

Nplate® (romiplostim) Non-oncology

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

Treatment of thrombocytopenia in individuals with immune thrombocytopenia 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 approval:

- Nplate is prescribed by or in consultation with a hematologist;
- 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 the patient 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.

The individual must meet **all** 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
- Reauthorization: 12 months

Dosing Recommendations

Immune Thrombocytopenia

The 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; February 2022.
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.