

Nplate[®] Hospital Billing and Coding Information

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.



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.

Item	Revenue Code ^{1,2}	Coding Information (HCPCS ³ /CPT ⁴ /ICD-10-CM ⁵)	Notes
Nplate®	<p>Medicare: 0636, drugs requiring detailed coding⁶</p> <p>Other Payers: 0250, general pharmacy; OR 0636, if required by a given payer⁶</p>	<p>J2802, injection, romiplostim, 1 mcg</p> <p>JW/JZ Modifiers: Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.⁷</p> <p>JG/TB Modifiers: Beginning January 1, 2023, Medicare requires that all claims submitted by 340B covered entities on OPPS claims (bill type 13X) for separately payable Part B drugs and biologicals must include modifiers “JG” (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) or “TB” (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities) on claim lines for drugs acquired through the 340B Drug Discount Program. While covered entities may use “JG” or “TB” modifier for claims with dates of service through December 31, 2024, beginning January 1, 2025, all covered entities must transition to the “TB” modifier.⁸</p>	<p>Effective Jan 1, 2025, the HCPCS has changed from J2796 to J2802, injection, romiplostim, 1 mcg.</p> <p>Nplate® is supplied in single-use vials containing 125 mcg, 250 mcg and 500 mcg deliverable romiplostim</p> <p>The NDC numbers for Nplate®, in the 11-digit format, are as follows:</p> <ul style="list-style-type: none"> - 125 mcg vial: 55513-0223-01 - 250-mcg vial: 55513-0221-01 - 500-mcg vial: 55513-0222-01 <p>Healthcare providers should ensure Billing Service Units (Box 46) are appropriately billed in multiples of 1 unit = 1 mcg.</p>
Administration	Appropriate revenue code for the cost center in which the service is performed	96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	
Diagnosis/Condition	N/A	Appropriate ICD-10-CM code(s) for patient condition	Example: D69.3 Immune thrombocytopenic purpura

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.

Please see additional Important Safety Information on page 4.

The CMS 1450 for Hospital Outpatient

Sample UB-04 (CMS 1450) Form — Hospital Outpatient Administration

1 Anytown Hospital 100 Main Street Anytown, Anystate 01010		2	3a PAT. CNTL. #	4 TYPE OF BILL
8 PATIENT NAME Smith, Jane		9 PATIENT ADDRESS 123 Main Street, Anytown, Anystate 12345		5 FED. TAX NO.
10 BIRTHDATE	11 SEX	12 DATE	13 HR	14 TYPE
31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE
34 OCCURRENCE DATE		35 OCCURRENCE DATE		36 OCCURRENCE DATE
37 OCCURRENCE DATE		38 OCCURRENCE DATE		39 OCCURRENCE DATE
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE
0636	Drugs/detailed coding	J2802-XX	MDDYY	45 SERV. DATE
0510	Clinic	96372	MDDYY	46 SERV. UNITS
47 TOTAL CHARGES		48 NON-COVERED CHARGES		49
XXXXX		XXXXX		
XXXXX		XXXXX		
PAGE OF		CREATION DATE		TOTALS
50 PAYER NAME		51 HEALTH PLAN ID	52 REL. INFO	53 ASG. BEN.
54 PRIOR PAYMENTS		55 EST. AMOUNT DUE	56 NPI	57 OTHER PRV ID
58		59 P. REL.	60 INSURED'S UNIQUE ID	61 GROUP NAME
62 INSURANCE GROUP NO.		63		64 DOCUMENT CONTROL NUMBER
65 EMPLOYER NAME		66		67
68		69		70
71		72		73
74		75		76
77		78		79
80		81		82
83		84		85
86		87		88
89		90		91
92		93		94
95		96		97
98		99		100

SERVICE UNITS (BOX 46)
Report units of service.
1 unit for J2802 corresponds to 1 mcg of Nplate®.
(i.e., 500 service units = 500 mcg).
Nplate® dose is 1-10 mcg/kg for ITP

TOTAL CHARGES (BOX 47)
Report appropriate charges for product used and related procedures.

REVENUE CODES (BOX 42) AND DESCRIPTIONS (BOX 43)
Product
Medicare: Use revenue code 0636, drugs requiring detailed coding.
Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer).
Related administration procedure
Use most appropriate revenue code for cost center where services were performed (eg, 0510, clinic).

PRODUCT AND PROCEDURE CODES (BOX 44)
Product
Use J2802, injection, romiplostim, 1 mcg.
JW (discarded units) or JZ (no discarded units) modifier required following HCPCS code with a hyphen (i.e., J3111-JZ) for Medicare Part B claims for drugs in single-use containers.
Related administration procedure
Use CPT code representing procedure performed, such as 96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug), subcutaneous or intramuscular.

DIAGNOSIS CODES (BOX 67)
Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis, eg, D69.3, immune thrombocytopenic purpura.

NOTE: Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.



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.

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 $\geq 50 \times 10^9/L$.

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 $\geq 5\%$ 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 $\geq 5\%$ of patients receiving Nplate® with $\geq 5\%$ 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 $\geq 25\%$ 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. Noridian Healthcare Solutions. Revenue Codes. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes>. Accessed October 04, 2024. 2. 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. 3. CMS. January 2021 Alpha-Numeric HCPCS File. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>. Accessed October 04, 2024. 4. American Medical Association (AMA). CPT 2021 Professional Edition. AMA; 2020. 5. CMS. ICD-10-CM Tabular list 2021. <https://www.cms.gov/medicare/icd-10/2021-icd-10-cm>. Accessed October 04, 2024. 6. CMS. CMS Manual System. Pub 100-04. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3728CP.pdf>. Accessed October 04, 2024. 7. CMS. Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy, available at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf>. Accessed October 04, 2024. 8. CMS. Revised Part B Inflation Rebate Guidance: Use of the 340B Modifier, December 14, 2023; available at <https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf>. Accessed October 18, 2024.

The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this section be considered a guarantee of coverage or reimbursement for any product or service.