

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	NPlate (romiplostim)
BILLING CODE	J2796
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Hospital, Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include immune globulins and Promacta QUANTITY LIMIT— 10 mcg/kg (actual body weight)
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

NPlate (romiplostim) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

IMMUNE THROMBOCYTOPENIC PURPURA (ITP)

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member has a documented diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND
3. Medication must be prescribed by or in consultation with a hematologist; AND
4. Member has ONE of the following conditions:
 - a) Current platelet count is $<30 \times 10^9/L$;
 - b) $30 \times 10^9/L$ to $50 \times 10^9/L$ with one of the following:
 - i) Symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma);
 - ii) Have risk factors for bleeding (i.e., on anticoagulant, lifestyle that predisposes member to trauma, comorbidity such as peptic ulcer disease, undergoing medical procedure where blood loss is anticipated); AND
5. Member had an inadequate response, intolerance, or contraindication to documented prior therapy with ONE of the following treatments:
 - a) Corticosteroids (prednisone, prednisolone, methylprednisolone, and dexamethasone);
 - b) Immunoglobulins;
 - c) Splenectomy.
6. **Dosage allowed:** Administer 1mcg/kg subcutaneously once weekly, then adjust the weekly dose by increments of 1 mcg/kg until the patient achieves a platelet count $\geq 50 \times 10^9/L$. Max dose 10 mcg/kg.

If member meets all the requirements listed above, the medication will be approved for 12 weeks.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement in platelet count from baseline; AND
3. Member's platelet count is less than $400 \times 10^9/L$.



If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers NPlate (romiplostim) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Any cause of thrombocytopenia other than chronic ITP
- Chronic Hepatitis C (CHC) Thrombocytopenia
- ITP with previous documented failure of Nplate
- Severe aplastic anemia
- Thrombocytopenia due to Myelodysplastic syndrome (MDS)

DATE	ACTION/DESCRIPTION
10/04/2018	New policy for NPlate created. Platelets requirement threshold expanded.

References:

1. Nplate [Package Insert]. Thousand Oaks, CA: Amgen, Inc.; October, 2017.
2. Diagnosis and treatment of idiopathic thrombocytopenic purpura: recommendations of the American Society of Hematology. Ann Intern Med. 1997 Feb 15;126(4):319-26.
3. Cooper N, Terrinoni I, Newland A. The efficacy and safety of romiplostim in adult patients with chronic immune thrombocytopenia. Ther Adv Hematol. 2012 Oct; 3(5): 291–298.
4. Bussel JB, Cheng G, Saleh MN, et al. Eltrombopag for the treatment of chronic idiopathic thrombocytopenic purpura. N Engl J Med. 2007; 357:2237.
5. Kuter DJ, et al. Romiplostim or standard of care in patients with immune thrombocytopenia. N Engl J Med. 2010 Nov 11;363(20):1889-99.
6. Kuter DJ, et al. Efficacy of romiplostim in patients with chronic immune thrombocytopenic purpura: a double-blind randomised controlled trial. Lancet. 2008 Feb 2;371(9610):395-403.
7. Kuter DJ, et al. Long-term treatment with romiplostim in patients with chronic immune thrombocytopenia: safety and efficacy. Br J Haematol. 2013 May;161(3):411-23.
8. Neunert C, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. Blood. 2011 Apr 21;117(16):4190-207.

Effective date: 10/19/2018

Revised date: 10/04/2018