

## PHARMACY POLICY STATEMENT

### Georgia 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 <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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