Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Romiplostim (Nplate®)	MP-RX-FP-63-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

Service Description

This document addresses the use of ***Romplostim (Nplate)*** , a thrombopoietin receptor agonist, approved by the Food and Drug Administration (FDA) for the treatment of children and adults with immune thrombocytopenia, an autoimmune disorder that can cause uncontrolled bleeding if left untreated.

Background Information

Nplate stimulates megakaryocyte proliferation and differentiation, increasing platelet production to treat thrombocytopenia in individuals with ITP who had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. 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 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.

Per specialty committee consensus opinion, ongoing treatment with Nplate (romiplostin) may be used to maintain an adequate platelet count (50 – 100 X 109/L) to decrease the risk of bleeding. For platelet count

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greater than 100,000/mm3, dose adjustments can be made using a cut-off platelet level of 100,000/mm^3 as a substitute for 200,000/mm3 in the FDA dosage and administration recommendations.

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.

Definitions and Measures

- Aplastic anemia: A condition that occurs when the body stops producing enough new blood cells.
- Immune thrombocytopenia: A bleeding disorder where the blood is unable to clot, as a result of a low number of platelets or thrombocytes.
- The International Prognostic Scoring System (IPSS): IPSS is the most widely used prognostic classification system for myelodysplastic syndrome (MDS). The IPSS-R is the revised international prognostic scoring system in MDS to better predict outcomes in newly diagnosed patients. The WHO classification-based Prognostic Scoring System (WPSS) allows for dynamic estimation of prognosis at multiple time points during the course of MDS.
- Maintenance therapy: Designed to maintain a condition to prevent a relapse.

Approved Indications

A. Patients with Immune Thrombocytopenia (ITP)
B. Patients with Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)

Other Uses

A. Myelodysplastic syndrome (MDS)
B. Chemotherapy Induced Thrombocytopenia (CIT)

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J2796	Injection, romiplostim, 10 micrograms [Nplate]

ICD-10	Description
D46.0-D46.9	Myelodysplastic syndromes
D69.3	Immune thrombocytopenic purpura
D69.41-D69.49	Other primary thrombocytopenia
D69.59	Other secondary thrombocytopenia
T66.XXXA	Radiation sickness, unspecified, initial encounter

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Clinical Criteria

A. Criteria For Initial Approval

i. Individual has a diagnosis of *immune (idiopathic) thrombocytopenia (ITP)* and the following criteria are met:
   A. 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**
   B. Individual has had a prior trial and insufficient response to one of the following confirmed:
      1. Corticosteroids; **OR**
      2. Immunoglobulins (for example IVIg or anti-D); **OR**
      3. Splenectomy

OR

ii. Individual has a diagnosis of *Myelodysplastic Syndrome (MDS)* and the following criteria are met:
   A. 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**
   B. Individual has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents or immunosuppressive therapy.

OR

iii. Individual has a diagnosis of *Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)* and the following criteria are met:
   A. Individual a diagnosis of Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS] (i.e., acute exposure to myelosuppressive doses of radiation); **AND**
   B. Individual has suspected or confirmed exposure to radiation levels greater than 2 gray (Gy).

OR

iv. Individual has a diagnosis of *Chemotherapy Induced Thrombocytopenia (CIT)* and the following criteria are met:
   A. Individual has a diagnosis of chemotherapy-induced thrombocytopenia (CIT); **AND**
   B. Individual meets one of the following criteria:
      1. Individual has platelets less than 100 x 109/L for at least 3 weeks following the last chemotherapy administration; **OR**

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2. Individual has platelets less than 100 x 109/L and there are delays in chemotherapy related to thrombocytopenia; **AND**

C. Individual was using a cytotoxic chemotherapy agent that is known to cause thrombocytopenia; **AND**

D. The goal of therapy is to maintain the dosing schedule and/or intensity of the chemotherapy regimen when such benefit outweighs the potential risks.

B. Criteria For Continuation of Therapy

i. Continuation requests for Nplate (romiplostim) for *ITP* may be approved if the following criteria are met:

A. Individual has a diagnosis of ITP and the following are met:

1. Documentation is provided that individual has demonstrated a response to therapy as confirmed by increased platelet counts; **AND**
2. Continuation of treatment is to maintain an adequate platelet count (50 – 100 X 109/L)* to decrease the risk of bleeding.

ii. Continuation requests for *MDS* may be approved if the following criteria are met:

A. 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.

iii. Continuation requests for *CIT* may be approved if the following criteria are met:

A. Individual has a diagnosis of CIT and the following are met:

1. Individual has demonstrated a response to therapy as confirmed by increased platelet counts; **AND**
2. Continuation of treatment is to maintain an adequate platelet count (100 - 150 X 109/L) to allow for the resumption of chemotherapy regimen as appropriate.

C. Authorization Duration

i. Approval Duration for ITP, MDS, and CIT:

A. Initial Approval Duration: : 6 months

B. Reauthorization Approval Duration: 12 month

ii. Approval Duration for HS-ARS: 1 single administration per episodeClick or tap here to enter text.

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Individual is using to normalize platelet counts;

OR

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ii. Individual is requesting for the treatment of low platelet count caused by any condition other than those conditions listed above;

OR

iii. Individual is using in combination with eltrombopag (Alvaiz or Promacta);

OR

iv. When the above criteria are not met and for all other indications

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Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Indication	Recommended Dosage
Immune Thrombocytopenia (ITP)	1 mcg/kg once weekly as a subcutaneous injection. Adjust dose based on platelet response.
Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS])	10 mcg/kg administered once as a subcutaneous injection. Administer the dose as soon as possible after suspected or confirmed exposure to myelosuppressive doses of radiation.
Exceptions	
N/A	

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1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. 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 4, 2023
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. 4
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
6. 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. Accessed on April 4, 2023.
    a. Hematopoietic Growth Factors. V2.2023. Revised March 6, 2023.
    b. Myelodysplastic Syndromes. V1.2023. Revised September 12, 2022.
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 4, 2023.
8. 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 .
9. Zheng, X Long et al. “ISTH guidelines for treatment of thrombotic thrombocytopenic purpura.” Journal of thrombosis and haemostasis: JTH vol. 18,10 (2020): 2496-2502. doi:10.1111/jth.15010

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Annual Review. 09/15/2024.	Wording and formatting changes. Update Background information, Approved indications, Other uses, Clinical criteria, and Limits or restrictions (Added recommended dosage per FDA indication). Coding Reviewed: Added ICD-10-CM T66.XXXA, D69.59	2/24/2025	3/6/2025
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023