

Nplate[®] Physician Billing and Coding Information

Nplate® is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in patients with chronic immune thrombocytopenia (ITP) 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 chronic 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	Coding Information (HCPCS/CPT/ICD-10-CM ³)	Notes
Nplate®	J2796, injection, romiplostim, 10 mcg	Nplate® is supplied in single-use vials containing 250 mcg and 500 mcg deliverable romiplostim The NDC numbers for Nplate®, in the 11-digit format, are as follows: - 250-mcg vial: 55513-0221-01 - 500-mcg vial: 55513-0222-01
Administration	96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	
Office visit	Relevant Evaluation and Management (E&M) code* [†]	See payer guidelines
Diagnosis/Condition	Appropriate ICD-10-CM code(s) for patient condition	Example: D69.3 Immune thrombocytopenic purpura

* Bill relevant E&M code only if a separately identifiable E&M service is performed. Document accordingly.

† Some payers, including Medicare, will not allow a Level 1 office visit to be billed with an injection/infusion code for the same date of service, and only allow for other levels when Modifier 25 is billed.

1. Centers for Medicare & Medicaid Services. 2015 Alpha-Numeric HCPCS File. Available at: <http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2015-Alpha-Numeric-HCPCS-File-%2%A0.html>. Accessed November 6, 2017.

2. American Medical Association. Current Procedural Terminology (CPT®) copyright 2014 American Medical Association. 2015. All Rights Reserved.

3. Centers for Medicare & Medicaid Services. 2018 ICD-10-CM Tabular List of Diseases and Injuries. Available at: <https://www.cdc.gov/nchs/icd/icd10cm.htm#icd2018>. Accessed November 6, 2017.

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® 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 chronic ITP.

Contact Amgen Assist® at 1-888-4ASSIST for assistance.
www.AmgenAssistOnline.com

Please see additional Important Safety Information on page 4.



The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration

HEALTH INSURANCE CLAIM FORM									
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12									
PICA <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>									
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA (BLK/LUNG) <input type="checkbox"/> OTHER <input type="checkbox"/>					1a. INSURED'S I.D. NUMBER (For Program in Item 1)				
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Doe, John D			3. PATIENT'S BIRTH DATE XX XX XX M <input type="checkbox"/> F <input type="checkbox"/>		4. INSURED'S NAME (Last Name, First Name, Middle Initial) Doe, John D				
5. PATIENT'S ADDRESS (No., Street) 5555 Any Street			6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>		7. INSURED'S ADDRESS (No., Street)				
CITY Anytown		STATE AS			CITY		STATE		
ZIP CODE 01010		TELEPHONE (Include Area Code) (xxx) xxx-xxxx			ZIP CODE		TELEPHONE (Include Area Code) ()		
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)			10. IS PATIENT'S CONDITION RELATED TO:		11. INSURED'S POLICY GROUP OR FECA NUMBER				
a. OTHER INSURED'S POLICY OR GROUP NUMBER			a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> NO		a. INSURED'S DATE OF BIRTH MM DD YY M <input type="checkbox"/> F <input type="checkbox"/>				
b. RESERVED FOR NUCC USE			b. AUTO ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO PLACE (State)		b. OTHER CLAIM ID (Designated by NUCC)				
c. RESERVED FOR NUCC USE			c. OTHER ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO		c. INSURANCE PLAN NAME OR PROGRAM NAME				
d. INSURANCE PLAN NAME OR PROGRAM NAME			10d. CLAIM CODES (Designated by NUCC)		d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>If yes, complete items 9, 9a, and 9d.</i>				
<p>PRODUCT CODE (BOX 24D) Document use of product with J2796, injection, romiplostim, 10 mcg.</p> <p>DIAGNOSIS CODE (BOX 21) Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis. Line A — primary diagnosis code. Example diagnosis code includes: D69.3, immune thrombocytopenic purpura.</p> <p>DIAGNOSIS CODE (BOX 24E) Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.</p> <p>SERVICE UNITS (BOX 24G) Report unit of service. 1 unit for J2796 corresponds to 10 mcg of Nplate®.</p> <p>PROCEDURE CODE (BOX 24D) Document product administration with appropriate CPT code. Use CPT code representing procedure performed, such as 96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular.</p>									
12. SIGNATURE OF PATIENT OR AUTHORIZED PERSON									
13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.									
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL									
15. OTHER DATE MM DD YY QUAL									
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE									
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)									
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)									
A. D69.3									
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY									
B. PLACE OF SERVICE									
C. EMG									
D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER									
E. DIAGNOSIS POINTER									
F. \$ CHARGES									
G. DAYS OR UNITS									
H. EPSON Family Plan									
I. ID, QUAL									
J. RENDERING PROVIDER ID #									
1. XX XX XX XX XX XX 11 J2796 A XXX XX X									
2. XX XX XX XX XX XX 11 96372 XXX XX									
3. NPI									
4. NPI									
5. NPI									
6. NPI									
25. FEDERAL TAX I.D. NUMBER									
28. TOTAL CHARGE \$									
29. AMOUNT PAID \$									
30. Rsvd for NUCC Use									
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)									
32. SERVICE FACILITY LOCATION INFORMATION									
33. BILLING PROVIDER INFO & PH # ()									
SIGNED DATE									
NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)									

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.

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

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.

Laboratory Monitoring

- Obtain CBCs, including platelet counts, weekly during the dose adjustment phase of Nplate® therapy and then monthly following establishment of a stable Nplate® dose.
- Obtain CBCs, including platelet counts, weekly for at least two weeks following discontinuation of Nplate®.

Adverse Reactions

- In the placebo-controlled trials, headache was the most commonly reported adverse drug reaction, occurring in 35% of patients receiving Nplate® and 32% of patients receiving placebo. Headaches were usually of mild or moderate severity.
- Most common adverse reactions ($\geq 5\%$ 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%).
- 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.

Women who become pregnant during Nplate treatment are encouraged to enroll in Amgen's Pregnancy Surveillance Program. Patients or their physicians should call 1-800-77-AMGEN (1-800-772-6436) to enroll.

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