Nplate® (Romiplostim) (for Indiana Only)

Policy Number: CSIND0214.01
Effective Date: July 1, 2021

Instructions for Use

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Related Policies
None

Application

This Medical Benefit Drug Policy only applies to the state of Indiana.

Coverage Rationale

Nplate is medically necessary for the treatment of chronic immune thrombocytopenic purpura (ITP). For medical necessity clinical coverage criteria for Nplate, refer to the InterQual® 2021, Apr. 2021 Release, CP: Specialty Rx Non-Oncology Romiplostim (Nplate).

Click here to view the InterQual® criteria.

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 federal, state, or contractual requirements 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
J2796	Injection, Romiplostim, 10 micrograms

Diagnosis Code	Description
D69.3	Immune thrombocytopenic purpura

Background

Immune thrombocytopenic purpura is an autoimmune disease that usually presents as a low platelet count and mucocutaneous bleeding. 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.[2]

The main theory to explain thrombocytopenia in ITP has been autoantibody-mediated platelet destruction. 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.[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 pseudothrombocytopenia, inherited giant platelet syndromes, and other hematologic disorders.[2]

Clinical Evidence

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

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 treatment of thrombocytopenia in the following: 1. Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy and 2. 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]

References

1. Nplate® [prescribing information]. Thousand Oaks, CA: Amgen; January 2021.
2. InterQual® 2020, April 2020 Release CP: Specialty Rx Non-Oncology, 2021 Change Healthcare LLC. Accessed March 2021.
3. Cines DB, Blanchette VS. Immune thrombocytopenic purpura. New England Journal of Medicine 2002; 346:995-1008.
4. Toltl LJ, Arnold DM. Pathophysiology and management of chronic immune thrombocytopenia. British Journal of Haematology 2011; 152:52-60.

Policy History/Revision Information

Date	Summary of Changes
07/01/2021	• New Medical Benefit Drug Policy

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, please 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.