



HOSPITAL OUTPATIENT 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

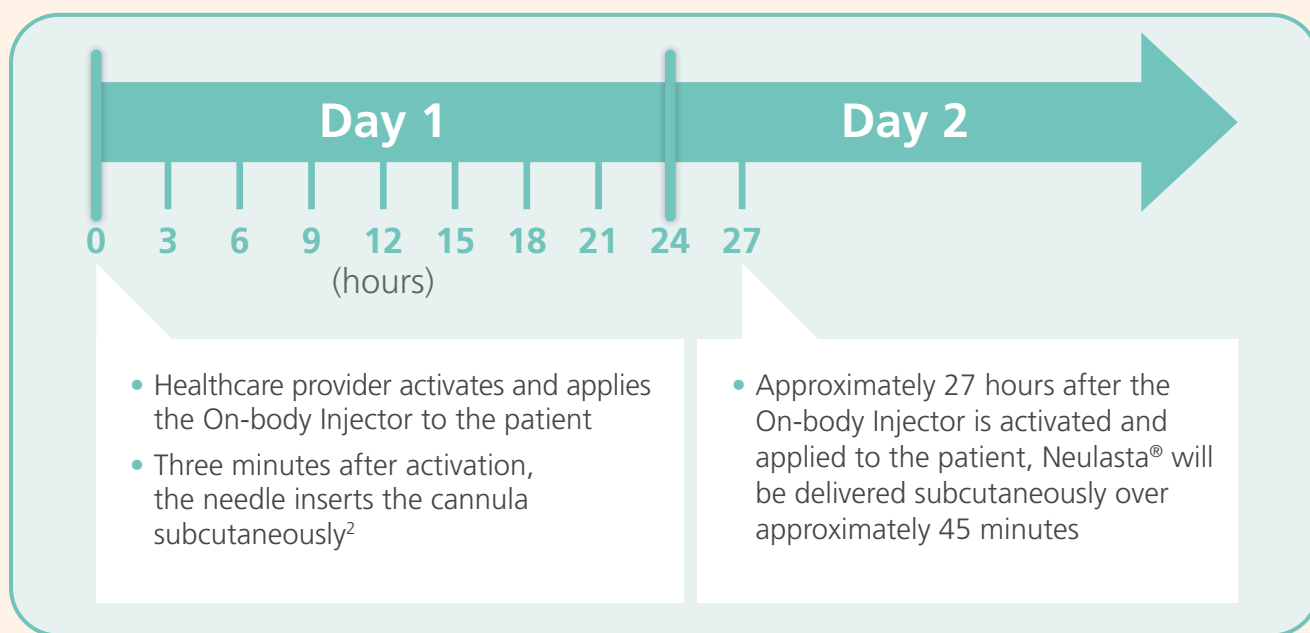
Neulasta® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.¹

Neulasta® Onpro® kit, which includes: the same Neulasta® as in the Prefilled Syringe with a different delivery option¹



- 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



* 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.

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

Item	Revenue Code ^{7,8}	Coding Information (HCPCS ⁵ /CPT ⁶ /ICD-10-CM)	Notes
Neulasta® Onpro® kit	<p>Medicare: 0636, drugs requiring detailed coding⁹</p> <p>Other Payers: 0250, general pharmacy; OR 0636, if required by a given payer⁹</p>	J2506 , injection, pegfilgrastim, excludes biosimilar, 0.5 mg	<p>Neulasta® is supplied as a 6 mg deliverable dose.¹</p> <p>Effective Jan 1, 2022, the HCPCS has changed from J2505 to J2506, injection, pegfilgrastim, excludes biosimilar, 0.5 mg.</p> <p>55513-0192-01 is the NDC number (in the 11-digit format) for Neulasta® Onpro® kit.¹</p> <p>Healthcare providers should ensure Service Units (Box 46) are appropriately billed.</p>
Administration of the On-body Injector	Appropriate revenue code for the cost center in which the service is performed	96377, application of on-body injector (includes cannula insertion) for timed subcutaneous injection	<p>Healthcare providers can initiate administration with the On-body Injector on the same day as the administration of chemotherapy.^{1,*}</p> <p>See payer guidelines for specific coding requirements.</p>
Diagnosis/Condition	N/A	Appropriate ICD-10-CM diagnosis code(s) for patient condition.	Allowable diagnosis codes may vary by payer.

