Neulasta® Onpro® kit (pegfilgrastim) injection

Neulasta® (pegfilgrastim) injection

NEUPOGEN® (FILGRASTIM) INJECTION

HOSPITAL OUTPATIENT CODING AND BILLING INFORMATION SHEET FOR NEULASTA® ONPRO®, NEULASTA®, AND NEUPOGEN®

Contact Amgen® SupportPlus for reimbursement and access resources at (866) 264-2778 or www.amgensupportplus.com

NEULASTA® ONPRO® KIT

NEULASTA® PREFILLED SYRINGE

NEUPOGEN®

Neulasta® (pegfilgrastim) is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.[1]

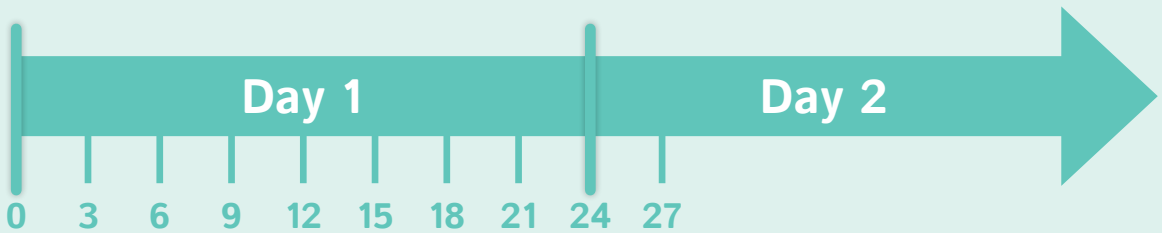
Neulasta® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.[1]

Neulasta® Onpro® kit, which includes:
the same Neulasta® as in the Prefilled Syringe with a different delivery option[1]



- Must be prepared and applied by a healthcare provider on the same day as chemotherapy[1]
- The prefilled syringe co-packaged in the Neulasta® Onpro® kit must only be used with the On-body Injector for Neulasta®
- Designed to deliver a full dose of Neulasta® approximately 27 hours after its activation[1]
  - As per the label, a healthcare provider may initiate administration with the On-body Injector for Neulasta® (also referred to as the "On-body Injector") on the same day as the administration of cytotoxic chemotherapy, and the On-body Injector is designed to deliver pegfilgrastim approximately 27 hours after application[1]

Apply today, deliver* Neulasta® tomorrow[1]



- Healthcare provider activates and applies the On-body Injector to the patient
- Three minutes after activation, the needle inserts the cannula subcutaneously[2]

- Approximately 27 hours after the On-body Injector is activated and applied to the patient, Neulasta® will be delivered subcutaneously over approximately 45 minutes

*The On-body Injector for Neulasta® is designed to deliver Neulasta® approximately 27 hours after activation.

Important Safety Information

Contraindication

- Neulasta® or NEUPOGEN® are contraindicated in patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors (G-CSFs), such as pegfilgrastim or filgrastim

Please see additional Important Safety Information on pages 11-12.

Neulasta® Onpro® kit
(pegfilgrastim) injection

Neulasta® delivered via the On-body Injector vs Neulasta® delivered via the manual use Neulasta® Prefilled Syringe

SELECT ATTRIBUTES	SAME	DIFFERENT
Active Ingredient[1]	✓	
Indication[1]	✓	
Route of Administration[1]	✓	
Deliverable Dose[1]	✓	
WAC[3,4]	✓	
J-code[5,*]	✓	
How Delivered and CPT Code[1,6,*]		✓
NDC Number[1,*]		✓

*See next page for coding and billing information sheet for Neulasta®.
NDC = National Drug Code; WAC = wholesale acquisition cost.

On-body Injector for Neulasta®

A missed dose could occur due to an On-body Injector for Neulasta® failure or leakage. If the patient misses a dose, a new dose should be administered by prefilled syringe for manual use, as soon as possible after detection.

The On-body Injector is backed by 24/7 telephone support and a full return policy.

Call **1-844-MYNEULASTA** at any time for assistance or answers to product-related questions.

Important Safety Information

Splenic Rupture

- Splenic rupture, including fatal cases, can occur following the administration of Neulasta® and NEUPOGEN®
- Evaluate for an enlarged or ruptured spleen in patients who report left upper abdominal or shoulder pain

Please see additional Important Safety Information on pages 11-12.

