Effective Date **10/1/2023**
Next Review Date… **10/1/2024**
Coverage Policy Number **IP0155**

Romiplostim

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Related Coverage Resources

Immune Globulin

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for romiplostim subcutaneous injection (**Nplate**®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Romiplostim (Nplate) is considered medically necessary when ONE of the following is met (1, 2, 3, or 4):

1. **Hematopoietic Syndrome of Acute Radiation Syndrome.** Individual meets the following criteria (A):
   A. The individual has been acutely exposed to myelosuppressive doses of radiation

2. **Immune Thrombocytopenia.** Individual meets **ALL** of the following criteria (A, B, and C):
   A. Individual meets **ONE** of the following (i or ii):
      i. Individual has a platelet count less than 30 x 10^9/L (< 30,000/mcL), prior to start of therapy

ii. Individual meets **BOTH** of the following (a and b):
a. Individual has a platelet count less than 50 x 10^9/L (< 50,000/mcL), prior to start of therapy
b. According to the prescriber, the individual is at an increased risk of bleeding

B. Individual meets **ONE** of the following (i or ii):
i. Documentation of **ONE** of the following:
a. Individual has had an inadequate response to **ONE** of the following (1, 2, 3, 4, 5, 6, or 7):
1) Systemic corticosteroids
2) Intravenous immunoglobulin [may require prior authorization]
3) Anti-D immunoglobulin [may require prior authorization]
4) Promacta (eltrombopag tablets and oral suspension) [may require prior authorization]
5) Tavalisse (fostamatinib tablets) [may require prior authorization]
6) Doptelet (avatrombopag tablets) [may require prior authorization]
7) Rituximab [may require prior authorization]
b. Individual has a contraindication or is intolerant to for **ALL** of the following (1, 2, 3, 4, 5, 6, and 7):
1) Systemic corticosteroids
2) Intravenous immunoglobulin [may require prior authorization]
3) Anti-D immunoglobulin [may require prior authorization]
4) Promacta (eltrombopag tablets and oral suspension) [may require prior authorization]
5) Tavalisse (fostamatinib tablets) [may require prior authorization]
6) Doptelet (avatrombopag tablets) [may require prior authorization]
7) Rituximab [may require prior authorization]
ii. Individual has undergone splenectomy

C. Medication is being prescribed by, or in consultation with, a hematologist

3. **Thrombocytopenia, Chemotherapy-Induced.** Individual meets **ALL** of the following criteria (A, B, C, and D):
A. Individual is 18 years of age or older
B. Individual has a platelet count < 100 x 10^9/L (<100,000/mcL), prior to start of therapy
C. Individual meets **ONE** of the following (i, ii, or iii):
i. Individual has thrombocytopenia at least 2 weeks after the most recent dose of chemotherapy for 2 week cycle regimens
ii. Individual has thrombocytopenia at least 3 weeks after the most recent dose of chemotherapy for either 3 or 4 week cycle regimens
iii. Individual has experienced a delay in chemotherapy administration related to thrombocytopenia
D. Medication is prescribed by or in consultation with a hematologist or an oncologist

4. **Thrombocytopenia in Myelodysplastic Syndrome (MDS).** Individual meets **ALL** of the following criteria (A, B, and C):
A. Individual has low- to intermediate-risk myelodysplastic syndrome (for example: IPSS-R score >1.5 to 4.5 points)
B. Individual meets **ONE** of the following (i or ii):
i. Individual has a platelet count less than 30 x 10^9/L (< 30,000/mcL), prior to start of therapy
ii. Individual meets **BOTH** of the following (a and b):
a. Individual has a platelet count less than 50 x 10^9/L (< 50,000/mcL), prior to start of therapy
b. According to the prescriber, the individual is at an increased risk of bleeding
C. Medication is being prescribed by, or in consultation with, a hematologist or an oncologist

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.

Reauthorization Criteria

Romiplostim (Nplate) is considered medically necessary for continued use when initial criteria are met **AND** there is documentation of beneficial response, **AND** the following:

1. Immune Thrombocytopenia
    a. Individual remains at risk for bleeding complications
2. Thrombocytopenia, Chemotherapy-Induced
    a. Individual continues to receive treatment with chemotherapy
3. Thrombocytopenia in Myelodysplastic Syndrome
    a. Individual remains at risk for bleeding complications

Examples of a beneficial response include increases in platelet counts, reduction in red blood cell transfusions, hemoglobin increase, and/or absolute neutrophil count increase.

Authorization Duration

Initial approval duration:

- Hematopoietic Syndrome of Acute Radiation Syndrome: one dose
- Immune Thrombocytopenia: up to 3 months
- Thrombocytopenia, Chemotherapy-Induced: up to 3 months
- Thrombocytopenia in Myelodysplastic Syndrome (MDS): up to 3 months

Reauthorization approval duration:

- Hematopoietic Syndrome of Acute Radiation Syndrome: Not applicable for continuation beyond initial approval duration
- Immune Thrombocytopenia: up to 12 months
- Thrombocytopenia, Chemotherapy-Induced: up to 12 months
- Thrombocytopenia in Myelodysplastic Syndrome (MDS): up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

Background

OVERVIEW

Nplate, a thrombopoietin receptor agonist, is indicated for the treatment of:[1]

- **Hematopoietic syndrome of acute radiation syndrome**, to increase survival in adults and pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation.
- **Immune thrombocytopenia (ITP), in adults** who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- **Immune thrombocytopenia (ITP), in pediatric patients ≥ 1 year of age** with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Nplate should only be utilized in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Nplate should not be used in an attempt to normalize platelet counts.

Guidelines

Nplate is mentioned in various clinical guidlines.

- **Chemotherapy Induced Thrombocytopenia:** The National Comprehensive Cancer Network (NCCN) guidelines for hematopoietic growth factors (version 2.2023 – March 6, 2023) recommend consideration of Nplate for the management of suspected chemotherapy induced thrombocytopenia (category 2A) in addition to other modalities (e.g., platelet transfusion, chemotherapy dose reduction, or change in treatment regimen).[14]
- **Immune Thrombocytopenia:** The American Society of Hematology has updated guidelines for ITP (2019). For adults with ITP for at least 3 months who are corticosteroid-dependent or unresponsive to a corticosteroid, a thrombopoietin receptor agonist (Nplate or Promacta® [eltrombopag tablets and oral suspension]) or a splenectomy are recommended.[2] In children with newly diagnosed ITP who have non-life-threatening mucosal bleeding, corticosteroids are recommended. For children who have non-life-threatening mucosal bleeding and do not respond to first-line treatment, thrombopoietin receptor agonists are recommended.
- **Myelodysplastic Syndrome (MDS):** NCCN recommendations regarding MDS (version 1.2023 – September 12, 2022) state to consider treatment with a thrombopoietin receptor agonist in patients with lower-risk MDS who have severe or life-threatening thrombocytopenia.[3] Data are available that describe the use of Nplate in patients with MDS.[4-13] The data with Nplate are discussed noting an increased rate of platelet response and decreased overall bleeding events among patients with low to intermediate risk MDS.

References

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