Neulasta® (pegfilgrastim) injection Onpro® kit

Neulasta® (pegfilgrastim) injection

NEUPOGEN® (FILGRASTIM) INJECTION

PHYSICIAN OFFICE CODING AND BILLING INFORMATION SHEET FOR NEULASTA® ONPRO®, NEULASTA®, AND NEUPOGEN®

Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4ASSIST or www.AmgenAssist360.com

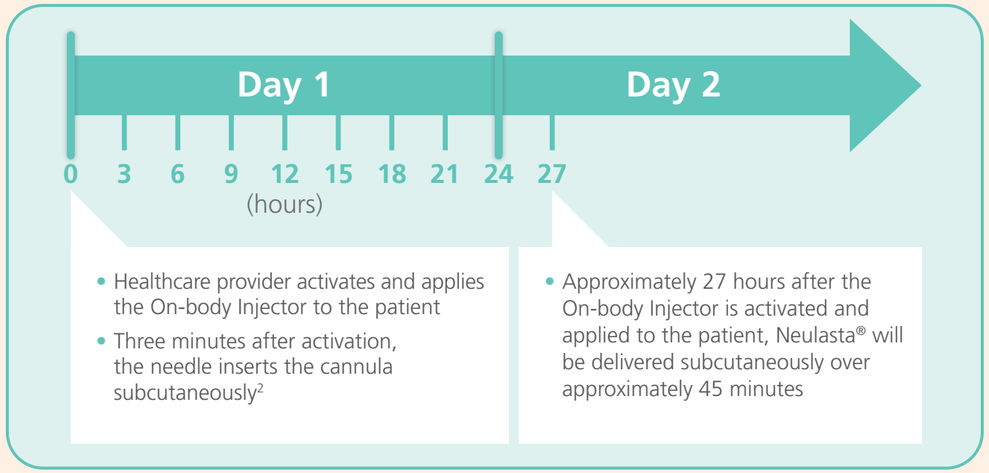
Neulasta® (pegfilgrastim) is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.[1]

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]



* 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 10-11.

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 single 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 10-11.

Physician Office – Billing Information Sheet for the Neulasta® Onpro® kit

Item	Coding Information (HCPCS[5]/CPT[6]/ICD-10-CM)	Notes
Neulasta® Onpro® kit	**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 24G) are appropriately billed.**
Administration of the On-body Injector	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.
Office visit	Relevant Evaluation and Management (E&M) code[†,‡]	See payer guidelines.
Diagnosis/ Condition	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.

† 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 (if appropriate) when modifier 25 is billed.

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.