Neulasta® Onpro® kit (pegfilgrastim) injection

Hospital Outpatient – Billing Information Sheet for the Neulasta® Onpro® kit

Item	Revenue Code[7,8]	Coding Information (HCPCS[5]/CPT[6]/ICD-10-CM)	Notes
Neulasta® Onpro® kit	**Medicare:** 0636, drugs requiring detailed coding[9] **Other Payers:** 0250, general pharmacy; **OR** 0636, if required by a given payer[9]	**J2506**, injection, pegfilgrastim, excludes biosimilar, 0.5 mg	Neulasta® is supplied as a 6 mg deliverable dose.[1] **Effective Jan 1, 2022, the HCPCS has changed from J2505 to J2506, injection, pegfilgrastim, excludes biosimilar, 0.5 mg.** 55513-0192-01 is the NDC number (in the 11-digit format) for Neulasta® Onpro® kit.[1] **Healthcare providers should ensure Service Units (Box 46) are appropriately billed.**
Administration of the On-body Injector	Appropriate revenue code for the cost center in which the service is performed	96377, application of on-body injector (includes cannula insertion) for timed subcutaneous injection	Healthcare providers can initiate administration with the On-body Injector on the same day as the administration of chemotherapy.[1,*] See payer guidelines for specific coding requirements.
Diagnosis/ Condition	N/A	Appropriate ICD-10-CM diagnosis code(s) for patient condition.	Allowable diagnosis codes may vary by payer.

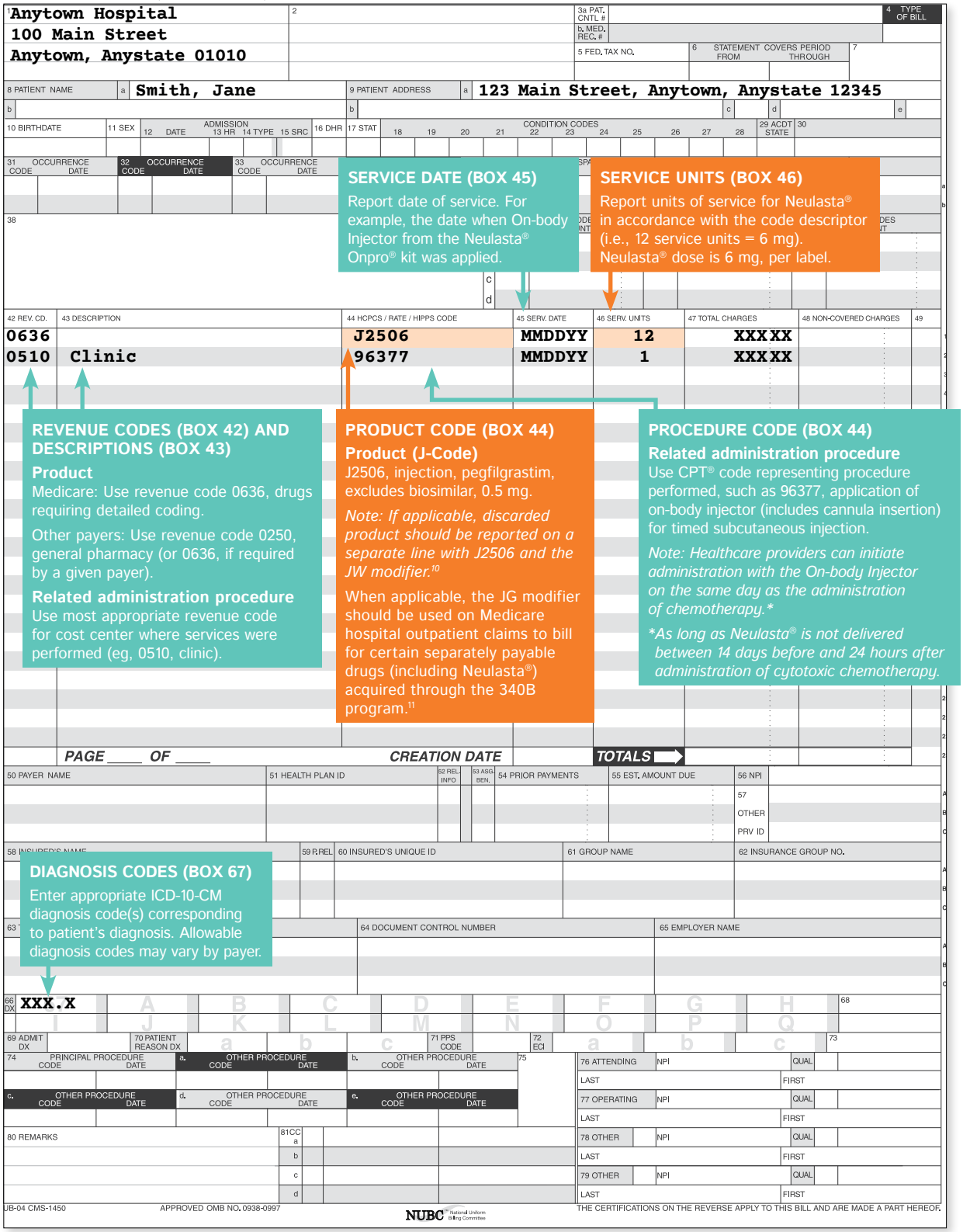
*As long as Neulasta® is not delivered between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
CPT = Current Procedural Terminology; HCPCS = Healthcare Common Procedure Coding System; ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification.
The information provided in this Coding and Billing Information document is of a general nature and for informational purposes only and is not intended to be a comprehensive list nor instructive. Coding and coverage policies change periodically and often without warning. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient and/or procedure, is always the responsibility of the provider or physician. The information provided in this section should in no way be considered a guarantee of coverage or reimbursement for any product or service.

