



CIGNA PHARMACY COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Coverage Policy Number 9002

Subject Romiplostim (Nplate®)

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Hyperlink to Related Coverage Policies

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), 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 participant'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 participant's benefit plan document **always supercedes** 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 group 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. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

CIGNA covers romiplostim (Nplate®) for the treatment of thrombocytopenia in individuals with chronic immune (idiopathic) thrombocytopenic purpura (ITP) when BOTH of the following criteria are met:

- insufficient response to corticosteroids, immunoglobulins, or splenectomy
- degree of thrombocytopenia and clinical condition increase the risk for bleeding

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

FDA Approved Indications

Nplate is indicated for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. 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.

FDA Recommended Dosing

Dosing includes an initial dose of 1 mcg/kg once weekly as a subcutaneous injection. Then adjust weekly dose by increments of 1 mcg/kg to achieve and maintain a platelet count ≥ 50 x 10⁹/L as necessary to reduce the risk

for bleeding. Nplate is given by a healthcare provider as a weekly subcutaneous (SC) injection. A platelet count is to be drawn every week and doses of Nplate adjusted accordingly.

Nplate is not available in pharmacies. It is available only through a restricted distribution program called the Nplate NEXUS (Network of Experts Understanding and Supporting Nplate and Patients) Program. Under the Nplate NEXUS Program, only prescribers and patients registered with the program are able to prescribe, administer, and receive product.

Drug Availability

Nplate is supplied in single-use vials containing 250 mcg and 500 mcg deliverable romiplostim.

General Background

Disease Overview

There are two types of ITP - acute (temporary or short-term) and chronic (long-lasting). Acute ITP generally lasts less than 6 months. It mainly occurs in children, both boys and girls, and is the most common type of ITP. It often occurs after an infection caused by a virus. Chronic ITP is long-lasting (6 months or longer) and mostly affects adults. However, some teenagers and even younger children can get this type of ITP. Chronic ITP affects women 2 to 3 times more often than men. Treatment depends on how severe the bleeding symptoms are and the platelet count. In mild cases, treatment may not be needed.

Pharmacology

Romiplostim is a recombinant fusion protein that binds thrombopoietin and subsequently stimulates platelet production. Romiplostim has a median peak serum concentration of 14 hours (range 7 to 50 hours). Half-life is 3.5 days. Increase in mean platelet count is directly proportional to dose. Platelet counts begin to increase on day 5 and peak between days 10 to 18 after initiation of romiplostim. Circulating TPO levels are modulated by a regulatory loop. Platelets and megakaryocytes bind to and clear TPO from the circulation resulting in TPO levels which are inversely proportional to platelet levels. Romiplostim levels are modulated in the same manner.

Clinical Efficacy

Clinical experience with romiplostim in treating patients with ITP is limited to two experimental trials, one extension trial, two dose-finding trials, and two pharmacodynamic trials. Compared to placebo, romiplostim increases and maintains platelet counts in ITP patients after 6 months of treatment. Durable platelet response, defined as a platelet count $\geq 50,000/\mu\text{L}$ for any 6 of the last 8 weeks of treatment, for the patients treated with romiplostim was 41/83 (49%) compared to placebo at 1/42 (2%). Overall response to romiplostim was lower in splenectomized patients than non-splenectomized patients, but both groups were superior to placebo ($p < 0.05$ for each).

Adverse Reactions

The most common adverse drug reaction reported with romiplostim is headache. Other adverse drug reactions include arthralgia, dizziness, insomnia, myalgias, pain in extremity, abdominal pain, shoulder pain, dyspepsia, and paresthesia. Rare but serious adverse reactions include bone marrow reticulin deposition, thromboembolic or bleeding events, and worsening thrombocytopenia after romiplostim discontinuation. No drug interactions are expected with romiplostim, although no interaction studies are available.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

HCPCS Codes	Description
J2796	Injection, romiplostim, 10 mcg

ICD-9-CM Diagnosis	Description
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Codes	
287.31	Immune thrombocytopenic purpura

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