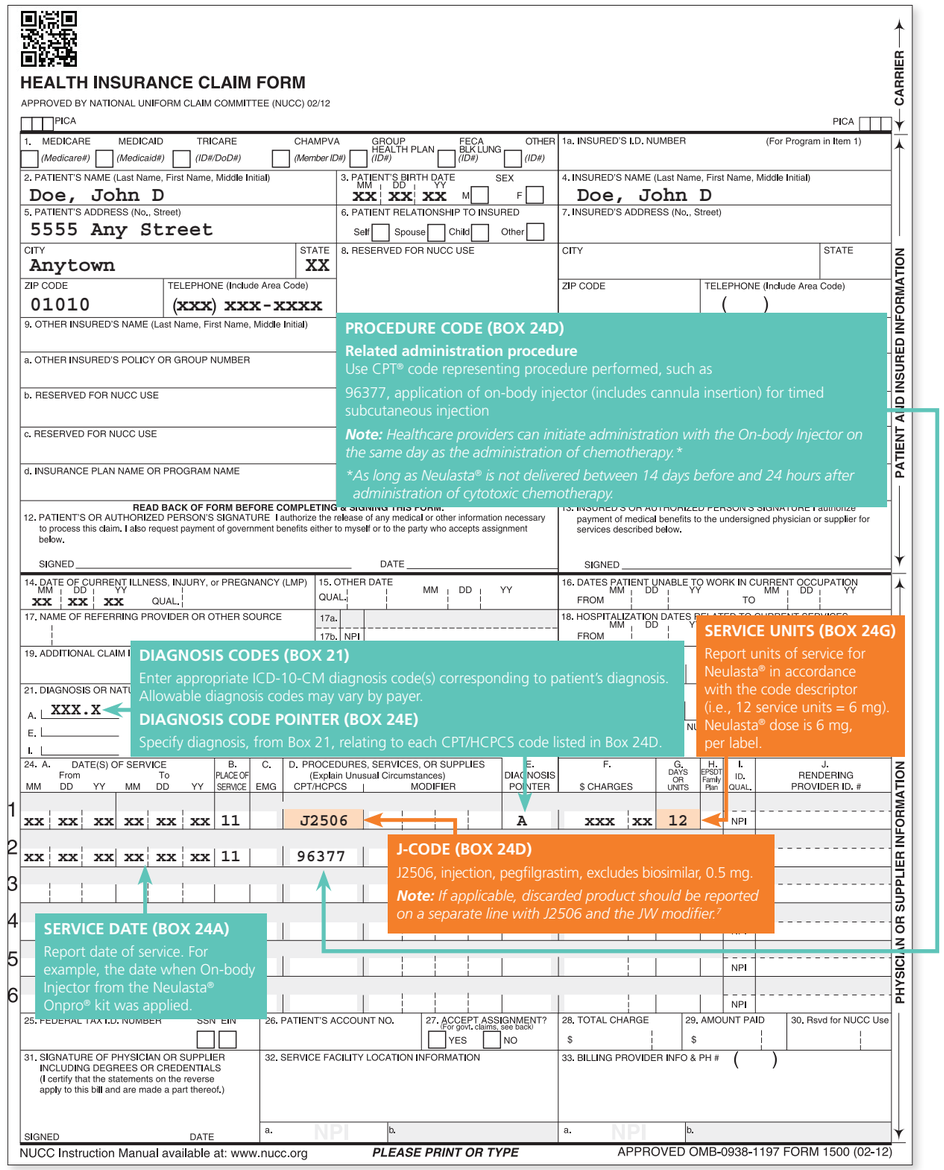
Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4ASSIST or www.AmgenAssist360.com

Neulasta® Onpro® kit (pegfilgrastim) injection

PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR THE NEULASTA® ONPRO® KIT

The CMS 1500 for Physician Office — Neulasta® Onpro® kit

Sample CMS 1500 Form — Physician Office Administration



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® Onpro® kit (pegfilgrastim) injection

Physician Office – Billing Information Sheet for the Neulasta® Prefilled Syringe

Item	Coding Information (HCPCS[5]/CPT[6]/ICD-10-CM)	Notes
Neulasta® Prefilled Syringe for Manual Injection	**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 24G) are appropriately billed.**
Administration of Neulasta® Prefilled Syringe for Manual Injection	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 diagnosis code(s) for patient condition.	Allowable diagnosis codes may vary by payer.

*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 (if appropriate) when modifier 25 is billed.