*As long as Neulasta® is not delivered between 14 days before and 24 hours after administration of cytotoxic chemotherapy. CPT = Current Procedural Terminology; HCPCS = Healthcare Common Procedure Coding System; ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification.

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

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



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

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

Anytown Hospital 100 Main Street Anytown, Anystate 01010		3a. PAT. CNTL. # b. MED. REC. #	4. TYPE OF BILL
5. FED. TAX NO.		6. STATEMENT COVERS PERIOD FROM THROUGH	
8. PATIENT NAME Smith, Jane		9. PATIENT ADDRESS 123 Main Street, Anytown, Anystate 12345	
10. BIRTHDATE	11. SEX	12. DATE	13. HR
14. TYPE	15. SRC	16. DHR	17. STAT
18-28. CONDITION CODES			
29. ACCT STATE			
31. OCCURRENCE CODE	32. OCCURRENCE DATE	33. OCCURRENCE DATE	34. OCCURRENCE DATE
35. OCCURRENCE DATE			
36. OCCURRENCE DATE			
37. OCCURRENCE DATE			
38. OCCURRENCE DATE			
39. OCCURRENCE DATE			
40. OCCURRENCE DATE			
41. OCCURRENCE DATE			
42. REV. CD. 0636 0510			
43. DESCRIPTION Clinic			
44. HCPCS / RATE / HIPPS CODE J2506 96377			
45. SERV. DATE MMDDYY MMDDYY			
46. SERV. UNITS 12 1			
47. TOTAL CHARGES XXX XX XXX XX			
48. NON-COVERED CHARGES			
49.			
PAGE ____ OF ____		CREATION DATE	
50. PAYER NAME		51. HEALTH PLAN ID	
52. REL. INFO		53. ASG. BEN.	
54. PRIOR PAYMENTS		55. EST. AMOUNT DUE	
56. NPI		57. OTHER PRV. ID	
58. INSURED'S NAME		59. R. REL.	
60. INSURED'S UNIQUE ID		61. GROUP NAME	
62. INSURANCE GROUP NO.		63.	
64. DOCUMENT CONTROL NUMBER		65. EMPLOYER NAME	
66. DX XXX.X			
67.			
68.		69.	
70. PATIENT REASON DX		71. PPS CODE	
72. ECI		73.	
74. PRINCIPAL PROCEDURE CODE a. OTHER PROCEDURE CODE b. OTHER PROCEDURE CODE		75.	
76. ATTENDING NPI LAST FIRST		77. OPERATING NPI LAST FIRST	
78. OTHER NPI LAST FIRST		79. OTHER NPI LAST FIRST	
80. REMARKS		81. CC a. b. c. d.	

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

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

REVENUE CODES (BOX 42) AND DESCRIPTIONS (BOX 43)
Product
 Medicare: Use revenue code 0636, drugs requiring detailed coding.
 Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer).
Related administration procedure
 Use most appropriate revenue code for cost center where services were performed (eg, 0510, clinic).

PRODUCT CODE (BOX 44)
Product (J-Code)
 J2506, injection, pegfilgrastim, excludes biosimilar, 0.5 mg.
Note: If applicable, discarded product should be reported on a separate line with J2506 and the JW modifier.¹⁰
 When applicable, the JG modifier should be used on Medicare hospital outpatient claims to bill for certain separately payable drugs (including Neulasta®) acquired through the 340B program.¹¹

PROCEDURE CODE (BOX 44)
Related administration procedure
 Use CPT® code representing procedure performed, such as 96377, application of on-body injector (includes cannula insertion) for timed subcutaneous injection.
*Note: Healthcare providers can initiate administration with the On-body Injector on the same day as the administration of chemotherapy.**
 *As long as Neulasta® is not delivered between 14 days before and 24 hours after administration of cytotoxic chemotherapy.

