SmartHealth Ascension

Romiplostim

(Nplate®) J2796 (10 micrograms)

Covered with prior authorization

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

- Initial requests for Nplate® (romiplostim) for ITP may be approved if the following criteria are met:
    - Individual has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) and the following are met:
        - Documentation is provided that individual has a platelet count of less than 30 x 109/L or active bleeding (ASH, 2011; Hicks et al., 2014); **AND**
        - Individual has had a prior trial and insufficient response to one of the following confirmed:
            - Corticosteroids; **OR**
            - Immunoglobulins (for example IVIg or anti-D); **OR**
            - Splenectomy.

- Continuation requests for Nplate® (romiplostim) for ITP may be approved if the following criteria are met:
    - Individual has a diagnosis of ITP and the following are met:
        - Documentation is provided that individual has demonstrated a response to therapy as confirmed by increased platelet counts; **AND**
        - Continuation of treatment is to maintain an adequate platelet count (50 – 100 X 10^9/L)***** to decrease the risk of bleeding.

***Note**: If platelet count is greater than 100 X 10^9/L, adjust the dose using a cut-off platelet level of 100 X10^9/L as a substitute for 200 X 10^9/L in the U.S. Food and Drug Administration (FDA) dosage and administration recommendations.

Approval Duration for ITP
Initial requests: 6 months
Continuation requests: 12 months

- Initial requests for Nplate® (romiplostim) for MDS may be approved if the following criteria are met:
    - Documentation is provided that individual has a diagnosis of lower risk myelodysplastic syndrome (MDS) [Lower risk defined as IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate)] (NCCN 2A); **AND**
    - Individual has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents or immunosuppressive therapy.

- Continuation requests for Nplate® (romiplostim) for MDS may be approved if the following criteria are met (NCCN MDS V3.2021):
    - Documentation is provided that individual has demonstrated a clinically significant response to therapy, such as an increase in platelet counts, decrease in bleeding events, or reduction in need for platelet transfusions.

- Initial requests for Nplate® (romiplostim) for CIT may be approved if the following criteria are met (NCCN 2A):
    - Individual has a diagnosis of chemotherapy-induced thrombocytopenia (CIT); **AND**
    - Individual meets one of the following criteria:
        - Individual has platelets less than 100 x 10^9/L for at least 3 weeks following the last chemotherapy administration; **OR**
        - Individual has platelets less than 100 x 10^9/L and there are delays in chemotherapy related to thrombocytopenia; **AND**
    - Individual was using a cytotoxic chemotherapy agent that is known to cause thrombocytopenia; **AND**
    - The goal of therapy is to maintain the dosing schedule and/or intensity of the chemotherapy regimen when such benefit outweighs the potential risks.

- Continuation requests for Nplate® (romiplostim) for CIT may be approved if the following criteria are met:
    - Individual has a diagnosis of CIT and the following are met:
        - Individual has demonstrated a response to therapy as confirmed by increased platelet counts; **AND**
        - Continuation of treatment is to maintain an adequate platelet count (100 - 150 X 10^9/L) to allow for the resumption of chemotherapy regimen as appropriate.

Approval Duration for MDS
Initial requests: 6 months
Continuation requests: 12 months

- Requests for Nplate® (romiplostim) for HS-ARS may be approved if the following criteria are met:
    - Individual has a diagnosis of Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS] (i.e., acute exposure to myelosuppressive doses of radiation); **AND**
    - Individual has suspected or confirmed exposure to radiation levels greater than 2 gray (Gy).

Approval Duration for HS-ARS
1 single administration per episode

- Initial requests for Nplate® (romiplostim) for CIT may be approved if the following criteria are met (NCCN 2A):
    - Individual has a diagnosis of chemotherapy-induced thrombocytopenia (CIT); **AND**
    - Individual meets one of the following criteria:
        - Individual has platelets less than 100 x 10^9/L for at least 3 weeks following the last chemotherapy administration; **OR**
        - Individual has platelets less than 100 x 10^9/L and there are delays in chemotherapy related to thrombocytopenia; **AND**
    - Individual was using a cytotoxic chemotherapy agent that is known to cause thrombocytopenia; **AND**
    - The goal of therapy is to maintain the dosing schedule and/or intensity of the chemotherapy regimen when such benefit outweighs the potential risks.

- Continuation requests for Nplate® (romiplostim) for CIT may be approved if the following criteria are met:
    - Individual has a diagnosis of CIT and the following are met:
        - Individual has demonstrated a response to therapy as confirmed by increased platelet counts; **AND**
        - Continuation of treatment is to maintain an adequate platelet count (100 - 150 X 10^9/L) to allow for the resumption of chemotherapy regimen as appropriate.

Approval Duration for CIT
Initial requests: 6 months
Continuation requests: 12 months

Dosing Recommendation:

- Dose ≤ 10 mcg/kg/week

Continuation reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Exclusion criteria:

- Nplate® (romiplostim) may not be approved when the above criteria are not met and for all other indications.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.
- Nplate® (romiplostim) may not be approved for the following:
    - Individual is using to normalize platelet counts; **OR**
    - Individual is requesting for the treatment of low platelet count caused by any condition other than those conditions listed above.

Note: Nplate is recommended for use to maintain a platelet count necessary to reduce the risk of bleeding, it is not recommended as therapy to increase or maintain platelet counts at normal levels.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Nplate® is a thrombopoietin (TPO) receptor agonist primarily used in the treatment of children and adults with immune thrombocytopenia, an autoimmune disorder that can cause uncontrolled bleeding if left untreated. Immune thrombocytopenia (ITP) is also called idiopathic thrombocytopenia purpura and immune thrombocytopenia purpura, which is an acquired autoimmune disorder characterized by low platelet counts caused by autoantibodies against platelet antigens. According to the National Institutes of Health, ITP occurs in approximately 1 in every 16,000 adults, causing unusual bruising or bleeding due to an abnormally low number of platelets in the blood. Nplate® is FDA approved for the treatment of thrombocytopenia in individuals with ITP who had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Nplate® is FDA indicated for the following:
- Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- Pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- Adults and pediatrics (including term neonates) acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS].

Limitations of use per label:
- Nplate® is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than 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.

The NCCN Drugs and Biologics Compendium and NCCN Clinical Practice Guideline offers a Category 2A recommendation for the treatment of individuals with lower risk MDS disease with severe or refractory thrombocytopenia using romiplostim following disease progression or no response to hypomethylating agents, immunosuppressive therapy, or clinical trial. “Lower risk defined as IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate).” NCCN also provides a 2A recommendation for use of Nplate® in chemotherapy-induced thrombocytopenia with the goal of allowing resumption of chemotherapy regimen when the benefits outweigh the risks.

Key References Accessed 8/2022:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. 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.
3. 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.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.
    a. Hematopoietic Growth Factors. V1.2022. Revised December 22, 2021.
    b. Myelodysplastic Syndromes. V3.2022. Revised January 13, 2022.
6. 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.
7. DeSouza S, Angelini D. Updated guidelines for immune thrombocytopenic purpura: Expanded management options. Cleveland Clinic Journal of Medicine. 2021; 88(12):664668-3866. Available from: https://www.ccjm.org/content/88/12/664#sec-1.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.