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

  - Must be prepared and applied by a healthcare provider on the same day as chemotherapy¹
  - 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 activation¹
    - 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 application¹

Apply today, deliver* Neulasta® tomorrow¹

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

<table>
<thead>
<tr>
<th>SELECT ATTRIBUTES</th>
<th>SAME</th>
<th>DIFFERENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Ingredient¹</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>Indication¹</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>Route of Administration¹</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>Deliverable Dose¹</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>WAC³,⁴</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>J-code⁵,*</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>How Delivered and CPT Code¹,⁶,*</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>NDC Number¹,⁶,*</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

* 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

#### Contraindication

- Neulasta® or NEUPGEN® 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.
## Important Safety Information

### Splenic Rupture
- Splenic rupture, including fatal cases, can occur following the administration of Neulasta® and NEUPGEN®.
- 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.

**Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4ASSIST or www.amgenassist360.com**

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### Coding and Billing Information

**Item**

**Coding Information (HCPCS/CPT/ICD-10-CM)**

**Notes**

<table>
<thead>
<tr>
<th>Item</th>
<th>Coding Information (HCPCS/CPT/ICD-10-CM)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neulasta® Onpro® kit</td>
<td>J2505, injection, pegfilgrastim, 6 mg</td>
<td>Neulasta® is supplied as a 6 mg deliverable dose.¹ Billing requirements may vary by payer; however, it may be important to document the NDC number (in the 11-digit format) on a claim in order to differentiate the Neulasta® Onpro® kit.¹</td>
</tr>
<tr>
<td>Administration of the On-body Injector</td>
<td>96377, application of on-body injector (includes cannula insertion) for timed subcutaneous injection</td>
<td>Healthcare providers can initiate administration with the On-body Injector on the same day as the administration of chemotherapy.¹ Effective January 1, 2018, the drug administration CPT code (96377) for use with the Neulasta® Onpro® kit will be designated as an active code under the Medicare Physician Fee Schedule.² See payer guidelines for specific coding requirements.</td>
</tr>
<tr>
<td>Office visit</td>
<td>Relevant Evaluation and Management (E&amp;M) code.¹</td>
<td>See payer guidelines.</td>
</tr>
<tr>
<td>Diagnosis/Condition</td>
<td>Appropriate ICD-10-CM diagnosis code(s) for patient condition.</td>
<td>Allowable diagnosis codes may vary by payer.</td>
</tr>
</tbody>
</table>

¹As long as Neulasta® is not delivered between 14 days before and 24 hours after administration of cytotoxic chemotherapy.

²Some payers, including Medicare, will not allow a Level 1 office visit to be billed with an injection/infusion code for the same date of service, and only allow for other levels when modifier 25 is billed.

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

**Sample CMS 1500 Form — Physician Office Administration**

**PROCEDURE CODE (BOX 24D)**

Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient’s diagnosis and indicate payer type by code.

**DIAGNOSIS CODES (BOX 21)**

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

**SERVICE UNITS (BOX 24G)**

Report units of service. 1 unit = 1 mL for the On-body Injector from the Neulasta® Onpro® kit.

**NDC CODE (BOX 24A)**

In order to distinguish the Neulasta® Onpro® kit, it may be important to document the NDC number in the shaded area of Box 24A or corresponding electronic field.

**SERVICE DATE (BOX 24A)**

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

**DIAGNOSIS CODE POINTER (BOX 24E)**

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

**PROCEDURE CODE POINTER (BOX 24F)**

Report specific procedure code from Box 24D. Report in the shaded area of Box 24F, relating to each CPT/HCPCS code listed in Box 24.

**BILLABLE DAYS (BOX 24I)**

Report the number of billable days (5) for the On-body Injector from the Neulasta® Onpro® kit.

**Note:** Specific payer requirements may vary. Some payers may require to report the NDC number in the shaded area of Box 24A or corresponding electronic field.

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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 it use 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.
## Physician Office – Billing Information Sheet for the Neulasta® Prefilled Syringe

<table>
<thead>
<tr>
<th>Item</th>
<th>Coding Information (HCPCS/CPT/ICD-10-CM)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neulasta® Prefilled Syringe for Manual Injection</td>
<td>J2505, injection, pegfilgrastim, 6 mg</td>
<td>Neulasta® is supplied as a 6 mg deliverable dose.¹</td>
</tr>
<tr>
<td>Administration of Neulasta® Prefilled Syringe for Manual Injection</td>
<td>96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular</td>
<td></td>
</tr>
<tr>
<td>Office visit</td>
<td>Relevant Evaluation and Management (E&amp;M) code¹</td>
<td>See payer guidelines.</td>
</tr>
<tr>
<td>Diagnosis/Condition</td>
<td>Appropriate ICD-10-CM diagnosis code(s) for patient condition.</td>
<td>Allowable diagnosis codes may vary by payer.</td>
</tr>
</tbody>
</table>

¹*Bill relevant E&M code only if a separately identifiable E&M service is performed. Document accordingly.

¹ Some payers, including Medicare, will not allow a Level 1 office visit to be billed with an injection/infusion code for the same date of service, and only allow for other levels when modifier 25 is billed.

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**

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The CMS 1500 for Physician Office — Neulasta® Prefilled Syringe

Sample CMS 1500 Form — Physician Office Administration

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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 it include 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.
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.¹

<table>
<thead>
<tr>
<th>Item</th>
<th>Coding Information (HCPCS / CPT / ICD-10-CM)</th>
<th>Notes</th>
</tr>
</thead>
</table>
| NEUPOGEN® | J1442, injection, filgrastim (G-CSF), 1 mcg | The NDC numbers for NEUPOGEN®, in the 11-digit format, are as follows:²
- 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.

¹ Some payers, including Medicare, will not allow a Level 1 office visit to be billed with an injection/infusion code for the same date of service, and only allow for other levels when Modifier 25 is billed.

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

The CMS 1500 for Physician Office — NEUPOGEN®
Sample CMS 1500 Form — Physician Office Administration

PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR NEUPOGEN®

PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR NEUPOGEN®
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 at the time of 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 manual use as soon as possible after detection.

Refer 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 risk 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 who have a history of serious allergic reactions to human granulocyte colony-stimulating factors (G-CSFs), such as pegfilgrastim or filgrastim.

Splenectomy
- Spontaneous 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®.

- 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®.
- Monitor platelet counts.

Leukocytosis
- White blood cell counts of ≥ 100,000/mm³ 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/mm³ may not result in increased 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
- May prevent the growth of any tumor type, including myeloid malignancies and myelodysplasia, but cannot be excluded.

Potential Device Failures
- A missed or partial dose has 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 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 NEUPOGEN® and Neulasta®.
- It may occur as early as the first week after start of therapy.
- Manifestations may include generalized signs and symptoms such as fever, left lower abdominal or back pain, 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, anorexia, malaise, peripheral edema, decreased hemoglobin, decreased appetite, asthenia, malaise, back pain, and alopecia

Most common adverse reactions in patients taking Neulasta®
- Bone pain
- Pain in extremity

Please see accompanying full prescribing Information for Neulasta® and NEUPOGEN®.
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References