Contact Amgen® SupportPlus for reimbursement and access resources at (866) 264-2778 or www.amgensupportplus.com

Neulasta® (pegfilgrastim) injection Onpro® kit

The CMS 1450 for Hospital Outpatient – the Neulasta® Onpro® kit

Sample UB-04 (CMS 1450) Form – Hospital Outpatient Administration



SERVICE DATE (BOX 45)
Report date of service. For example, the date when On-body Injector from the Neulasta® Onpro® kit was applied.

SERVICE UNITS (BOX 46)
Report units of service for Neulasta® in accordance with the code descriptor (i.e., 12 service units = 6 mg). Neulasta® dose is 6 mg, per label.

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 CODE (BOX 44)

Product (J-Code)
J2506, injection, pegfilgrastim, excludes biosimilar, 0.5 mg.

Note: If applicable, discarded product should be reported on a separate line with J2506 and the JW modifier.[10]

When applicable, the JG modifier should be used on Medicare hospital outpatient claims to bill for certain separately payable drugs (including Neulasta®) acquired through the 340B program.[11]

PROCEDURE CODE (BOX 44)

Related administration procedure
Use CPT® code representing procedure performed, such as 96377, application of on-body injector (includes cannula insertion) for timed subcutaneous injection.

*Note: Healthcare providers can initiate administration with the On-body Injector on the same day as the administration of chemotherapy.**

**As long as Neulasta® is not delivered between 14 days before and 24 hours after administration of cytotoxic chemotherapy.*

DIAGNOSIS CODES (BOX 67)
Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis. Allowable diagnosis codes may vary by payer.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be a directive, nor does the use of the recommended codes guarantee reimbursement. Physicians and staff may deem other codes or policies more appropriate. Providers should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

Neulasta® (pegfilgrastim) injection Onpro® kit

Hospital Outpatient – Billing Information Sheet for the Neulasta® Prefilled Syringe

Item	Revenue Code[7,8]	Coding Information (HCPCS[5]/CPT[6]/ICD-10-CM)	Notes
Neulasta® Prefilled Syringe for Manual Injection	**Medicare:** 0636, drugs requiring detailed coding[9] **Other Payers:** 0250, general pharmacy; **OR** 0636, if required by a given payer[9]	**J2506**, injection, pegfilgrastim, excludes biosimilar, 0.5 mg	Neulasta® is supplied as a 6 mg deliverable dose.[1] **Effective Jan 1, 2022, the HCPCS has changed from J2505 to J2506, injection, pegfilgrastim, excludes biosimilar, 0.5 mg.** 55513-0190-01 is the NDC number (in the 11-digit format) for the Neulasta® prefilled syringe for manual injection.[1] **Healthcare providers should ensure Service Units (Box 46) are appropriately billed.**
Administration of Neulasta® Prefilled Syringe for Manual Injection	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 diagnosis code(s) for patient condition.	Allowable diagnosis codes may vary by payer.

The information provided in this Coding and Billing Information document is of a general nature and for informational purposes only and is not intended to be a comprehensive list nor instructive. Coding and coverage policies change periodically and often without warning. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient and/or procedure, is always the responsibility of the provider or physician. The information provided in this section should in no way be considered a guarantee of coverage or reimbursement for any product or service.

Important Safety Information

Acute Respiratory Distress Syndrome (ARDS)

- ARDS has occurred in patients receiving Neulasta® and NEUPOGEN®
- Evaluate patients who develop a fever and lung infiltrates or respiratory distress after receiving Neulasta® or NEUPOGEN®
- Discontinue Neulasta® or NEUPOGEN® in patients with ARDS