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

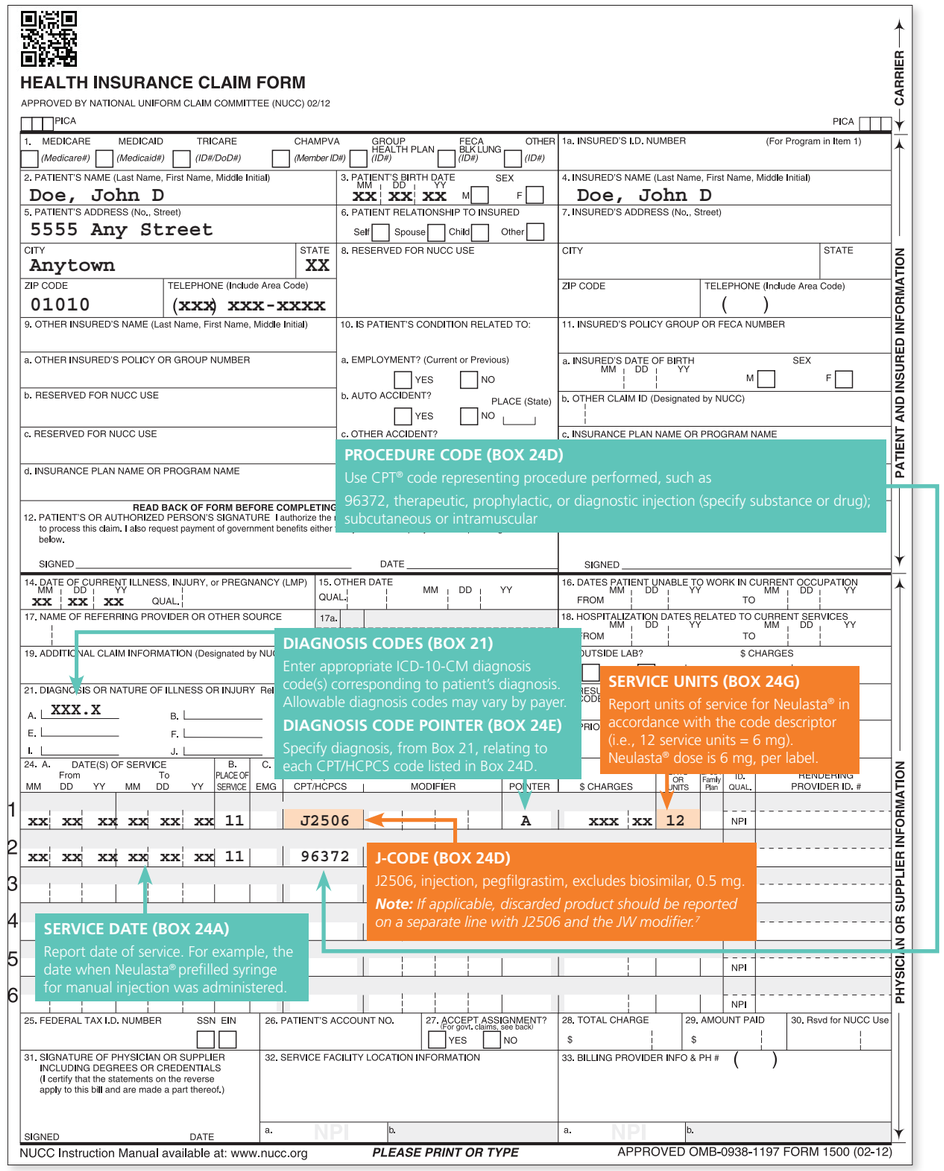
Please see additional Important Safety Information on pages 10-11.

Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4ASSIST or www.AmgenAssist360.com

Neulasta® (pegfilgrastim) injection

The CMS 1500 for Physician Office — Neulasta® Prefilled Syringe

Sample CMS 1500 Form — Physician Office Administration



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Neulasta® (pegfilgrastim) injection

Physician Office – 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.[8]

Item	Coding Information (HCPCS[5]/CPT[6]/ICD-10-CM)	Notes
NEUPOGEN®	J1442, injection, filgrastim (G-CSF), 1 mcg	The NDC numbers for NEUPOGEN®, in the 11-digit format, are as follows:[8] - 300-mcg vial: 55513-0530-10 - 300-mcg prefilled syringe: 55513-0924-10 - 480-mcg vial: 55513-0546-10 - 480-mcg prefilled syringe: 55513-0209-10
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 diagnosis code(s) for patient condition.	Allowable diagnosis codes may vary by payer.

*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 (if appropriate) when Modifier 25 is billed.

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 10-11.

