

Nplate® (romiplostim)

When requesting Nplate® (romiplostim), the individual requiring treatment must be diagnosed with the following FDA-approved indication or approved compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Treatment of thrombocytopenia in individuals with chronic immune thrombocytopenia who had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Approved Off-label Compendial use

Treatment of thrombocytopenia due to myelodysplastic syndrome (MDS).

Coverage Guidelines

Chronic Immune Thrombocytopenia

The individual must meet **all** of the following criteria for approval:

- Nplate is prescribed by or in consultation with a hematologist; AND
- The patient meets one of the following:
 - The patient has tried at least one other therapy (e.g., corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Promacta, Tavalisse, or Rituxan); OR
 - The patient has undergone splenectomy.

Thrombocytopenia in Myelodysplastic Syndrome

The individual must meet **all** of the following criteria for approval:

- Nplate is prescribed by or in consultation with a hematologist or an oncologist;
- The patient has low- to intermediate-risk MDS; AND
- According to the prescribing physician the patient has clinically significant thrombocytopenia (e.g., low platelet counts [$< 30,000 \text{ mm}^3$] {pretreatment}; is platelet transfusion-dependent; active bleeding; and/or a history of bleeding at low platelet counts).

Approval duration: 1 year

Dosing Recommendations

Chronic Immune Thrombocytopenia

Approve up to 10mcg/kg subcutaneously no more frequently than once weekly.

Thrombocytopenia in Myelodysplastic Syndrome

Approve up to 1,500mcg subcutaneously no more frequently than twice weekly.

References

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12. Brierley CK, Steensma DP. Thrombopoiesis-stimulating agents and myelodysplastic syndromes. *Br J Haematol*. 2015;169:309-323.
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