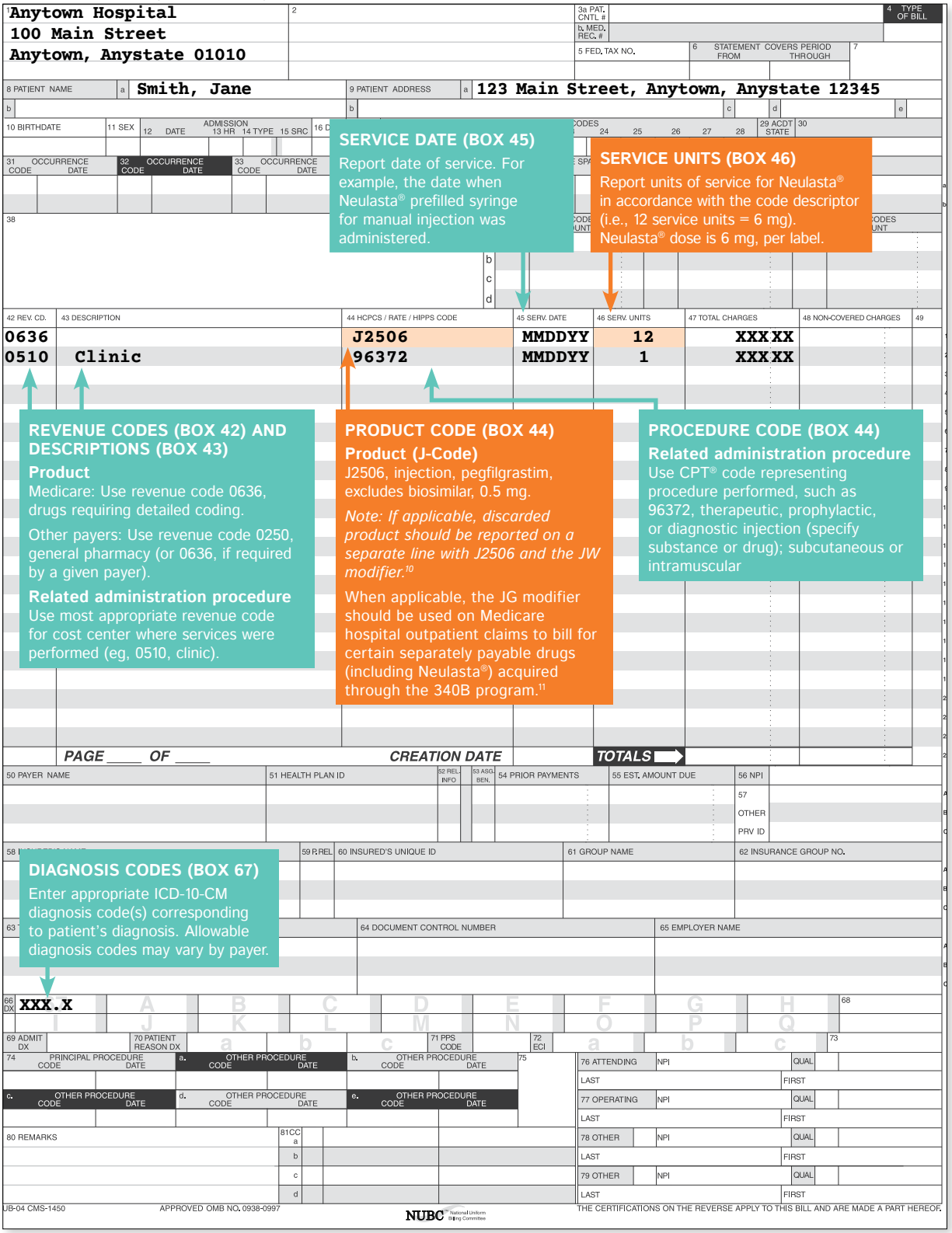
Please see additional Important Safety Information on pages 11-12.

Contact Amgen® SupportPlus for reimbursement and access resources at (866) 264-2778 or www.amgensupportplus.com

Neulasta® (pegfilgrastim) injection

The CMS 1450 for Hospital Outpatient – the Neulasta® Prefilled Syringe

Sample UB-04 (CMS 1450) Form – Hospital Outpatient Administration



SERVICE DATE (BOX 45)
Report date of service. For example, the date when Neulasta® prefilled syringe for manual injection was administered.

SERVICE UNITS (BOX 46)
Report units of service for Neulasta® in accordance with the code descriptor (i.e., 12 service units = 6 mg). Neulasta® dose is 6 mg, per label.

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 CODE (BOX 44)

Product (J-Code)
J2506, injection, pegfilgrastim, excludes biosimilar, 0.5 mg.

