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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Hematological Agents	**Original Policy Date:**	January 9, 2015
Subject:	Nplate	**Page:**	1 of 5

Last Review Date: March 8, 2024

Nplate

Description

Nplate (romiplostim)

Background
Nplate (romiplostim) works as an analog to the protein thrombopoietin (TPO) and binds to the TPO receptor, similar to endogenous TPO to stimulate platelet production (1).

Regulatory Status
FDA-approved indications: Nplate is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in: (1)

1. Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
2. Pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Npate is also indicated to increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS]).

Limitations of Use: (1)

- Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than chronic ITP.
- Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding.
- Nplate should not be used in an attempt to normalize platelet counts.

Nplate may increase blast cell counts and cause risk of progression to acute myelogenous leukemia. Platelet count increases may also increase the risk of thrombosis. Thrombocytopenia may occur in rare cases due to the formation of Nplate reactive antibodies (1).

Nplate must be held when platelet levels reach >400 x 10^9/L (400,000 platelets per microliter) and platelet levels monitored weekly to evaluate any decrease in levels and need for re-initiation of therapy. If platelet levels remain above 400 x 10^9/L (400,000 platelets per microliter) after two weeks, Nplate therapy must be discontinued (1).

The use of Nplate to increase survival in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation is based on efficacy studies conducted in adult animals. Efficacy studies of Nplate could not be conducted in humans with acute radiation syndrome for ethical and feasibility reasons (1).

The safety and effectiveness of Nplate in pediatric patients less than 1 year of age with ITP have not been established (1).

Related policies

Cablivi, Promacta

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Nplate may be considered **medically necessary** if the conditions indicated below are met.

Nplate may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Immune Thrombocytopenia (ITP)
   a. 1 year of age or older
   b. Inadequate response or intolerant to corticosteroids,

immunoglobulins, or splenectomy
c. Platelet count at time of diagnosis less than 50,000 platelets per microliter
d. **Age 1-17 only:** Patient has had ITP for at least 6 months
e. **NOT** used in combination with another thrombopoietin receptor agonist (e.g., Promacta, Doptelet) or with Tavalisse (fostamatinib disodium hexahydrate)

2. Hematopoietic Syndrome of Acute Radiation Syndrome

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Immune Thrombocytopenia (ITP)
   a. 1 year of age or older
   b. Patient has **ONE** of the following:
      i. Platelet count 50,000 - 200,000 platelets per microliter
      ii. Platelet count greater than 200,000 platelets per microliter or less than or equal to 400,000 platelets per microliter with agreement that therapy will be adjusted to the minimum platelet count needed to reduce the bleeding risk
   c. **NOT** used in combination with another thrombopoietin receptor agonist (e.g., Promacta, Doptelet) or with Tavalisse (fostamatinib disodium hexahydrate)

2. Hematopoietic Syndrome of Acute Radiation Syndrome

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Nplate (romiplostim) works as an analog to the protein thrombopoietin (TPO) and binds to the TPO receptor, similar to endogenous TPO to stimulate platelet production. The use of Nplate to increase survival in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation is based on efficacy studies conducted in adult animals. Efficacy studies of Nplate could not be conducted in humans with acute radiation syndrome for ethical and feasibility reasons. The safety and efficacy of Nplate in patients less than 1 year of age with ITP have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Nplate while maintaining optimal therapeutic outcomes.

References

1. Nplate [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2022.

Policy History

Date	Action
December 2014	Addition to PA
March 2015	Annual review and reference update
March 2016	Annual review Policy number change from 5.10.20 to 5.85.20
December 2016	Annual editorial review and reference update Added age limit to renewal section
September 2017	Annual editorial review Verbiage for platelet count changed from 10^9/L to number of platelets per microliter
September 2018	Annual editorial review and reference update Addition of “no dual therapy with Tavalisse” to initiation and renewal criteria
December 2018	Addition of new indication: pediatric patients 1 year of age and older with ITP for at least 6 months who have had an inadequate response to corticosteroids, immunoglobulins, or splenectomy

March 2019	Annual review
June 2019	Annual review
November 2019	Removed “chronic” requirement for diagnosis
December 2019	Annual review
September 2020	Annual review
February 2021	Addition of indication: Hematopoietic Syndrome of Acute Radiation Syndrome
March 2021	Annual editorial review and reference update
September 2022	Annual review and reference update
June 2023	Annual review
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.