

Nplate[®]

Physician 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	Coding Information (HCPCS ¹ /CPT ² /ICD-10-CM ³)	Notes
Nplate®	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
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: www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2015-Alpha-Numeric-HCPCS-File-%C2%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: 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® (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 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration

HEALTH INSURANCE CLAIM FORM										CARRIER	
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12										PICA	
<div> <input type="checkbox"/> MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA <input type="checkbox"/> BLK LUNG <input type="checkbox"/> OTHER </div>										PICA	
1. PATIENT'S NAME (Last Name, First Name, Middle Initial)			3. PATIENT'S BIRTH DATE		SEX		4. INSURED'S NAME (Last Name, First Name, Middle Initial)			1a. INSURED'S I.D. NUMBER (For Program in Item 1)	
Doe, John D			XX XX XX		M		Doe, John D				
5. PATIENT'S ADDRESS (No., Street)			6. PATIENT RELATIONSHIP TO INSURED		7. INSURED'S ADDRESS (No., Street)						
5555 Any Street			Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>								
CITY		STATE		8. RESERVED FOR NUCC USE		CITY		STATE			
Anytown		AS									
ZIP CODE		TELEPHONE (Include Area Code)		10. IS PATIENT'S CONDITION RELATED TO:		11. INSURED'S POLICY GROUP OR FECA NUMBER					
01010		(xxx) xxx-xxxx									
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)			a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous)		a. INSURED'S DATE OF BIRTH		SEX		
					<input type="checkbox"/> YES <input type="checkbox"/> NO		MM DD YY		M <input type="checkbox"/> F <input type="checkbox"/>		
			b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT?		b. OTHER CLAIM ID (Designated by NUCC)				
					<input type="checkbox"/> YES <input type="checkbox"/> NO						
			c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT?		c. INSURANCE PLAN NAME OR PROGRAM NAME				
					<input type="checkbox"/> YES <input type="checkbox"/> NO						
d. INSURANCE PLAN NAME OR PROGRAM NAME			10d. CLAIM CODES (Designated by NUCC)		d. IS THERE ANOTHER HEALTH BENEFIT PLAN?		d. IS THERE ANOTHER HEALTH BENEFIT PLAN?				
					<input type="checkbox"/> YES <input type="checkbox"/> NO		If yes, complete items 9, 9a, and 9d.				
12. PRODUCT CODE (BOX 24D)			13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE			13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE			13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE		
Document use of product with J2796, injection, romiplostim, 10 mcg.			I authorize the release of any medical or other information necessary to complete this form.			I authorize the release of any medical or other information necessary to complete this form.			I authorize the release of any medical or other information necessary to complete this form.		
SIGNED			DATE			SIGNED			DATE		
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP)			15. OTHER DATE			16. OCCUPATION			16. SERVICES		
XX XX XX			QUAL			DD YY			DD YY		
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE			17a. NPI			17b. NPI					
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)											
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)			ICD-10								
A. D69.3											
E.											
F.											
G.											
H.											
I.											
J.											
K.											
L.											
24. A. DATE(S) OF SERVICE			B. PLACE OF SERVICE			C. EMG			D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)		
MM DD YY			MM DD YY						CPT/HCPCS MODIFIER		
1 XX XX XX XX XX XX 11									J2796		
2 XX XX XX XX XX XX 11									96372		
3											
4											
5											
6											
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			a. NPI			b. NPI		
						a. NPI			b. NPI		

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.

Please see Important Safety Information on page 4.



Risk of Progression of Myelodysplastic Syndromes to Acute Myelogenous Leukemia

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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.

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%).

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.