

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Nplate (romiplostim)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Nplate (romiplostim)

APPROVAL CRITERIA

Requests for initial therapy with Nplate (romiplostim) may be approved if the following criteria are met:

- I. Individual has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) and the following are met:
 - A. Individual has a platelet count of less than $30 \times 10^9/L$ or active bleeding (ASH, 2011; Hicks et al., 2014); **AND**
 - B. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and insufficient response to
 1. Corticosteroids; **OR**
 2. Immunoglobulins (for example IVIg or anti-D); **OR**
 3. Splenectomy.

Requests for Nplate (romiplostim) may be approved if the following criteria are met:

- I. Individual has a diagnosis of low risk myelodysplastic syndrome (MDS) and the following criteria are met (NCCN 2A):
 - A. Individual has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents, or immunosuppressive therapy.

Requests for maintenance therapy with Nplate (romiplostim) may be approved if the following criteria are met:

- I. Individual has a diagnosis of ITP and the following are met:
 - A. Individual demonstrated response to therapy as evidenced by increased platelet counts; **AND**
 - B. Continuation of treatment is to maintain an adequate platelet count ($50-100 \times 10^9/L$)* to decrease the risk of bleeding.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

*Note: If platelet count is greater than 100×10^9 , adjust the dose using a cut-off platelet level of 100×10^9 as a substitute for $200 \times 10^9/L$ in the U.S. Food and Drug Administration (FDA) dosage and administration recommendations.

Nplate (romiplostim) may **not** be approved for the following:

- I. Individual is using to normalize platelet counts; **OR**
- II. Individual is requesting for the treatment of low platelet count caused by any condition other than those conditions listed above; **OR**
- III. When the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 13, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Hicks LK, Bering H, Carson KR, et al. Five hematologic tests and treatments to question. *Blood*. 2014; 124(24):3524-3528. Available from: <http://www.bloodjournal.org/content/bloodjournal/124/24/3524.full.pdf?sso-checked=true>.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 13, 2020.
 - a. Myelodysplastic Syndromes. V2.2020. Revised February 28, 2020.
7. Neunert C, Terrell DR, Arnold DM, et al. The American Society of Hematology (ASH) 2019 evidence-based practice guideline for immune thrombocytopenia. *Blood Adv*. 2019; 3(23):3829-3866. Available from: <https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for>. Accessed on: April 13, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.