Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 68.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Nplate (romiplostim)

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
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. 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

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Nplate (romiplostim) is used for the treatment of chronic immune (idiopathic) thrombocytopenia purpura (ITP). Its mechanism of action 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/µL and bleeding symptoms; **OR**
    - ITP with platelets less than 30,000/µL and a documented history of significant bleeding; **OR**
    - a platelet count of less than 20,000/µL

*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

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/µL and bleeding symptoms; **OR**
    - ITP with platelets less than 30,000/µL and a documented history of significant bleeding; **OR**
    - a platelet count of less than 20,000/µL

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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

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.

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)

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