

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;
- Meets one of the following:
 - Has a platelet count $< 30 \times 10^9/L$ ($< 30,000/\mu L$); OR
 - 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:
 - Has tried at least one other therapy (e.g., corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Promacta, Tavalisse, Doptelet, or rituximab); OR
 - Has undergone splenectomy.

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

- 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.

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;
- Has low- to intermediate-risk MDS;
- Meets one of the following:

- Has a platelet count $< 30 \times 10^9/L$ ($< 30,000/\mu L$); OR
- 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:

- 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.

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;
- Is greater than or equal to 18 years of age;
- Has a platelet count $< 100 \times 10^9/L$ ($< 100,000/\mu L$);
- Meets one of the following:
 - Has thrombocytopenia at least 3 weeks after the most recent dose of chemotherapy; OR
 - Has experienced a delay in chemotherapy administration related to thrombocytopenia.

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

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

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

Hematopoietic Syndrome of Acute Radiation Syndrome

Recommended up to 10 mcg/kg subcutaneously given once.

Thrombocytopenia in Myelodysplastic Syndrome

Recommended 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.
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