Note: If applicable, discarded product should be reported on a separate line with J2506 and the JW modifier.[10]

When applicable, the JG modifier should be used on Medicare hospital outpatient claims to bill for certain separately payable drugs (including Neulasta®) acquired through the 340B program.[11]

PROCEDURE CODE (BOX 44)

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. Allowable diagnosis codes may vary by payer.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be a directive, nor does the use of the recommended codes guarantee reimbursement. Physicians and staff may deem other codes or policies more appropriate. Providers should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

Neulasta® (pegfilgrastim) injection

Hospital Outpatient – Billing Information Sheet for NEUPOGEN®

NEUPOGEN® (filgrastim) is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.[12]

Item	Revenue Code[7,8]	Coding Information (HCPCS[5]/CPT[6]/ICD-10-CM)	Notes
NEUPOGEN®	**Medicare:** 0636, drugs requiring detailed coding[9] **Other Payers:** 0250, general pharmacy; **OR** 0636, if required by a given payer[9]	J1442, injection, filgrastim (G-CSF), 1 mcg	The NDC numbers for NEUPOGEN®, are as follows:[12] **Vials** • Single-dose vials containing 300 mcg/mL of filgrastim: - Carton of 10 vials NDC 55513-530-10 or NDC 55513-530-20. • Single-dose vials containing 480 mcg/1.6 mL (300 mcg/mL) of filgrastim: - Carton of 10 vials NDC 55513-546-10 or NDC 55513-546-20. **Prefilled Syringes** • Single-dose, prefilled syringe containing 300 mcg/0.5 mL of filgrastim: - Carton of 1 prefilled syringe NDC 55513-924-91. - Carton of 10 prefilled syringes NDC 55513-924-10 or NDC 55513-924-20. • Single-dose, prefilled syringe containing 480 mcg/0.8 mL of filgrastim: - Carton of 1 prefilled syringe: NDC 55513-209-91. - Carton of 10 prefilled syringes: NDC 55513-209-10 or NDC 55513-209-20.

Important Safety Information

Serious Allergic Reactions

- Serious allergic reactions, including anaphylaxis can occur in patients receiving Neulasta® and NEUPOGEN®
- Provide symptomatic treatment for allergic reactions
- Majority of events occurred upon initial exposure and can recur within days after discontinuation of initial anti-allergic treatment
- Permanently discontinue Neulasta® or NEUPOGEN® in patients with serious allergic reactions

Please see additional Important Safety Information on pages 11-12.

Contact Amgen® SupportPlus for reimbursement and access resources at (866) 264-2778 or www.amgensupportplus.com

NEUPOGEN® (FILGRASTIM) INJECTION

Hospital Outpatient – Billing Information Sheet for NEUPOGEN® (cont'd)

NEUPOGEN® (filgrastim) is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.[12]

Item	Revenue Code[7,8]	Coding Information (HCPCS[5]/CPT[6]/ICD-10-CM)	Notes
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 diagnosis code(s) for patient condition.	Allowable diagnosis codes may vary by payer.

Important Safety Information

Allergies to Acrylics

- On-body Injector for Neulasta® uses acrylic adhesives
- Patients who are allergic to acrylic adhesives may have a significant reaction

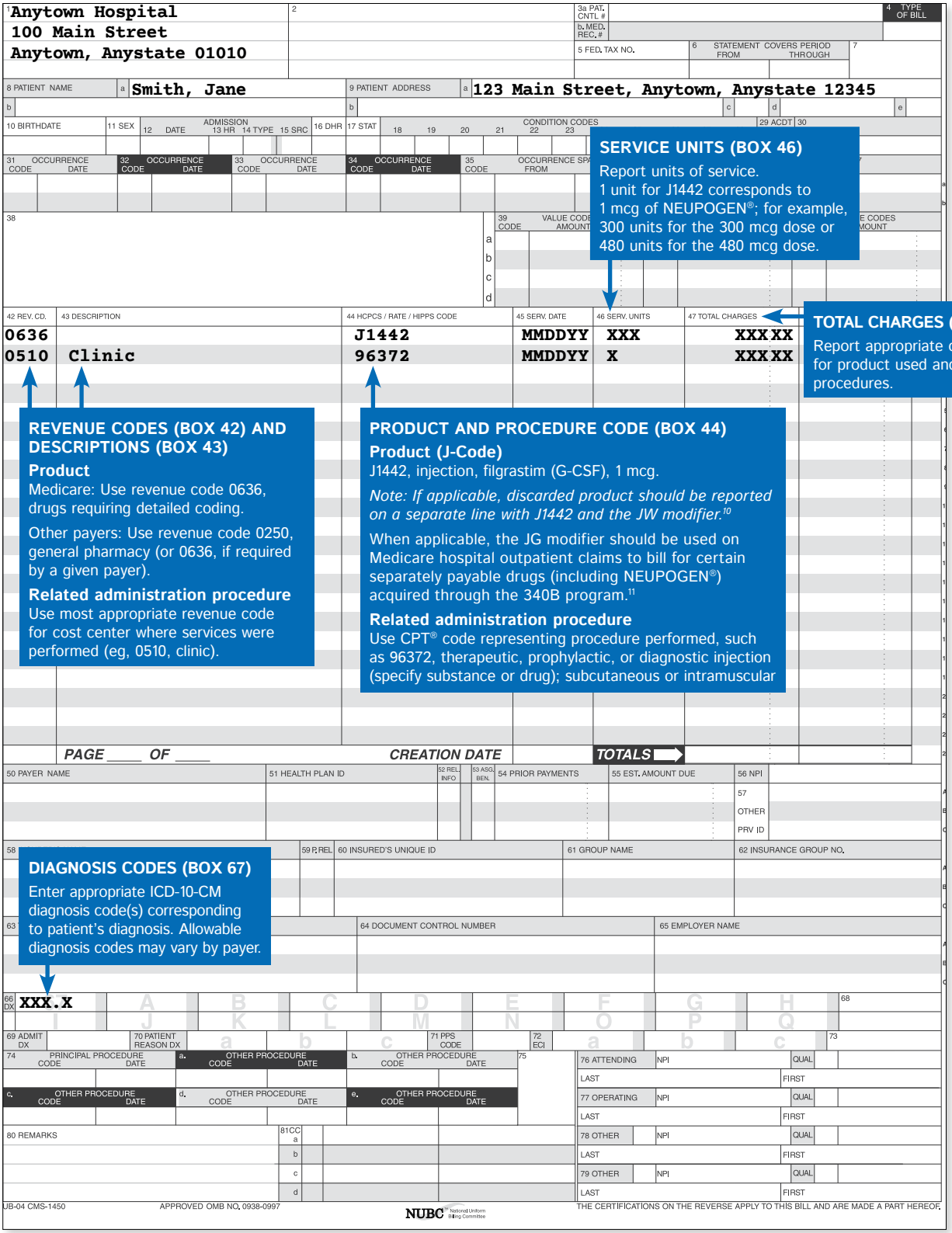
Please see additional Important Safety Information on pages 11-12.

