

Nplate[®] Hospital Billing and Coding 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.

Item	Revenue Code ^{1,2}	Coding Information (HCPCS ³ /CPT ⁴ /ICD-10-CM ⁵)	Notes
Nplate®	Medicare: 0636, drugs requiring detailed coding ⁶	J2796, injection, romiplostim, 10 mcg	Nplate® is supplied in single-use vials containing 125 mcg, 250 mcg and 500 mcg deliverable romiplostim The NDC numbers for Nplate®, in the 11-digit format, are as follows: - 125 mcg vial: 55513-0223-01 - 250-mcg vial: 55513-0221-01 - 500-mcg vial: 55513-0222-01
	Other Payers: 0250, general pharmacy; OR 0636, if required by a given payer ⁶		
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

1. Noridian Healthcare Solutions. Revenue Codes. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes>. Accessed March 4, 2021.

2. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual - Chapter 25. Completing and Processing the Form CMS-1450 Data Set. www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf. Accessed March 2, 2021.

3. CMS. January 2021 Alpha-Numeric HCPCS File. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>. Accessed March 2, 2021.

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 March 2, 2021.

6. CMS. CMS Manual System. Pub 100-04. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3728CP.pdf>. Accessed March 2, 2021.

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.

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.

Contact Amgen Assist 360™ at 1-888-4ASSIST for assistance.
www.AmgenAssist360.com

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
15 SRC	16 DHR	17 STAT	18	19
20	21	22	23	24
25	26	27	28	29 ACCT STATE
30	31 OCCURRENCE DATE	32 OCCURRENCE DATE	33 OCCURRENCE DATE	34 OCCURRENCE DATE
35 OCCURRENCE DATE	36 OCCURRENCE DATE	37	38	39 VALUE CODES AMOUNT
40	41	42	43	44
45	46	47	48	49
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
60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.	63	64
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

SERVICE UNITS (BOX 46)
Report units of service.
1 unit for J2796 corresponds to 10 mcg of Nplate.

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 J2796, injection, romiplostim, 10 mcg.
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.

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

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- 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.