Nplate (romiplostim)

**Line(s) of Business:**
- HMO; PPO; QUEST Integration
- Medicare Advantage

**Original Effective Date:** 10/01/2015

**Current Effective Date:** 03/01/2018

**POLICY**

**A. INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

**FDA-Approved Indications**
- Treatment of thrombocytopenia in patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy

**B. REQUIRED DOCUMENTATION**

The following information is necessary to initiate the prior authorization review:
- Current platelet counts
- Previous drug therapies received for ITP in member’s chart or medical record (initial requests only)

**C. INITIAL CRITERIA FOR APPROVAL**

**Chronic or persistent immune thrombocytopenia (ITP)**

Authorization of 6 months may be granted to members requesting Nplate for the initial treatment of chronic or persistent ITP who meet ALL of the following criteria:
1. Secondary causes of thrombocytopenia have been ruled out (eg, drug-induced, chronic liver disease, infection).
2. Member had an inadequate response or intolerance to documented prior therapy with corticosteroids, immunoglobulins, or splenectomy.
3. Current platelet count is <30x10^9/L OR 30x10^9/L to 50x10^9/L with symptomatic bleeding (eg, significant mucous membrane bleeding, gastrointestinal bleeding or trauma) or risk factors for bleeding (See Section F).

**D. CONTINUATION OF THERAPY**

1. No previous authorization/precertification:
   All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section C.
2. Reauthorization:
Chronic or persistent ITP
Members requesting continuation of therapy with Nplate must have been previously authorized by HMSA/CVS or meet criterion (1) and criterion (1) of Initial Criteria for Approval (See Section C).
   a. Authorization of 3 months may be granted to members with a current platelet count <50x10⁹/L for whom the platelet count is not sufficient to prevent clinically important bleeding and who have not received a maximal Nplate dose for at least 4 weeks.
   b. Authorization of 12 months may be granted to members with a current platelet count <50x10⁹/L for whom the current platelet count is sufficient to prevent clinically important bleeding.
   c. Authorization of 12 months may be granted to members with a current platelet count of 50x10⁹/L to 200x10⁹/L.
   d. Authorization of 12 months may be granted to members with a current platelet count >200 x10⁹/L for whom Nplate dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

E. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. APPENDIX
Examples of risk factors for bleeding (not all inclusive)
- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidity (eg, peptic ulcer disease, hypertension)
- Mandated anticoagulation therapy
- Profession or lifestyle predisposes member to trauma (eg, construction worker, fireman, professional athlete)

G. ADMINISTRATIVE GUIDELINES
Precertification is required. Please refer to the [HMSA medical policy web site](#) for the fax form.

H. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.
I. REFERENCES


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