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

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



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

Item	Revenue Code ^{7,8}	Coding Information (HCPCS ⁵ /CPT ⁶ /ICD-10-CM)	Notes
Neulasta® Prefilled Syringe for Manual Injection	Medicare: 0636, drugs requiring detailed coding ⁹	J2506 , injection, pegfilgrastim, excludes biosimilar, 0.5 mg	<p>Neulasta® is supplied as a 6 mg deliverable dose.¹</p> <p>Effective Jan 1, 2022, the HCPCS has changed from J2505 to J2506, injection, pegfilgrastim, excludes biosimilar, 0.5 mg.</p> <p>55513-0190-01 is the NDC number (in the 11-digit format) for the Neulasta® prefilled syringe for manual injection.¹</p> <p>Healthcare providers should ensure Service Units (Box 46) are appropriately billed.</p>
	Other Payers: 0250, general pharmacy; OR 0636, if required by a given payer ⁹		
Administration of Neulasta® Prefilled Syringe for Manual Injection	Appropriate revenue code for the cost center in which the service is performed	96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	
Diagnosis/Condition	N/A	Appropriate ICD-10-CM diagnosis code(s) for patient condition.	Allowable diagnosis codes may vary by payer.

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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



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

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

1 Anytown Hospital 100 Main Street Anytown, Anystate 01010		2		3a PAT. CNTL. # b. MED. REC. #		4 TYPE OF BILL	
5 FED. TAX NO.				6 STATEMENT COVERS PERIOD FROM THROUGH			
8 PATIENT NAME a Smith, Jane		9 PATIENT ADDRESS a 123 Main Street, Anytown, Anystate 12345					
10 BIRTHDATE		11 SEX		12 DATE		13 HR	
14 TYPE		15 SRC		16 DHR		17 STAT	
18		19		20		21	
22		23		24		25	
26		27		28		29 ACDT STATE	
30		31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE	
34		35		36		37	
38		39		40		41	
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE	
46 SERV. UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49	
0636		Clinic		J2506		MMDDYY	
0510				96372		MMDDYY	
						12	
						XXXXX	
						1	
						XXXXX	
PAGE		OF		CREATION DATE		TOTALS	
50 PAYER NAME		51 HEALTH PLAN ID		52 REL. INFO		53 ABIL. BEN.	
54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI		57 OTHER PRV ID	
58 INSURED'S NAME		59 R.REL.		60 INSURED'S UNIQUE ID		61 GROUP NAME	
62 INSURANCE GROUP NO.		63		64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME	
66 DX		67		68		69	
70 PATIENT REASON DX		71 PPS CODE		72 ECI		73	
74 PRINCIPAL PROCEDURE CODE DATE		75 OTHER PROCEDURE CODE DATE		76 ATTENDING NPI		77 QUAL	
78 LAST		79 FIRST		80 LAST		81 FIRST	
82 OTHER NPI		83 QUAL		84 LAST		85 FIRST	
86 OTHER NPI		87 QUAL		88 LAST		89 FIRST	
90 OTHER NPI		91 QUAL		92 LAST		93 FIRST	
80 REMARKS		81CC a		81CC b		81CC c	
81CC d		82		83		84	
UB-04 CMS-1450		APPROVED OMB NO. 0938-0997		NUBC		THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.	

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

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

REVENUE CODES (BOX 42) AND DESCRIPTIONS (BOX 43)
Product
Medicare: Use revenue code 0636, drugs requiring detailed coding.
Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer).
Related administration procedure
Use most appropriate revenue code for cost center where services were performed (eg, 0510, clinic).

