

Nplate® (romiplostim)

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

FDA-Approved Non-oncology Indication

Nplate is indicated for the treatment of thrombocytopenia in patients with immune thrombocytopenia (ITP) who had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Coverage Guidelines

Immune Thrombocytopenia

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

- Meets one of the following:
 - o Has a platelet count $< 30 \times 10^9/L$ ($< 30,000/\mu L$); OR
 - o Has a platelet count $< 50 \times 10^9/L$ ($< 50,000/\mu L$) and is at an increased risk of bleeding;
- Meets one of the following:
 - o Has tried at least one other therapy (e.g., corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Promacta, Tavalisse, Doptelet, or rituximab); OR
 - o Has undergone splenectomy.
- Nplate is prescribed by or in consultation with a hematologist.

The individual must meet **both** of the following criteria for reauthorization:

- Has demonstrated a beneficial clinical response (e.g., increased platelet counts, maintenance of platelet counts, and/or decreased frequency of bleeding episodes);
- Remains at risk for bleeding complications.

Approval duration (initial): 3 month

Approval duration (renewal): 12 month

Dosing Recommendation

The recommended initial dose of Nplate is 1 mcg/kg of actual body weight administered subcutaneously once weekly with dose adjustments based upon the platelet count response, not to exceed 10 mcg/kg.

References

1. Nplate® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; March 2025.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv.* 2019;3(23):3829-3866.