Contact Amgen® SupportPlus for reimbursement and access resources at (866) 264-2778 or www.amgensupportplus.com

NEUPOGEN® (FILGRASTIM) INJECTION

The CMS 1450 for Hospital Outpatient – NEUPOGEN®

Sample UB-04 (CMS 1450) Form – Hospital Outpatient Administration



SERVICE UNITS (BOX 46)
Report units of service.
1 unit for J1442 corresponds to 1 mcg of NEUPOGEN®; for example, 300 units for the 300 mcg dose or 480 units for the 480 mcg dose.

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 CODE (BOX 44)

Product (J-Code)
J1442, injection, filgrastim (G-CSF), 1 mcg.

Note: If applicable, discarded product should be reported on a separate line with J1442 and the JW modifier.[10]

When applicable, the JG modifier should be used on Medicare hospital outpatient claims to bill for certain separately payable drugs (including NEUPOGEN®) acquired through the 340B program.[11]

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. Allowable diagnosis codes may vary by payer.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be a directive, nor does the use of the recommended codes guarantee reimbursement. Physicians and staff may deem other codes or policies more appropriate. Providers should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

NEUPOGEN® (FILGRASTIM) INJECTION

Special Instructions for the On-body Injector (OBI) for Neulasta®

A healthcare provider must fill the on-body injector (OBI) with Neulasta® using the co-packaged prefilled syringe and then apply the OBI to the patient's skin (abdomen or back of arm). The back of the arm may only be used if there is a caregiver available to monitor the status of the OBI. Approximately 27 hours after the OBI is applied to the patient's skin, Neulasta® will be delivered over approximately 45 minutes. A healthcare provider may initiate administration with the OBI on the same day as the administration of cytotoxic chemotherapy, as long as the OBI delivers Neulasta® no less than 24 hours after the administration of cytotoxic chemotherapy.

The prefilled syringe co-packaged in the Neulasta® Onpro® kit contains additional solution to compensate for liquid loss during delivery through the OBI. If this syringe is used for manual subcutaneous injection, the patient will receive an overdose. If the prefilled syringe for manual use is used with the OBI, the patient may receive less than the recommended dose.

Do not use the OBI to deliver any other drug product except the Neulasta® prefilled syringe co-packaged with the OBI. Use of the OBI has not been studied in pediatric patients.

The OBI should be applied to intact, non-irritated skin on the arm or abdomen.

A missed dose could occur due to an OBI failure or leakage. Instruct patients using the OBI to notify their healthcare professional immediately in order to determine the need for a replacement dose of pegfilgrastim if they suspect that the device may not have performed as intended. If the patient misses a dose, a new dose should be administered by prefilled syringe for manual use as soon as possible after detection.

Review the Patient Information and Patient Instructions for Use with the patient and provide the instructions to the patient.

Refer to the Healthcare Provider Instructions for Use for the OBI for full administration information.

