BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Romiplostim (NPlate)

File Name:	romiplostim_nplate
Origination:	6/2016
Last CAP Review:	11/2019
Next CAP Review:	11/2020
Last Review:	11/2019

Description of Procedure or Service

Romiplostim (NPlate®) is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP), and pediatric patients 1 year of age or older with ITP for at least 6 months, who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

ITP is a condition that may cause unusual bruising or bleeding due to an abnormally low number of platelets in the blood.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Romiplostim (NPlate) when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Romiplostim (NPlate) is covered

Romiplostim may be considered medically necessary for the following clinical conditions:

1. For the diagnosis of chronic idiopathic thrombocytopenia (ITP) in adults; **OR**
2. For pediatric patients 1 year of age or older with ITP for at least 6 months; **AND**
3. For a platelet count ≤30 x 10^9/L, or upon start of therapy; **AND**
4. History of trial and failure with; or documented intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroids or immunoglobulins (IVIG or anti-D); **OR**
5. Insufficient response to or not a candidate for splenectomy.

After 8 weeks, continued treatment may be considered medically necessary for the following clinical conditions:

1. Approval obtained through the initial coverage criteria; **AND**

2. Platelet count is ≥50 x 10^9/L; **OR**

3. Platelet count has increased sufficiently to avoid clinically important bleeding.

When Romiplostim (NPlate) is not covered

Romiplostim (NPlate) is considered not medically necessary when the criteria under "When Romiplostim (NPlate) is covered" are not met.

Romiplostim is considered investigational when used for indications outside of FDA labeling.

Policy Guidelines

Limitations of Use:

- 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.

Dosage and Administration:

- Initial dose of 1 mcg/kg once weekly as a subcutaneous injection.
- Adjust weekly dose by increments of 1 mcg/kg to achieve and maintain a platelet count ≥ 50 x 10^9 /L as necessary to reduce the risk for bleeding.
- Do not exceed the maximum weekly dose of 10 mcg/kg. Do not dose if platelet count is > 400 x 10^9 /L.
- Discontinue NPlate if platelet count does not increase after 4 weeks at the maximum dose.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *J2796*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration (FDA). Prescribing Information.
http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125268s077lbl.pdf

Medical Director review 6/2016.

Specialty Matched Consultant Advisory Panel 11/2016

Specialty Matched Consultant Advisory Panel 11/2017

Specialty Matched Consultant Advisory Panel 11/2018

Amgen Inc. Nplate (romiplostim) for injection, for subcutaneous use. Highlights of prescribing information. October 2019. Available at: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/nplate/nplate_pi_hcp_english.pdf. Last accessed October 2019.

Specialty Matched Consultant Advisory Panel 11/2019

Policy Implementation/Update Information

7/1/16 New policy developed. Romiplostim (NPlate) may be considered medically necessary for the following clinical conditions: 1.Diagnosis of chronic idiopathic thrombocytopenia (ITP); **and** 2. platelet count ≤30 x 10^9/L), or upon start of therapy; **and** 3.history of trial and failure of; or a documented intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroids or immunoglobulins (IVIg or anti-D); **or** 4. insufficient response to or is not a candidate for splenectomy. Medical director review 6/2016. Policy noticed 7/1/16 for effective date 8/30/16. (lpr)

12/30/16 Specialty Matched Consultant Advisory Panel review 11/30/2016. No change to policy intent. (lpr)

12/15/17 Specialty Matched Consultant Advisory Panel review 11/29/2017. No change to policy statement. (lpr)

1/15/19 Minor typographical edits made to Policy Statement for clarity. No change to policy intent. Specialty Matched Consultant Advisory Panel review 11/28/2018. (krc)

12/10/19 Updated "When Covered" section to include additional indication for pediatric patients age 1 year and older with ITP for at least 6 months. Updated Description section to reflect addition of this indication. Reference added. Specialty Matched Consultant Advisory Panel review 11/20/2019. (krc)