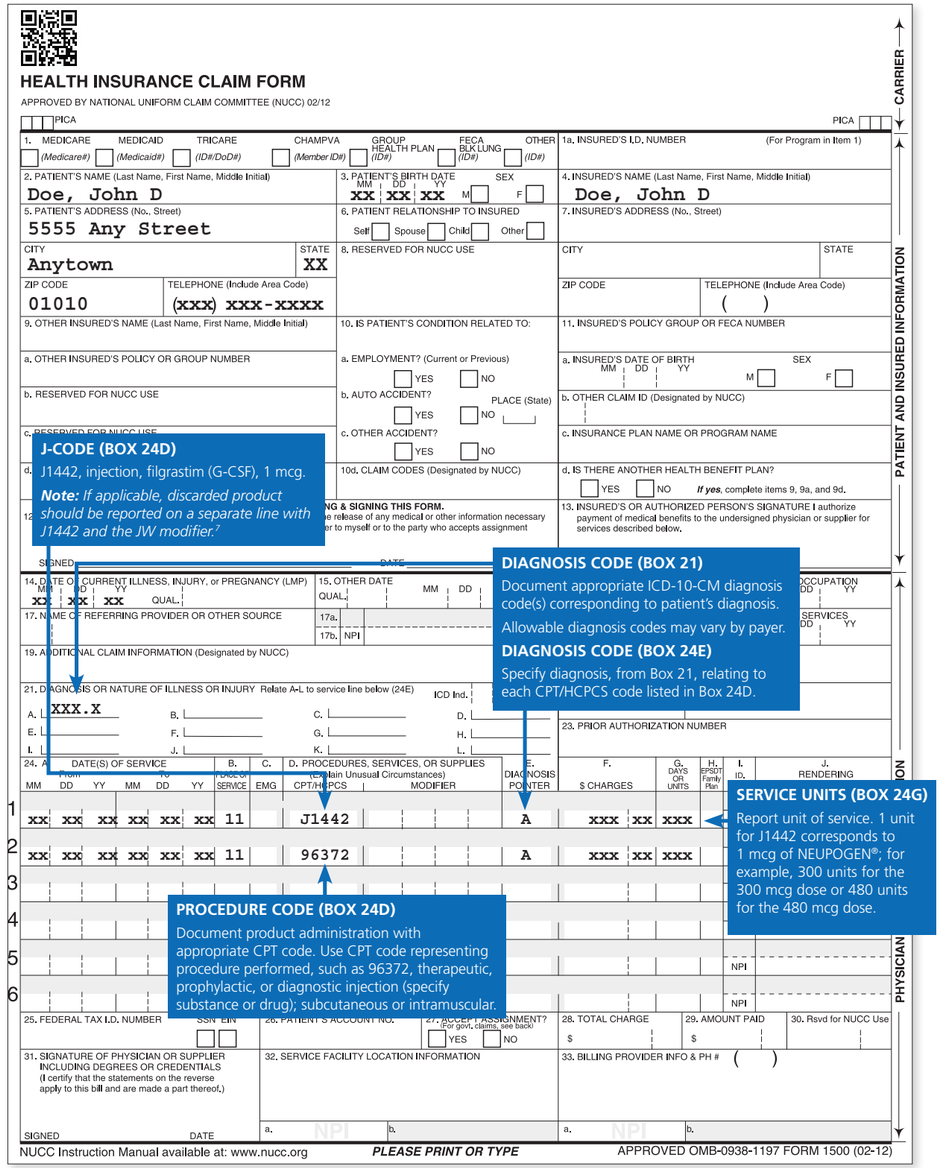
Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4ASSIST or www.AmgenAssist360.com

NEUPOGEN® (FILGRASTIM) INJECTION

PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR NEUPOGEN®

The CMS 1500 for Physician Office — NEUPOGEN®

Sample CMS 1500 Form — Physician Office Administration



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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 single 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

Please see additional Important Safety Information on page 11.

Thrombocytopenia

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

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

Aortitis

- Aortitis has been reported in patients receiving Neulasta® and 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, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count).
- Consider aortitis in patients who develop these signs and symptoms without known etiology. Discontinue Neulasta® and NEUPOGEN® if aortitis 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

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 accompanying full Prescribing Information for Neulasta® and NEUPOGEN®.

