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.

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	Revenue Code[1,2]	Coding Information (HCPCS[3]/CPT[4]/ICD-10-CM[5])	Notes
Nplate®	**Medicare:** 0636, drugs requiring detailed coding[6] **Other Payers:** 0250, general pharmacy; **OR** 0636, if required by a given payer[6]	**J2802,** injection, romiplostim, 1 mcg **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] **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]	**Effective Jan 1, 2025, the HCPCS has changed from J2796 to J2802, injection, romiplostim, 1 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 **Healthcare providers should ensure Billing Service Units (Box 46) are appropriately billed in multiples of 1 unit = 1 mcg.**
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

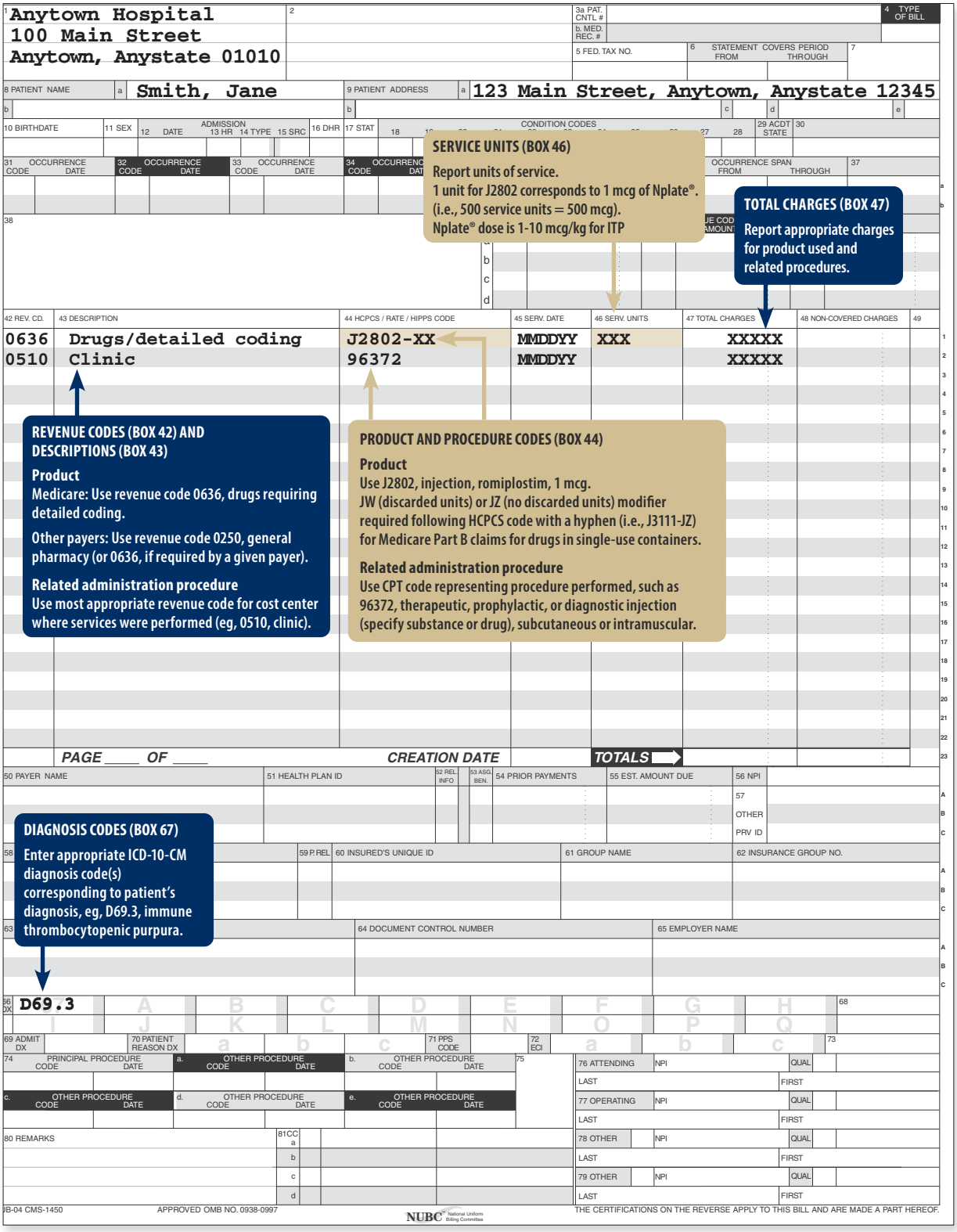
Risk of Progression of Myelodysplastic Syndromes to Acute Myelogenous Leukemia

- 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



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.

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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.

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.

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