Nplate® (Romiplostim)

Policy Number: CS2026D0214K
Effective Date: April 1, 2026

➲ Instructions for Use

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Related Policies
None

Application

This Medical Benefit Drug Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Arizona	Refer to the state's Medicaid clinical policy
Florida	Refer to the state's Medicaid clinical policy
Indiana	Refer to the state's Medicaid clinical policy
Kansas	Refer to the state's Medicaid clinical policy
North Carolina	None
Ohio	Nplate® (Romiplostim) (for Ohio Only)
Pennsylvania	Refer to the state's Medicaid clinical policy
Washington	Refer to the state's Medicaid clinical policy

Coverage Rationale

Nplate (romiplostim) is proven and medically necessary for the treatment of chronic immune thrombocytopenic purpura (ITP) when all of the following criteria are met:

- For **initial therapy**, **all** of the following:
  - Diagnosis of chronic immune thrombocytopenic purpura (ITP); **and**
  - Documented baseline platelet count < 30 x 109/L; **and**
  - History of insufficient response, contraindication, or intolerance to **one** of the following:
    - Corticosteroids; **or**
    - Immunoglobulins; **or**
    - Splenectomy

    and
  - Prescribed by or in consultation with a hematologist; **and**
    Nplate is not being used to treat thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP; **and**
  - Nplate is not being used to normalize platelet counts; **and**
  - Nplate is initiated and titrated according to U.S. Food and Drug Administration labeled dosing for ITP; **and**
  - Initial authorization is for no more than 12 months

- For **continuation of therapy**, **all** of the following:
  - Patient has previously received Nplate subcutaneous injection; **and**
  - Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding (platelet count ≥ 50 × 10^9/L as necessary to reduce the risk for bleeding); **and**
  - Nplate is not being used to treat thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP; **and**
  - Nplate is not being used to normalize platelet counts; **and**
  - Nplate is dosed according to U.S. Food and Drug Administration labeled dosing for ITP; **and**
  - Authorization is for no more than 12 months

Nplate (romiplostim) is medically necessary for the treatment of Myelodysplastic Syndromes (MDS) when all of the following criteria are met:

- For **initial therapy**, **all** of the following:
  - Diagnosis of lower risk myelodysplastic syndrome (IPSS-R very low, low, intermediate); **and**
  - **One** of the following:
    - Severe thrombocytopenia; **or**
    - Refractory thrombocytopenia

    and
  - **One** of the following:
    - Disease progression after hypomethylating agent(s) (HMA) or immunosuppressive therapy (IST); **or**
    - No response to HMA or IST; **or**
    - Relapse disease after HMA or IST

    and
  - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
  - Patient does not show evidence of progressive disease while on Nplate therapy; **and**
  - Patient demonstrates clinically significant response to therapy as defined by **one** of the following:
    - Increased platelet counts; **or**
    - Decreased bleeding events; **or**
    - Reduced need for platelet transfusion

    and
  - Authorization is for no more than 12 months

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. 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 Code	Description
J2802	Injection, romiplostim, 1 mcg

Diagnosis Code	Description
D46.Z	Other myelodysplastic syndromes
D46.9	Myelodysplastic syndrome, unspecified
D69.3	Immune thrombocytopenic purpura

Background

Immune thrombocytopenic purpura is an autoimmune disease that usually presents as a low platelet count and mucocutaneous bleeding. The prevalence of ITP is approximately 12 per 100,000. ITP diagnosis is classified as primary or as secondary (to another disease) and as acute (of six months or less in duration) or chronic (12 months or greater). Adult and childhood ITP present with different symptoms. Healthy children often present with onset of petechiae or purpura after an illness. In most children (70%), the illness will have resolved by 6 months with or without treatment. ITP in adults is usually chronic and the onset is often insidious.[3]

The pathogenesis of ITP is related to a combination of impaired platelet production and increased platelet destruction caused primarily by antiplatelet autoantibodies. An immune basis for ITP matches characteristics of the disease treatment including the efficacy of intravenous immune globulin and shortened survival of transfused platelets due to their rapid destruction. A second finding forced a change in the understanding of ITP: TPO receptor agonists. TPO agonists works by stimulating the TPO receptor causing an increase in the production of megakaryocytes and platelets. The efficacy of TPO receptor agonists matches other labelled autologous platelet studies that showed insufficient platelet production as likely another mechanism of thrombocytopenia in ITP.[2,3]

ITP is a diagnosis of exclusion that is made in patients with thrombocytopenia. Secondary causes of the disease include the following: systemic lupus erythematosus, the antiphospholipid syndrome, immunodeficiency status, lymphoproliferative disorders, HIV, hepatitis C, and medications such as heparin and quinidine. Bleeding duration can help to distinguish acute from chronic immune thrombocytopenic purpura. Lack of systemic symptoms can help to rule out secondary causes. A peripheral-blood smear is needed to rule out pseudo thrombocytopenia, inherited giant platelet syndromes, and other hematologic disorders.

Clinical Evidence

Reference the Clinical Studies information provided in the product labeling.[1]

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 after no response to hypomethylating agents or immunosuppressive therapy. Lower risk defined as IPSS-R (Very Low, Low, Intermediate).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Nplate® is a thrombopoietin receptor agonist indicated for the following:

- Treatment of thrombocytopenia in 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.[1]
- Increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation.

References

1. Nplate® [prescribing information]. Thousand Oaks, CA: Amgen; February 2025.
2. Cines DB, Blanchette VS. Immune thrombocytopenic purpura. New England Journal of Medicine 2002; 346:995-1008.
3. Toltl LJ, Arnold DM. Pathophysiology and management of chronic immune thrombocytopenia. British Journal of Hematology 2011; 152:52-60.
4. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/guidelines/nccn-guidelines. Accessed June 4, 2025.

Policy History/Revision Information

Date	Summary of Changes
04/01/2026	**Template Update** • Removed content/language pertaining to the state of Louisiana **Supporting Information** • Archived previous policy version CS2025D0214J

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.