

UPDATED J-CODE AND DOSE DESCRIPTOR FOR NEULASTA® ONPRO® AND NEULASTA®

ACTION REQUIRED:

Use J2506 for services on and after January 1, 2022.

For dates of service on and after January 1, 2022, the Healthcare Common Procedure Coding System (HCPCS) Code J2506 must be used for Neulasta® Onpro® and Neulasta® per the Centers for Medicare & Medicaid Services (CMS).

The HCPCS Code J2505 will no longer be accepted. The coding change is summarized in the table below:

HCPCS Code for Claims Starting January 1, 2022 ¹	Description ¹
J2506	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg

NDC ²				Description ²		Quantity ²		CPT Code ³	
Neulasta® Onpro® kit		55513-192-01		6 mg/0.6 mL prefilled syringe		1 vial per carton		96377, application of on-body injector (includes cannula insertion) for timed subcutaneous injection	
Neulasta® single-dose prefilled syringe for manual use		55513-190-01		6 mg/0.6 mL prefilled syringe		1 vial per carton		96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	

CPT = Current Procedural Terminology.

Indication

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.

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

Please see additional Important Safety Information on the following pages.

Important Safety Information

Contraindication

- Neulasta® (pegfilgrastim) is contraindicated in patients with a history of serious allergic reactions to pegfilgrastim or filgrastim
- Reactions have included anaphylaxis

Splenic Rupture

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



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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 (1-888-427-7478) or visit www.AmgenAssist360.com.

Monday to Friday, 9:00 am to 8:00 pm ET

Important Safety Information

Acute Respiratory Distress Syndrome (ARDS)

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

Serious Allergic Reactions

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

Please see additional Important Safety Information on the following pages.



Special Instructions and Important Safety Information

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)**.

Important Safety Information for Neulasta® (pegfilgrastim)

Contraindication

- Neulasta® is contraindicated in patients with a history of serious allergic reactions to pegfilgrastim or filgrastim
- Reactions have included anaphylaxis

Splenic Rupture

- Splenic rupture, including fatal cases, can occur following the administration of Neulasta®
- 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®
- Evaluate patients who develop a fever and lung infiltrates or respiratory distress after receiving Neulasta®
- Discontinue Neulasta® in patients with ARDS

Serious Allergic Reactions

- Serious allergic reactions, including anaphylaxis can occur in patients receiving Neulasta®
- Majority of events occurred upon initial exposure and can recur within days after discontinuation of initial anti-allergic treatment

- Permanently discontinue Neulasta® in patients with serious allergic reactions

Allergies to Acrylics

- On-body injector (OBI) 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, severe and sometimes fatal sickle cell crises can occur in patients receiving Neulasta®
- Discontinue Neulasta® if sickle cell crisis occurs

Glomerulonephritis

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

Please see additional Important Safety Information on the following page.

Important Safety Information (cont'd)

Leukocytosis

- Increased white blood cell counts of $100 \times 10^9/L$ have been observed
- Monitoring of complete blood count (CBC) during pegfilgrastim therapy is recommended

Thrombocytopenia

- Thrombocytopenia has been reported in patients receiving pegfilgrastim. Monitor platelet counts

Capillary Leak Syndrome (CLS)

- CLS has been reported after G-CSF administration, including 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

Potential for Tumor Growth Stimulatory Effects on Malignant Cells

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

Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients With Breast and Lung Cancer

- MDS and AML have been associated with the use of 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

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®. 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® if aortitis is suspected

Nuclear Imaging

- Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone imaging results

Most common adverse reactions

- Bone pain
- Pain in extremity

Please [click here](#) for full Prescribing Information for Neulasta®.

Neulasta® Injection: 6 mg/0.6 mL in a single-dose prefilled syringe for manual use only.

Neulasta® 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).

The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this document be considered a guarantee of coverage or reimbursement for any product or service.

References:

1. 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. 2. Neulasta® (pegfilgrastim) prescribing information, Amgen. 3. American Medical Association. Current Procedural Terminology (CPT®) 2021 Professional Edition. American Medical Association. 2020.



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