



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 initial approval:

- Nplate is prescribed by or in consultation with a hematologist; AND
- The patient meets one of the following:
 - The patient has a platelet count $< 30 \times 10^9/L$ ($< 30,000/\mu L$); OR
 - The patient has a platelet count $< 50 \times 10^9/L$ ($< 50,000/\mu L$) and the patient is at an increased risk of bleeding; 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, Doptelet, or rituximab); OR
 - The patient has undergone splenectomy.

Approval duration (Initial): 3 months

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

- The patient has demonstrated a beneficial clinical response (e.g., increased platelet counts); AND
- The patient remains at risk for bleeding complications

Approval duration (Renewal): 1 year

Thrombocytopenia in Myelodysplastic Syndrome

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

- Nplate is prescribed by or in consultation with a hematologist or an oncologist; AND
- The patient has low- to intermediate-risk MDS; AND
- The patient meets one of the following:
 - The patient has a platelet count $< 30 \times 10^9/L$ ($< 30,000/\mu L$); OR

- The patient has a platelet count $< 50 \times 10^9/L$ ($< 50,000/\mu L$) and the patient is at an increased risk of bleeding

Approval duration (Initial): 3 months

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

- The patient has demonstrated a beneficial clinical response (e.g., increased platelet counts); AND
- The patient remains at risk for bleeding complications

Approval duration (Renewal): 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

1. Nplate® injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; October 2019.
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.
3. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (Version 2.2020 – February 28, 2020). ©2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed March 9, 2020.
4. Giagounidis A, Mufti GJ, Fenaux P, et al. Results of a randomized, double-blind study of romiplostim versus placebo in patients with low/intermediate-1-risk myelodysplastic syndrome and thrombocytopenia. *Cancer.* 2014;120:1838-1846.
5. Kantarjian HM, Giles FJ, Greenberg PL, et al. Phase 2 study of romiplostim in patients with low- or intermediate-risk myelodysplastic syndrome receiving azacitidine therapy. *Blood.* 2010;116(17):3163-3170.
6. Sekeres MA, Kantarjian H, Fenaux P, et al. Subcutaneous or intravenous administration of romiplostim in thrombocytopenic patients with lower risk myelodysplastic syndromes. *Cancer.* 2011;117:992-1000.
7. Fenaux P, Muus P, Kantarjian H, et al. Romiplostim monotherapy in thrombocytopenia patients with myelodysplastic syndromes: long-term safety and efficacy. *Br J Haematol.* 2017;178:906-913.
8. Greenberg PL, Garcia-Manero G, Moore M, et al. A randomized controlled trial of romiplostim in patients with low- or intermediate-risk myelodysplastic syndrome receiving decitabine. *Leuk Lymphoma.* 2013;54(2):321-328.
9. Kantarjian H, Fenaux P, Sekeres MA, et al. Safety and efficacy of romiplostim in patients with lower-risk myelodysplastic syndrome and thrombocytopenia. *J Clin Oncol.* 2010;28(3):437-444.
10. Wang ES, Lyons RM, Larson RA, et al. A randomized, double-blind, placebo-controlled phase 2 study evaluating the efficacy and safety of romiplostim treatment of patients with low or intermediate-1 risk myelodysplastic syndrome receiving lenalidomide. *J Hematol Oncol.* 2012;5:71.
11. 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.
12. Brierley CK, Steensma DP. Thrombopoiesis-stimulating agents and myelodysplastic syndromes. *Br J Haematol.* 2015;169:309-323.
13. Prica A, Sholzberg M, Buckstein R. Safety and efficacy of thrombopoietin-receptor agonists in myelodysplastic syndromes: a systematic review and meta-analysis of randomized controlled trials. *Br J Haematol.* 2014;167:626-638.