For any OBI problems, call Amgen at **1-800-772-6436** or **1-844-MYNEULASTA (1-844-696-3852).**

Indication and Important Safety Information for Neulasta® (pegfilgrastim) and NEUPOGEN® (filgrastim)

Indication

Neulasta® and NEUPOGEN® are indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Neulasta® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Important Safety Information

Contraindication

- Neulasta® or NEUPOGEN® are contraindicated in patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors (G-CSFs), such as pegfilgrastim or filgrastim

Splenic Rupture

- Splenic rupture, including fatal cases, can occur following the administration of Neulasta® and NEUPOGEN®
- Evaluate for an enlarged or ruptured spleen in patients who report left upper abdominal or shoulder pain

Acute Respiratory Distress Syndrome (ARDS)

- ARDS has occurred in patients receiving Neulasta® and NEUPOGEN®
- Evaluate patients who develop a fever and lung infiltrates or respiratory distress after receiving Neulasta® or NEUPOGEN®
- Discontinue Neulasta® or NEUPOGEN® in patients with ARDS

Serious Allergic Reactions

- Serious allergic reactions, including anaphylaxis can occur in patients receiving Neulasta® and NEUPOGEN®
- Provide symptomatic treatment for allergic reactions
- Majority of events occurred upon initial exposure and can recur within days after discontinuation of initial anti-allergic treatment
- Permanently discontinue Neulasta® or NEUPOGEN® in patients with serious allergic reactions

Allergies to Acrylics

- On-body Injector for Neulasta® uses acrylic adhesives
- Patients who are allergic to acrylic adhesives may have a significant reaction

Use in Patients with Sickle Cell Disorders

- In patients with sickle cell trait or disease, sickle cell crisis, in some cases fatal, can occur in patients receiving Neulasta® and NEUPOGEN®. Discontinue if sickle cell crisis occurs.

Glomerulonephritis

- Has occurred in patients receiving NEUPOGEN® and Neulasta®
- Diagnoses based on azotemia, hematuria, proteinuria, and renal biopsy
- Generally, events resolved after dose reduction or discontinuation of NEUPOGEN® and Neulasta®
- If suspected, evaluate for cause and if cause is likely, consider dose-reduction or interruption of Neulasta® or NEUPOGEN®

Capillary Leak Syndrome (CLS)

- CLS has been reported after G-CSF administration, including NEUPOGEN® and Neulasta®
- Characterized by hypotension, hypoalbuminemia, edema, and hemoconcentration
- Episodes vary in frequency, severity, and may be life-threatening if treatment is delayed
- Patients with symptoms should be closely monitored and receive standard symptomatic treatment, which may include intensive care

Thrombocytopenia

- Thrombocytopenia has been reported in patients who received NEUPOGEN® and pegfilgrastim
- Monitor platelet counts

Please see additional Important Safety Information on page 12.

NEUPOGEN® (FILGRASTIM) INJECTION

Leukocytosis

- White blood cell counts of ≥ 100,000/mm^3 have been observed in patients who received NEUPOGEN® and Neulasta®
- Monitor CBCs during Neulasta® therapy and at least twice weekly for NEUPOGEN®
- Adjust NEUPOGEN® dosing as clinically indicated to help mitigate risk of leukocytosis
- Dosages of NEUPOGEN® that increase the absolute neutrophil count (ANC) beyond 10,000/mm^3 may not result in any additional clinical benefit
- Discontinuation of NEUPOGEN® therapy usually resulted in a 50% decrease in circulating neutrophils within 1 to 2 days, with a return to pretreatment levels in 1 to 7 days

Cutaneous Vasculitis

- Moderate or severe cases of cutaneous vasculitis have been reported in patients treated with NEUPOGEN®
- Most reports involved patients with severe chronic neutropenia on long-term NEUPOGEN® therapy
- Hold NEUPOGEN® therapy in patients with cutaneous vasculitis
- NEUPOGEN® dose may be reduced when the symptoms resolve and ANC has decreased

Potential Effect on Malignant Cells

- G-CSF receptor has been found on tumor cell lines
- The possibility that NEUPOGEN® or Neulasta® acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, cannot be excluded

Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML)

Patients with Severe Chronic Neutropenia

- Confirm the diagnosis of SCN before initiating NEUPOGEN® therapy
- MDS and AML have been reported to occur in the natural history of congenital neutropenia without cytokine therapy
- Cytogenetic abnormalities, transformation to MDS, and AML have also been observed in patients treated with NEUPOGEN® for SCN
- Based on available data including a postmarketing surveillance study, the risk of developing MDS and AML appears to be confined to the subset of patients with congenital neutropenia.
- Abnormal cytogenetics and MDS have been associated with the eventual development of myeloid leukemia
- The effect of NEUPOGEN® on the development of abnormal cytogenetics and the effect of continued NEUPOGEN® administration in patients with abnormal cytogenetics or MDS are unknown. Monitor patients for signs and symptoms of MDS/AML in these settings.
- If a patient with SCN develops abnormal cytogenetics or myelodysplasia, the risks and benefits of continuing NEUPOGEN® should be carefully considered

Patients with Breast and Lung Cancer

- MDS and AML have been associated with the use of NEUPOGEN® and Neulasta® in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer. Monitor patients for signs and symptoms of MDS/AML in these settings.

