

**Policy: MBP 68.0**

**Section: Medical Benefit Pharmaceutical Policy**

**Subject: Nplate (romiplostim)**

**Applicable line of business:**

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

**I. Policy:**

Nplate (romiplostim)

**II. Purpose/Objective:**

To provide a policy of coverage regarding Nplate (romiplostim)

**III. Responsibility:**

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

**Commercial**

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**Medicare**

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

**CHIP**

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**DESCRIPTION:**

Nplate (romiplostim) increases platelet production through binding and activation of the thrombopoietin (TPO) receptor with a mechanism analogous to endogenous TPO.

**CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee**

Nplate (romiplostim) will be considered medically necessary for the commercial, exchange and CHIP lines of business when all of the following criteria are met:

**Immune Thrombocytopenia (ITP)**

- Physician supplied documentation of a diagnosis of immune thrombocytopenia (ITP) **AND**
- Physician supplied documentation of a therapeutic failure on, intolerance to, or contraindication to corticosteroids, immunoglobulins\*, rituximab\*, splenectomy, and eltrombopag (Promacta)\* **AND**
- Physician supplied documentation of:
  - symptomatic ITP with platelets less than 30,000/ $\mu$ L and bleeding symptoms **OR**
  - ITP with platelets less than 30,000/ $\mu$ L and a documented history of significant bleeding **OR**
  - a platelet count of less than 20,000/ $\mu$ L

\*requires prior authorization

**AUTHORIZATION DURATION:**

If an exception is made, Nplate will be authorized for an initial period of three (3) months. Subsequent authorizations will be for a period of six (6) months and will require medical record documentation of platelet count greater than or equal to 50,000/microL and continued or sustained reduction in bleeding events.

**Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)**

- Medical record documentation of Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS) **AND**
- Medical record documentation of suspected or confirmed acute exposure to myelosuppressive doses of radiation (estimated as radiation levels greater than 2 gray [Gy]).

**AUTHORIZATION DURATION:** One-time authorization for one administration of Nplate

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Nplate (romiplostim) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

**Immune Thrombocytopenia (ITP)**

- Physician supplied documentation of a diagnosis of immune thrombocytopenia (ITP) **AND**
- Physician supplied documentation of a therapeutic failure on, intolerance to, or contraindication to corticosteroids, immunoglobulins\*, or splenectomy **AND**
- Physician supplied documentation of:
  - symptomatic ITP with platelets less than 30,000/ $\mu$ L and bleeding symptoms **OR**
  - ITP with platelets less than 30,000/ $\mu$ L and a documented history of significant bleeding **OR**
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**LINE OF BUSINESS:**

**Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.**

**REFERENCES:**

1. Nplate [prescribing information]. Thousand Oaks, CA: Amgen Inc; February 2022.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. American Society of Hematology (ASH). Blood Advances; 2019 Dec 3; 3(23):3829-3866 [cited 2023 Dec 27]. Available from: <https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for>

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 4/8/09

**Revised:** 11/18/2014 (revised criteria at P&T), 3/17/20 (removal of “chronic ITP” & update of auth duration criteria), 7/20/21 (HS-ARS), 3/15/22 (plt count update, risk of bleeding delete), 3/9/23 (LOB carve out, Medicaid business segment), 12/31/23 (references added), 2/11/25 (LOB table, taglines, removed Medicaid business segment, updated description)

**Reviewed:** 6/10, 10/11, 2/12, 11/18/2014, 11/2/2015, 9/28/16, 7/31/17, 7/10/18, 5/21/19, 2/1/20, 1/19/21, 2/19/24

**MA UM Committee approval:** 12/31/23, 12/31/24