

| Market Applicability/Effective Date | | | | | | | | | | | | | | | |
|-------------------------------------|----|----------|--------|--------|----|-----|----|----|----|----|----|----|-----|-----|----|
| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | X | N/A | N/A | X | N/A | X | X | X | X | X | X | N/A | N/A | NA |

*FHK- Florida Healthy Kids

Nplate (romiplostim)

CG-DRUG-75

| Override(s) | Approval Duration |
|---------------------|-------------------|
| Prior Authorization | 1 year |

| Medications |
|----------------------|
| Nplate (romiplostim) |

APPROVAL CRITERIA

Initial treatment requests for Nplate (romiplostim) may be approved when used for the treatment of thrombocytopenia in individuals who meet **all** of the following criteria:

- I. Chronic immune thrombocytopenia (ITP); **AND**
- II. Individual's degree of thrombocytopenia (platelet count less than 30,000/mm³) and clinical condition increase the risk for bleeding; **AND**
- III. Individual demonstrated an insufficient response to corticosteroids, immunoglobulins (such as, IVIg or anti-D), or splenectomy.

Maintenance therapy requests for Nplate (romiplostim) for ongoing treatment of chronic ITP **may be approved** when the following criterion is met:

- I. Individual demonstrated response to therapy as evidenced by increased platelet counts, and the goal of ongoing treatment is to maintain an adequate platelet count (50,000-100,000/mm³)* to decrease the risk of bleeding.

*Note: If platelet count is greater than 100,000/mm³, adjust the dose using a cut-off platelet level of 100,000/mm³ as a substitute for 200,000/mm³ in the U.S. Food and Drug Administration (FDA) dosage and administration recommendations (please refer to product labeling).

Nplate (romiplostim) may be approved for treatment of myelodysplastic syndrome (MDS) when the following criteria are met:

- I. Individual has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents, or immunosuppressive therapy.

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.

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| Applicable | X | X | N/A | N/A | X | N/A | X | X | X | X | X | X | N/A | N/A | NA |

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Nplate (romiplostim) **may not be approved** when the above criteria are not met, including but not limited to **any** of the following:

- I. Treatment used in an attempt to normalize platelet counts;
- II. Low platelet count caused by any condition other than chronic ITP.

| State Specific Mandates | | |
|-------------------------|----------------|---|
| State name | Date effective | Mandate details (including specific bill if applicable) |
| N/A | N/A | N/A |

Key References:

Children’s Hospital Boston. ICON1: Treatment decisions and outcomes in pediatric refractory ITP. NLM Identifier: NCT01971684. Last updated June 13, 2017. Available at: <https://clinicaltrials.gov/ct2/show/NCT01971684?term=NCT01971684&rank=1>. Accessed on September 21, 2017.

NCCN Clinical Practice Guidelines in Oncology®. © 2017 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on November 3, 2017.

Myelodysplastic Syndromes (V.1.2018). Revised August 29, 2017.

Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. Blood. 2011; 117(16):4190-4207.

Nplate® (romiplostim) [Product Information]. Thousand Oaks, CA. Amgen, Inc. June 5, 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125268s160lbl.pdf. Accessed on September 21, 2017.

Romiplostim Monograph. Lexicomp® Online, American Hospital Formulary Services® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised August 22, 2014. Accessed on September 21, 2017.

Romiplostim (systemic). In: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. June 16, 2017. Available at: <http://www.micromedexsolutions.com>. Accessed on September 21, 2017.

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