Simultaneous Use with Chemotherapy and Radiation Therapy Not Recommended

- Safety and efficacy of NEUPOGEN® given simultaneously with cytotoxic chemotherapy and radiation have not been established
- Do not use NEUPOGEN® 24 hours before or after cytotoxic chemotherapy
- Avoid simultaneous use of NEUPOGEN® with chemotherapy and radiation

Nuclear Imaging

- Increased hematopoietic activity of the bone marrow has been associated with transient positive bone-imaging changes have been seen in patients taking Neulasta® or NEUPOGEN®.
- Consider when interpreting bone-imaging results

Potential Device Failures

- Missed or partial doses have been reported in patients receiving pegfilgrastim via the on-body injector (OBI) due to the device not performing as intended
- In the event of a missed or partial dose, patients may be at increased risk of events such as neutropenia, febrile neutropenia and/or infection than if the dose had been correctly delivered
- Instruct patients to notify their healthcare professional immediately in order to determine the need for a replacement dose if they suspect that the device may not have performed as intended

Large and Medium Vessel Arteritis

- Serious large and medium vessel arteritis, including aortitis, has been reported in patients receiving NEUPOGEN®. It may occur as early as the first week after start of therapy.
- Manifestations may include generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, headache, neck pain, and increased inflammatory markers (e.g., C-reactive protein and white blood cell count).
- Consider arteritis in patients who develop these signs and symptoms without known etiology. Consider appropriate clinical management and discontinue NEUPOGEN® as needed if arteritis is suspected.
- Serious large and medium vessel arteritis, including aortitis, has been reported in patients receiving Neulasta®. It may occur as early as the first week after start of therapy.
- Manifestations may include generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, headache, neck pain, and increased inflammatory markers (e.g., C-reactive protein and white blood cell count).
- Consider arteritis in patients who develop these signs and symptoms without known etiology. Consider appropriate clinical management and discontinue Neulasta® as needed if arteritis is suspected.

Most common adverse reactions in patients taking NEUPOGEN®

- Anemia, constipation, diarrhea, oral pain, vomiting, asthenia, malaise, peripheral edema, decreased hemoglobin, decreased appetite, oropharyngeal pain, and alopecia

Most common adverse reactions in patients taking Neulasta®

- Bone pain
- Pain in extremity

Dosing Form – Professional:

NEUPOGEN® is administered by subcutaneous injection, short intravenous infusion (15 to 30 minutes), or continuous intravenous infusion.

- Prefilled Syringe: Injection: 300 mcg/0.5 mL in a single-dose prefilled syringe; Injection: 480 mcg/0.8 mL in a single-dose prefilled syringe

Neulasta® is administered by subcutaneous injection.

- Injection: 6 mg/0.6 mL in a single-dose prefilled syringe for manual use only.
- Injection: 6 mg/0.6 mL in a single-dose prefilled syringe co-packaged with the on-body injector (OBI) for Neulasta (Neulasta Onpro kit).

Please see full Prescribing Information for Neulasta® and full Prescribing Information for NEUPOGEN®.

Neulasta® (pegfilgrastim) injection

NEUPOGEN® (FILGRASTIM) INJECTION

AMGEN® Support+

We're right here, right when you need us

Personalized support you and your patients can count on

Amgen® SupportPlus Co-Pay Program

The Amgen SupportPlus Co-Pay Program may help eligible patients with commercial or private insurance lower their out-of-pocket costs*

Encourage your patients with commercial or private insurance to check eligibility and enroll.

*Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full terms and conditions.

Financial Support

Learn more about how Amgen SupportPlus can help your patients access their prescribed medication.

Visit AmgenSupportPlus.com to learn more.

HCP Support Center

Our **Amgen® SupportPlus Representatives** can assist with issues around patient coverage, prior authorizations, co-pay programs, and more.

Benefits Verification

- Verify patient's insurance plan coverage details

Prior Authorization Requirements

- Provide payer-specific prior authorization forms
- Provide information to providers on payer-specific authorization requirements and submission methods

Call Amgen SupportPlus at (866) 264-2778
Monday - Friday 8:30 am - 8:00 pm ET

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