

Nplate® (romiplostim) injection

When requesting Nplate® (romiplostim), 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 Indication

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

Approved Off-Label Compendial Use

- None

Coverage Guidelines

Chronic Immune Thrombocytopenia

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

- Has a diagnosis of chronic immune thrombocytopenia
- Has a platelet count less than $50 \times 10^9/L$ at the time of treatment initiation with romiplostim
- Has experienced an insufficient response to corticosteroids, immunoglobulins, or splenectomy

Approval duration: 12 months

Additional Information for Prescribers

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Nplate® (romiplostim) is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than chronic ITP.
- Nplate® (romiplostim) should be used only in individuals with ITP whose degree of thrombocytopenia and clinical condition increases the risk of bleeding.
- Nplate® (romiplostim) should not be used in an attempt to normalize platelet counts.
- Initial dose of 1 mcg/kg once weekly as a subcutaneous injection.
- Adjust weekly dose by increments of 1 mcg/kg to achieve and maintain a platelet count greater than or equal to $50 \times 10^9/L$ as necessary to reduce the risk for bleeding.

- Do not exceed the maximum weekly dose of 10 mcg/kg.
- Do not dose if platelet count is greater than $400 \times 10^9/L$.
- Discontinue Nplate® (romiplostim) if the platelet count does not increase after 4 weeks at the maximum dose.

References

1. Nplate® prescribing information. Thousand Oaks, CA: Amgen Inc.: Revised April 2016.
http://pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/nplate/nplate_pi_hcp_english.ashx. Accessed April 21, 2017
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed April 21, 2017.
<https://www.micromedexsolutions.com>