Nplate®
Physician Billing and Coding Information

Nplate® romiplostim injection

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. CMS. January 2021 Alpha-Numeric HCPCS File. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. Accessed March 2, 2021.
2. American Medical Association (AMA). *CPT 2021 Professional Edition*. AMA; 2020.
3. CMS. ICD-10-CM Tabular list 2021. https://www.cms.gov/medicare/icd-10/2021-icd-10-cm. 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.

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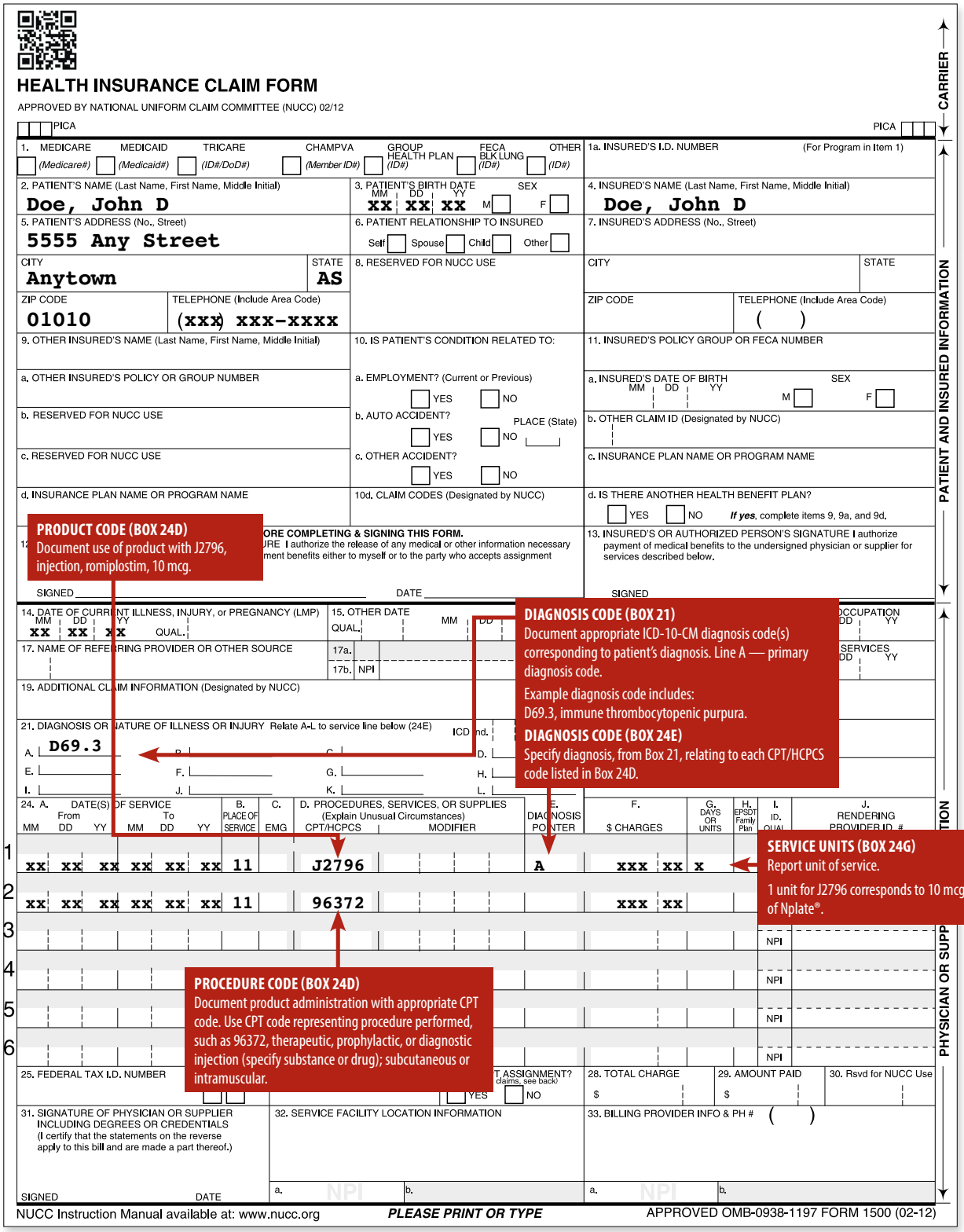
The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

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 MM DD YY: xx xx xx SEX M F

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 Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY: Anytown STATE: AS

8. RESERVED FOR NUCC USE

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) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES 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? YES NO *If yes*, complete items 9, 9a, and 9d.

12. ...ORE COMPLETING & SIGNING THIS FORM. ...URE I authorize the release of any medical or other information necessary ...ment benefits either to myself or to the party who accepts assignment

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY: xx xx xx QUAL.

15. OTHER DATE QUAL. MM DD

...OCCUPATION MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

...SERVICES MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

21. DIAGNOSIS OR ...NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD ...nd.

A. D69.3 B. C. D. E. F. G. H. I. J. K. L.

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. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. #

1	xx	xx	xx	xx	xx	xx	11		J2796		A	xxx	xx	x	NPI
2	xx	xx	xx	xx	xx	xx	11		96372			xxx	xx		NPI
3															NPI
4															NPI
5															NPI
6															NPI

25. FEDERAL TAX I.D. NUMBER ...T ASSIGNMENT? claims, see back) YES NO

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.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPP...TION

NUCC Instruction Manual available at: www.nucc.org **PLEASE PRINT OR TYPE** APPROVED OMB-0938-1197 FORM 1500 (02-12)

PRODUCT CODE (BOX 24D)
Document use of product with J2796, injection, romiplostim, 10 mcg.

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.

DIAGNOSIS CODE (BOX 24E)
Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

SERVICE UNITS (BOX 24G)
Report unit of service.

1 unit for J2796 corresponds to 10 mcg of Nplate®.

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.

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.

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.

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