

Nplate® (romiplostim)

When requesting Nplate® (romiplostim), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indications

- Treatment of thrombocytopenia in individuals with immune thrombocytopenia who had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- To increase survival in individuals acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS]).

Approved Off-label Compendial Uses

- Treatment of thrombocytopenia due to myelodysplastic syndrome (MDS).
- Treatment of chemotherapy induced thrombocytopenia.

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; 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.

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.

Hematopoietic Syndrome of Acute Radiation Syndrome

The individual must have been acutely exposed to myelosuppressive doses of radiation.

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.

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.

Chemotherapy Induced Thrombocytopenia

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 a platelet count $< 100 \times 10^9/L$ ($< 100,000/\mu L$); AND
- The patient meets one of the following:
 - The patient has thrombocytopenia at least 3 weeks after the most recent dose of chemotherapy; OR
 - The patient has experienced a delay in chemotherapy administration related to thrombocytopenia.

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 continues to receive treatment with chemotherapy.

Approval duration:

- Initial authorization: Hematopoietic Syndrome of Acute Radiation Syndrome 1 dose, all other indications 3 months
- Reauthorization: Chemotherapy induced thrombocytopenia 6 months, immune thrombocytopenia and thrombocytopenia in MDS 1 year

Dosing Recommendations

Immune Thrombocytopenia and Chemotherapy Induced Thrombocytopenia

Approve up to 10 mcg/kg subcutaneously no more frequently than once weekly.

Hematopoietic Syndrome of Acute Radiation Syndrome

Approve up to 10 mcg/kg subcutaneously given once.

Thrombocytopenia in Myelodysplastic Syndrome

Approve up to 1,500 mcg subcutaneously no more frequently than twice weekly.

Nplate® (romiplostim)

References

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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.
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