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.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit 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 when all of the following criteria are met:
- Physician supplied documentation of a diagnosis of chronic immune (idiopathic) thrombocytopenia purpura (ITP); AND
- Physician supplied documentation of a therapeutic failure on, 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
  - a platelet count of less than 20,000/µ and an increased risk of bleeding

*requires prior authorization

AUTHORIZATION DURATION:
If an exception is made, Nplate will be authorized for an initial period of three (3) months and continued coverage will require medical record documentation of improvement in symptoms and/or platelet count response above 20,000/ µL. Subsequent authorizations will be for a period of six (6) months and will then require medical record documentation of dosing to maintain a platelet count between 50,000/ µL and 100,000/ µL.

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)

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