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.

PROCEDURE

A. Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a hematologist or oncologist
- Must be administered by or under the direction of the prescriber or a healthcare provider
- Must be age 1 year or older
- Must have a diagnosis of immune thrombocytopenic purpura (ITP).
    - Pediatric patients must have had ITP for at least 6 months.
- Must have a previous inadequate response or intolerance to corticosteroids, immunoglobulins, or a splenectomy as documented through platelet response
- Must have a platelet count <30 x 10^9/L prior to initiation

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. Reauthorization Criteria:

- 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
- Utilize the lowest dose of Nplate to achieve and maintain platelet count

≥50 x 10^9/L
  - If platelet count is >200 x 10^9/L for 2 consecutive weeks, reduce the dose by 1 mcg/kg
  - If the platelet count is >400 x 10^9/L, do not dose. Continue to assess the platelet count weekly. After the platelet count has fallen to <200 x 10^9/L, resume at a dose reduced by 1 mcg/kg.

- All prior authorization renewals are reviewed every 6 months to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6-month intervals based upon 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.

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

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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	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2020*