NEW J-CODE AND DOSE DESCRIPTOR/ BILLING UNIT FOR NPLATE®

ACTION REQUIRED:

Use J2802 and bill service units in multiples of 1 unit = 1 mcg for services on and after January 1, 2025.[1]

Healthcare Common Procedure Coding System (HCPCS) Code **J2802, injection, romiplostim, 1 mcg** must be used for Nplate® for dates of service on and after January 1, 2025, per the Centers for Medicare & Medicaid Services (CMS).

- IMPORTANT: Ensure when billing service units, shift to using multiples of **1 unit = 1 mcg**.

SERVICE DATES	J-CODE & DOSE DESCRIPTOR	SERVICE / BILLING UNITS	BILLING EXAMPLE
New Coding Effective 1/1/2025	**J2802 Injection, romiplostim, 1 mcg[1]**	**1 service unit = 1 mcg of Nplate®**	**500 mcg dose = 500 service units billed**
Previous Coding 12/31/2024 or prior	**J2796** Injection, romiplostim, 10 mcg	1 service unit = 10 mcg of Nplate®	500 mcg dose = 50 service units billed

Additional step may be required if using CMS-1500 Form to bill ≥ 1,000 mcg.

Check with the specific payer or your billing software system **if it only allows 3-digits in the Service Units box** on CMS-1500 Form, Box 24 G, and follow guidance below for these instances:

- An entry requiring ≥ 1,000 service units may need to be split into two lines in the billing system or claim form. In Box 24 on CMS-1500 Form:
  - Report 999 units in one row in Box 24 G.
  - Report remaining units on next line in Box 24 G.
  - Check with individual payers to determine if a modifier is needed on the second line for Nplate® service units.

Nplate® NDC and CPT codes have not changed. See next page for current NDC and CPT code information.

INDICATIONS

Nplate® is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Nplate® is indicated for the treatment of thrombocytopenia in 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.

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 increase the risk for bleeding. Nplate® should not be used in an attempt to normalize platelet counts.

Please see additional Important Safety Information on the following pages.

IMPORTANT SAFETY INFORMATION

Risk of Progression of Myelodysplastic Syndromes to Acute Myelogenous Leukemia

- In Nplate® (romiplostim) clinical trials of patients with myelodysplastic syndromes (MDS) and severe thrombocytopenia, progression from MDS to acute myelogenous leukemia (AML) has been observed.
- Nplate® is not indicated for the treatment of thrombocytopenia due to MDS or any cause of thrombocytopenia other than ITP.

Nplate® romiplostim injection

Reminder: No change to Nplate® NDC numbers and CPT code

Nplate® NDC[2] numbers per vial size:
- 125-mcg vial: 55513-0223-01
- 250-mcg vial: 55513-0221-01
- 500-mcg vial: 55513-0222-01

CPT[3] Code:
96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

Contact Amgen SupportPlus at (866)264-2778, Monday - Friday 9:00 am - 8:00 pm EST to learn how Amgen can help. Or visit AmgenSupportPlus.com.

AMGEN Support+

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Thrombotic/Thromboembolic Complications

- Thrombotic/thromboembolic complications may result from increases in platelet counts with Nplate® use. Portal vein thrombosis has been reported in patients with chronic liver disease receiving Nplate®.
- To minimize the risk for thrombotic/thromboembolic complications, do not use Nplate® in an attempt to normalize platelet counts. Follow the dose adjustment guidelines to achieve and maintain a platelet count of ≥ 50 x 10^9/L.

Loss of Response to Nplate®

- Hyporesponsiveness or failure to maintain a platelet response with Nplate® should prompt a search for causative factors, including neutralizing antibodies to Nplate®.
- To detect antibody formation, submit blood samples to Amgen (1-800-772-6436). Amgen will assay these samples for antibodies to Nplate® and thrombopoietin (TPO).
- Discontinue Nplate® if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks at the highest weekly dose of 10 mcg/kg.

Adverse Reactions

Adult ITP

- In the placebo-controlled trials of adult ITP patients, headache was the most commonly reported adverse drug reaction, occurring in 35% of patients receiving Nplate® and 32% of patients receiving placebo. Adverse drug reactions in adults with a ≥ 5% higher patient incidence in Nplate® versus placebo were Arthralgia (26%, 20%), Dizziness (17%, 0%), Insomnia (16%, 7%), Myalgia (14%, 2%), Pain in Extremity (13%, 5%), Abdominal Pain (11%, 0%), Shoulder Pain (8%, 0%), Dyspepsia (7%, 0%), and Paresthesia (6%, 0%).
- The safety profile of Nplate® was similar across patients, regardless of ITP duration. The following adverse reactions (at least 5% incidence and at least 5% more frequent with Nplate® compared with placebo or standard of care) occurred in Nplate® patients with ITP duration up to 12 months: bronchitis, sinusitis, vomiting, arthralgia, myalgia, headache, dizziness, diarrhea, upper respiratory tract infection, cough, nausea and oropharyngeal pain. The adverse reaction of thrombocytosis occurred with an incidence of 2% in adults with ITP duration up to 12 months.

Pediatric ITP

- The most common adverse reactions experienced by ≥ 5% of patients receiving Nplate® with ≥ 5% higher incidence in the Nplate® arm across the two placebo-controlled trials were contusion (41%), upper respiratory tract infection (31%), oropharyngeal pain (25%), pyrexia (24%), diarrhea (20%), rash (15%), and upper abdominal pain (14%).
- In pediatric patients of age ≥ 1 year receiving Nplate® for ITP, adverse reactions with an incidence of ≥ 25% in the two randomized trials were: contusion (41%), upper respiratory tract infection (31%), and oropharyngeal pain (25%).
- In a long term, single arm, open label pediatric safety study, headache occurred in 78/203 patients (38%); the incidence rates of other adverse reactions were similar to those reported in the placebo-controlled studies.

Nplate® administration may increase the risk for development or progression of reticulin fiber formation within the bone marrow. This formation may improve upon discontinuation of Nplate®. In a clinical trial, one patient with ITP and hemolytic anemia developed marrow fibrosis with collagen during Nplate® therapy.

Please click here for full Nplate® Prescribing Information, including Medication Guide.

References:

1. Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations Third Quarter, 2024 HCPCS Coding Cycle. https://www.cms.gov/files/document/2024-hcpcs-application-summary-quarter-3-2024-drugs-and-biologicals.pdf. Accessed November 1, 2024. **2.** Nplate® (romiplostim) prescribing information, Amgen. **3.** American Medical Association. Current Procedural Terminology (CPT®) 2021 Professional Edition. American Medical Association. 2020.

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Nplate® romiplostim injection