Neulasta® (pegfilgrastim) injection

NEUPOGEN® (FILGRASTIM) INJECTION

AMGEN ASSIST 360™
Support, Simplified

See How We Can Help Your Patients

Offering the tools, information, and support for Amgen products that make a difference for you and your patients

BENEFIT VERIFICATION

Submit, store, and retrieve benefit verifications for all your patients currently on an Amgen product

AMGEN REIMBURSEMENT SPECIALISTS

Connect with an Amgen Reimbursement Counselor, or schedule a visit with a Field Reimbursement Specialist

AMGEN NURSE NAVIGATORS*

A single point of contact for Amgen Assist 360™ services, designed to help your patients find the resources† that are most important to them

* Amgen Nurse Navigators are only available to patients that are prescribed certain products. Nurse Navigators are there to support, not replace, your treatment plan and do not provide medical advice or case management services. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

† Resources include referrals to independent nonprofit patient assistance programs. Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Amgen has no control over these programs and provides referrals as a courtesy only.

Call 1-888-4ASSIST (888-427-7478)
Monday to Friday, 9:00 AM to 8:00 PM EST,
or visit www.AmgenAssist360.com

References

1. Neulasta® (pegfilgrastim) prescribing information, Amgen. **2.** Neulasta® (pegfilgrastim) Onpro® kit Healthcare Provider Instructions for Use, Amgen. **3.** RED BOOK Online®. Neulasta® (pegfilgrastim) injection Onpro® kit. https://www.micromedexsolutions.com/micromedex2/librarian/CS/62DD04/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/03D81D/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/redbook.ShowProductSearchResults?SearchTerm=NEULASTA%20ONPRO&searchType=redbookProductName&searchTermId=44479&searchContent=REDBOOK&searchFilterAD=filterADActive&searchFilterRepackager=filterExcludeRepackager&searchPattern=%5Eneulasta. Accessed September 23, 2021. **4.** RED BOOK Online®. Neulasta® (pegfilgrastim) injection. https://www.micromedexsolutions.com/micromedex2/librarian/CS/62DD04/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/03D81D/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/redbook.ShowProductSearchResults?SearchTerm=NEULASTA&searchType=redbookProductName&searchTermId=30621&searchContent=REDBOOK&searchFilterAD=filterADActive&searchFilterRepackager=filterExcludeRepackager&searchPattern=%5Eneulasta. Accessed September 23, 2021. **5.** Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions. https://www.cms.gov/files/document/2021-hcpcs-application-summary-bi-annual-1-2021-non-drug-and-non-biological-items-and-services.pdf. Accessed November 1, 2021. **6.** American Medical Association. Current Procedural Terminology (CPT®) 2021 Professional Edition. American Medical Association. 2020. **7.** Centers for Medicare & Medicaid Services. Medicare Program JW Modifier. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf. Accessed October 8, 2021. **8.** NEUPOGEN® (filgrastim) prescribing information, Amgen.

AMGEN®

Amgen
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
www.amgen.com

Neulasta® (pegfilgrastim) injection Onpro® kit

Neulasta® (pegfilgrastim) injection

NEUPOGEN® (FILGRASTIM) INJECTION

PHYSICIAN OFFICE CODING AND BILLING INFORMATION SHEET FOR NEULASTA® ONPRO®, NEULASTA®, AND NEUPOGEN®

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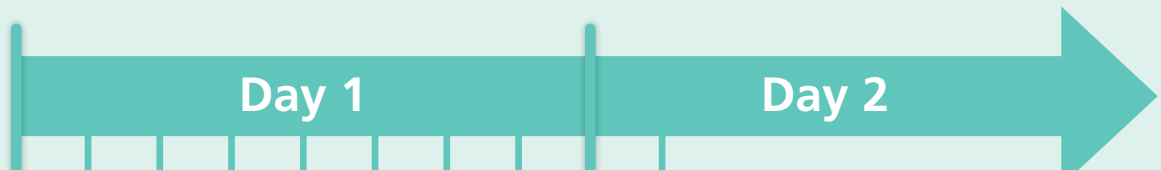
Neulasta® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.[1]

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 10-11.

Neulasta® (pegfilgrastim) injection Onpro® kit

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 single 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 10-11.

