L or higher with a history of bleeding).
    - Patient progressed or had no response to hypomethylating agents (e.g.,azacitidine, decitabine, etc.) and immunosuppressive therapy, or clinical trial (optional).

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Nplate will be considered investigational or experimental for any other use and will not be covered.

D. <u>Reauthorization Criteria:</u>

All prior authorization renewals are reviewed every 6 months to determine the Medical Necessity for continuation of therapy (Reauthorization is not applicable to Hematopoietic Syndrome of Acute Radiation Syndrome). Authorization may be extended at 6-month intervals based upon:

<u>MPC Renewal:</u>

- Chart documentation from the provider that the member's disease has improved based upon the prescriber's assessment and documented improvement in platelet count from baseline.
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: thrombotic/thromboembolic complications, risk of progression of myelodysplastic syndromes to acute myelogenous leukemia, etc.
- Member is not receiving any other thrombopoietin receptor agonists or mimetic ((e.g., lusutrombopag, eltrombopag, avatrombopag, etc.) or fostamatinib.)
- Must not be concurrently receiving a rituximab productMust be prescribed by a hematologist or oncologist
- Discontinue Nplate if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks of therapy at the maximum

weekly dose of 10 mcg/kg

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion 1A (Initial Authorization Criteria)
- Provider has documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment and documented improvement in platelet count from baseline.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	6 months
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

HCPCS Codes:

Code	Description
J2796	Injection, romiplostim, 10 mcg

REFERENCES

1. Nplate [package insert]. Amgen Inc. Thousand Oaks, CA. October 2019.
2. Nplate Nexus Program Brochure. Amgen Inc. Thousand Oaks, CA. August 2008.
3. Bussel JB, Kuter DJ, George JN, et al. AMG 531, a thrombopoiesis-stimulating protein, for chronic ITP. New England Journal of Medicine. 2006; 355: 1672-1681.
4. Newland A, Caulier MT, Kappers-Klunne M, et al. An open-label, unit dose finding study of AMG 531, a novel thrombopoiesis-stimulating peptibody, in patients with immune thrombocytopenia purpura. British Journal of Haematology. 2006; 135: 547-553.
5. Kuter DJ, Bussel JB, Lyons RM, et al. Efficacy of romiplostim in patients with chronic immune thrombocytopenia purpura: a double-blind randomized controlled trial. Lancet. 2008;371: 395-403.
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7. British Committee for Standards In Haematology General Haematology Task Force. Guidelines for the investigation and management of idiopathic thrombocytopenic purpura in adults, children, and pregnancy. British Journal of Haematology. 2003; 120: 574-596.
8. Tiu RV, Sekeres MA. The role of AMG-531 in the treatment of thrombocytopenia in idiopathic thrombocytopenic purpura and myelodysplastic syndromes. Expert Opinion on Biological Therapy. 2008: 8(7); 1021-1030.
9. Stasi R, Evangelista ML, Amadori S. Novel thrombopoietic agents, a review of their use in idiopathic thrombocytopenic purpura. Drugs. 2008: 68(7); 901-912.
10. Stasi R, Evangelista ML, Stipa E, et al. Idiopathic thrombocytopenic purpura: Current concepts in pathophysiology and management. Thrombosis and Haemostasis. 2008: 99; 4-13.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/2026*
Annual Review	*02/2025*
Selected Revision *Additional requirement for Immune Thrombocytopenia – M*ember must not be concurrently receiving a rituximab product	*11/2024*
Annual Review *Change in Non-MPC renewal to renewal from previous insurer*	*02/2024*
Annual review	*02/2023*
Selected Revision *Addition of MPC vs Non-MPC Renewal Criteria*	*10/2022*
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2020*