

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 indications.

FDA-approved indication

- Nplate (romiplostim) is indicated for the treatment of thrombocytopenia in individuals with chronic immune thrombocytopenia who had an insufficient response to corticosteroids, immunoglobulins, and splenectomy.

Approved Off-label Compendial use(s)

- For the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS)

Coverage Guidelines

Chronic Immune Thrombocytopenia

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

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

Approval duration: 1 year

Thrombocytopenia in Myelodysplastic Syndrome

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

- The drug is prescribed by or in consultation with a hematologist or an oncologist
- The patient has low- to intermediate-risk MDS
- 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 Guidelines

- Chronic Immune Thrombocytopenia:
 - o Initial: 1 mcg/kg once weekly as a subcutaneous injection
 - o Adjust the weekly dose of Nplate by increments of 1mcg/kg until the patient achieves a desired platelet count (e.g., $\geq 50 \times 10^9/L$) as needed to reduce the risk for bleeding; approve up to a maximum weekly dose of 10 mcg/kg
- Thrombocytopenia in MDS
 - o The starting dose is 750 mcg SC once weekly with dose adjustments by 250 mcg (250 mcg every other week to 1,000 mcg weekly); OR
 - o 500 to 750 mcg SC once weekly; OR
 - o 750 mcg SC once weekly or 750 mcg SC twice weekly; OR
 - o 250 mcg, 500 mcg, 750 mcg, 1,000 mcg, or 1,500 mcg SC once weekly or twice weekly; OR
 - o 750 mcg SC once weekly; OR
 - o 300 mcg, 700 mcg, 1,000 mcg, or 1,500 mcg SC once weekly

References

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13. Kantarjian HM, Fenaux P, Sekeres MA, et al. Long-term follow-up for up to 5 years on the risk of leukaemic progression in thrombocytopenic patients with lower-risk myelodysplastic syndromes treated with romiplostim or placebo in a randomized double-blind trial. *Lancet Haematol*. 2018;5(3):e117-e126.
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