Physician Office – Billing Information Sheet for the Neulasta® Onpro® kit

Item	Coding Information (HCPCS[5]/CPT[6]/ICD-10-CM)	Notes
Neulasta® Onpro® kit	**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 24G) are appropriately billed.**
Administration of the On-body Injector	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.
Office visit	Relevant Evaluation and Management (E&M) code[†,‡]	See payer guidelines.
Diagnosis/ Condition	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.

† 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 (if appropriate) when modifier 25 is billed.

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 Assist 360™ for reimbursement and access resources at 1-888-4ASSIST or www.AmgenAssist360.com

Neulasta® (pegfilgrastim) injection Onpro® kit

The CMS 1500 for Physician Office — Neulasta® Onpro® kit

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: XX

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)

a. OTHER INSURED'S POLICY OR GROUP NUMBER

b. RESERVED FOR NUCC USE

c. RESERVED FOR NUCC USE

d. INSURANCE PLAN NAME OR PROGRAM NAME

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

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 YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES MM DD FROM

19. ADDITIONAL CLAIM I

21. DIAGNOSIS OR NATU

A. XXX.X

E.

I.

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		J2506		A	xxx xx	12			NPI
2 xx xx xx	xx xx xx	11		96377							
3											
4											
5											NPI
6											NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. 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.

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CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

PROCEDURE CODE (BOX 24D)

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 21)

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

DIAGNOSIS CODE POINTER (BOX 24E)

Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

SERVICE UNITS (BOX 24G)

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.

J-CODE (BOX 24D)

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.*[7]

SERVICE DATE (BOX 24A)

Report date of service. For example, the date when On-body Injector from the Neulasta® Onpro® kit was applied.

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

Physician Office – Billing Information Sheet for the Neulasta® Prefilled Syringe

Item	Coding Information (HCPCS[5]/CPT[6]/ICD-10-CM)	Notes
Neulasta® Prefilled Syringe for Manual Injection	**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 24G) are appropriately billed.**
Administration of Neulasta® Prefilled Syringe for Manual Injection	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 diagnosis code(s) for patient condition.	Allowable diagnosis codes may vary by payer.

*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 (if appropriate) when modifier 25 is billed.

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 10-11.

Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4ASSIST or www.AmgenAssist360.com

Neulasta® (pegfilgrastim) injection

The CMS 1500 for Physician Office — Neulasta® Prefilled Syringe

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: XX

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?

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

READ BACK OF FORM BEFORE COMPLETING

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the … to process this claim. I also request payment of government benefits either … below.

SIGNED DATE

SIGNED

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

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NU…

OUTSIDE LAB? $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Rel…

A. XXX.X B. E. F. I. J.

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY | B. PLACE OF SERVICE | C. EMG | CPT/HCPCS | MODIFIER | POINTER | $ CHARGES | DAYS OR UNITS | Family Plan | ID. QUAL. | RENDERING PROVIDER ID. #

1	xx	xx	xx	xx	xx	xx	11		J2506		A	xxx	xx	12		NPI
2	xx	xx	xx	xx	xx	xx	11		96372							NPI
3																NPI
4																NPI
5																NPI
6																NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. 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.

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CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

PROCEDURE CODE (BOX 24D)

Use CPT® code representing procedure performed, such as

96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

DIAGNOSIS CODES (BOX 21)

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

DIAGNOSIS CODE POINTER (BOX 24E)

Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

SERVICE UNITS (BOX 24G)

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.

J-CODE (BOX 24D)

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.*[7]

SERVICE DATE (BOX 24A)

Report date of service. For example, the date when Neulasta® prefilled syringe for manual injection was administered.

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

Physician Office – 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.[8]

Item	Coding Information (HCPCS[5]/CPT[6]/ICD-10-CM)	Notes
NEUPOGEN®	J1442, injection, filgrastim (G-CSF), 1 mcg	The NDC numbers for NEUPOGEN®, in the 11-digit format, are as follows:[8] - 300-mcg vial: 55513-0530-10 - 300-mcg prefilled syringe: 55513-0924-10 - 480-mcg vial: 55513-0546-10 - 480-mcg prefilled syringe: 55513-0209-10
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 diagnosis code(s) for patient condition.	Allowable diagnosis codes may vary by payer.

*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 (if appropriate) when Modifier 25 is billed.

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

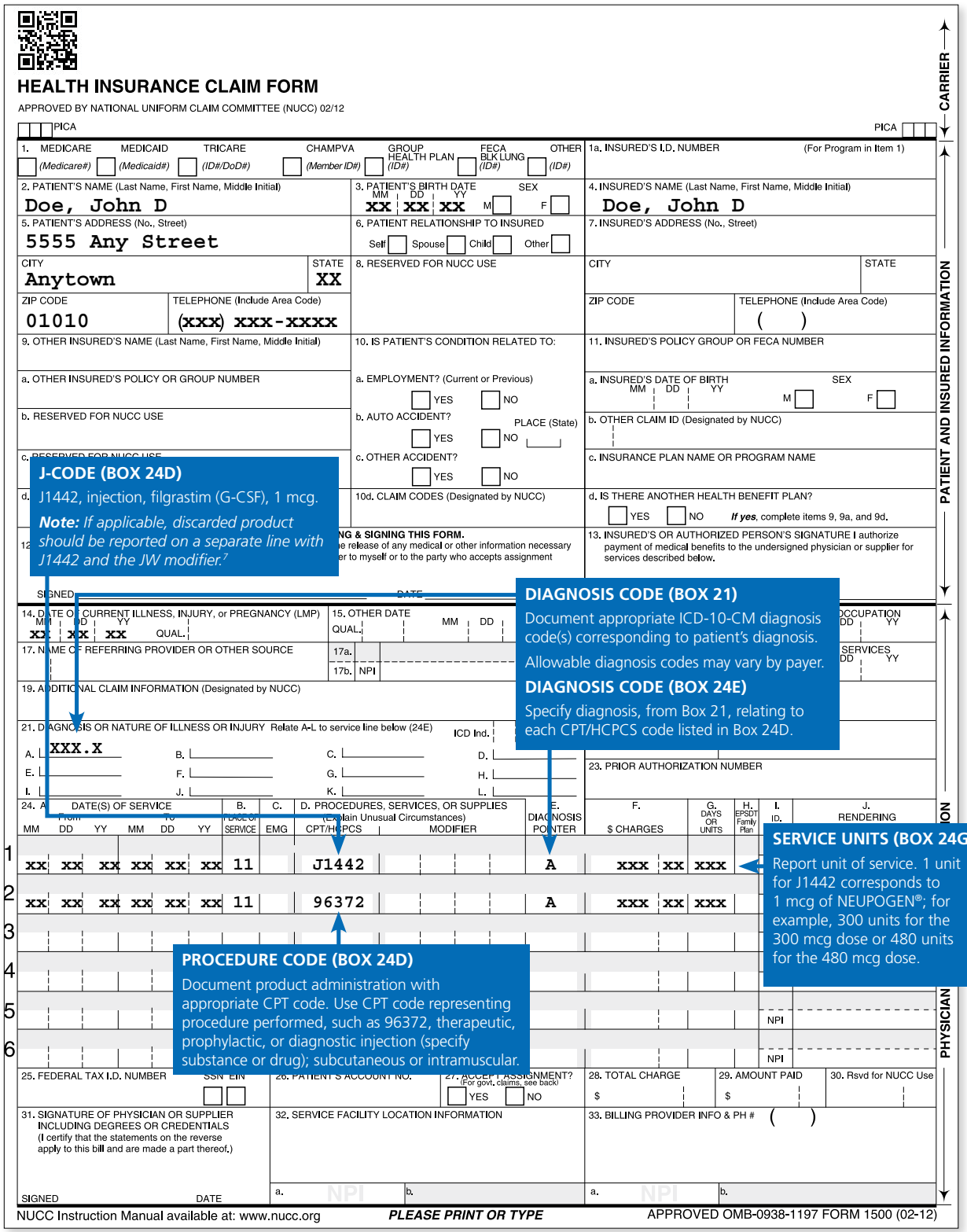
Please see additional Important Safety Information on pages 10-11.

Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4ASSIST or www.AmgenAssist360.com

NEUPOGEN® (FILGRASTIM) INJECTION

The CMS 1500 for Physician Office — NEUPOGEN®

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: XX

8. RESERVED FOR NUCC USE

ZIP CODE: 01010 TELEPHONE (Include Area Code): (xxx) xxx-xxxx

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. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

10d. CLAIM CODES (Designated by NUCC)

12. ...NG & SIGNING THIS FORM. ...e release of any medical or other information necessary ...er to myself or to the party who accepts assignment

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 DATE

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 Ind.

A. XXX.X B. C. D.

E. F. G. H.

I. J. K. L.

23. PRIOR AUTHORIZATION NUMBER

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.	J. RENDERING
1 xx	xx	xx	xx	xx	xx	11		J1442		A	xxx	xx	xxx		
2 xx	xx	xx	xx	xx	xx	11		96372		A	xxx	xx	xxx		
3															
4															
5														NPI	
6														NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. 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.

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CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN

J-CODE (BOX 24D)

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.*[7]

DIAGNOSIS CODE (BOX 21)

Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis.

Allowable diagnosis codes may vary by payer.

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 J1442 corresponds to 1 mcg of NEUPOGEN®; for example, 300 units for the 300 mcg dose or 480 units for the 480 mcg dose.

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 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 single 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

Please see additional Important Safety Information on page 11.

Thrombocytopenia

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

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

Aortitis

- Aortitis has been reported in patients receiving Neulasta® and 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, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count).
- Consider aortitis in patients who develop these signs and symptoms without known etiology. Discontinue Neulasta® and NEUPOGEN® if aortitis 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

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

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* Amgen Nurse Navigators are only available to patients that are prescribed certain products. Nurse Navigators are there to support, not replace, your treatment plan and do not provide medical advice or case management services. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

† Resources include referrals to independent nonprofit patient assistance programs. Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Amgen has no control over these programs and provides referrals as a courtesy only.

Call 1-888-4ASSIST (888-427-7478)
Monday to Friday, 9:00 AM to 8:00 PM EST,
or visit www.AmgenAssist360.com

References

1. Neulasta® (pegfilgrastim) prescribing information, Amgen. **2.** Neulasta® (pegfilgrastim) Onpro® kit Healthcare Provider Instructions for Use, Amgen. **3.** RED BOOK Online®. Neulasta® (pegfilgrastim) injection Onpro® kit. https://www.micromedexsolutions.com/micromedex2/librarian/CS/62DD04/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/03D81D/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/redbook.ShowProductSearchResults?SearchTerm=NEULASTA%20ONPRO&searchType=redbookProductName&searchTermId=44479&searchContent=REDBOOK&searchFilterAD=filterADActive&searchFilterRepackager=filterExcludeRepackager&searchPattern=%5Eneulasta. Accessed September 23, 2021. **4.** RED BOOK Online®. Neulasta® (pegfilgrastim) injection. https://www.micromedexsolutions.com/micromedex2/librarian/CS/62DD04/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/03D81D/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/redbook.ShowProductSearchResults?SearchTerm=NEULASTA&searchType=redbookProductName&searchTermId=30621&searchContent=REDBOOK&searchFilterAD=filterADActive&searchFilterRepackager=filterExcludeRepackager&searchPattern=%5Eneulasta. Accessed September 23, 2021. **5.** Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions. https://www.cms.gov/files/document/2021-hcpcs-application-summary-bi-annual-1-2021-non-drug-and-non-biological-items-and-services.pdf. Accessed November 1, 2021. **6.** American Medical Association. Current Procedural Terminology (CPT®) 2021 Professional Edition. American Medical Association. 2020. **7.** Centers for Medicare & Medicaid Services. Medicare Program JW Modifier. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf. Accessed October 8, 2021. **8.** NEUPOGEN® (filgrastim) prescribing information, Amgen.

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