PRODUCT CODE (BOX 44)
Product (J-Code)
J2506, injection, pegfilgrastim, excludes biosimilar, 0.5 mg.
Note: If applicable, discarded product should be reported on a separate line with J2506 and the JW modifier.¹⁰
When applicable, the JG modifier should be used on Medicare hospital outpatient claims to bill for certain separately payable drugs (including Neulasta®) acquired through the 340B program.¹¹

PROCEDURE CODE (BOX 44)
Related administration procedure
Use CPT® code representing procedure performed, such as 96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

NEULASTA® PREFILLED SYRINGE

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.



Hospital Outpatient – Billing Information Sheet for NEUPOGEN®

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

Item	Revenue Code ^{7,8}	Coding Information (HCPCS ⁵ /CPT ⁶ /ICD-10-CM)	Notes
NEUPOGEN®	Medicare: 0636, drugs requiring detailed coding ⁹	J1442, injection, filgrastim (G-CSF), 1 mcg	The NDC numbers for NEUPOGEN®, in the 11-digit format, are as follows: ¹² - 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
	Other Payers: 0250, general pharmacy; OR 0636, if required by a given payer ⁹		
Administration	Appropriate revenue code for the cost center in which the service is performed	96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	
Diagnosis/Condition	N/A	Appropriate ICD-10-CM diagnosis code(s) for patient condition.	Allowable diagnosis codes may vary by payer.

Important Safety Information

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 1450 for Hospital Outpatient – NEUPOGEN®

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

1 Anytown Hospital 100 Main Street Anytown, Anystate 01010		2		3a PAT. CNTL. # b. MED. REC. #		4 TYPE OF BILL	
5 FED. TAX NO.				6 STATEMENT COVERS PERIOD FROM		7 THROUGH	
8 PATIENT NAME a Smith, Jane				9 PATIENT ADDRESS a 123 Main Street, Anytown, Anystate 12345			
10 BIRTHDATE		11 SEX		12 DATE		13 ADMISSION HR	
14 TYPE		15 SRC		16 DHR		17 STAT	
18		19		20		21	
22		23		24		25	
26		27		28		29	
30		31		32		33	
34		35		36		37	
38		39		40		41	
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE	
46 SERV. UNITS		47 TOTAL CHARGES		48		49	
0636		Clinic		J1442		MMDDYY XXX	
0510				96372		MMDDYY X	
						XXXXXX	
						XXXXXX	

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

TOTAL CHARGES (BOX 47)
Report appropriate charges for product used and related procedures.

REVENUE CODES (BOX 42) AND DESCRIPTIONS (BOX 43)
Product
Medicare: Use revenue code 0636, drugs requiring detailed coding.
Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer).
Related administration procedure
Use most appropriate revenue code for cost center where services were performed (eg, 0510, clinic).

PRODUCT AND PROCEDURE CODE (BOX 44)
Product (J-Code)
J1442, injection, filgrastim (G-CSF), 1 mcg.
Note: If applicable, discarded product should be reported on a separate line with J1442 and the JW modifier.¹⁰
When applicable, the JG modifier should be used on Medicare hospital outpatient claims to bill for certain separately payable drugs (including NEUPOGEN®) acquired through the 340B program.¹¹
Related administration procedure
Use CPT® code representing procedure performed, such as 96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

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

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



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 $\geq 100,000/\text{mm}^3$ 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 $10,000/\text{mm}^3$ 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®.





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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

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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/PFAActionId/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/F14A98/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/63A00B/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFAActionId/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. Value Healthcare Services. Understanding Hospital Revenue Codes. <http://valuehealthcareservices.com/education/understanding-hospital-revenue-codes/>. Accessed September 12, 2021. 8. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual - Chapter 25. Completing and Processing the Form CMS-1450 Data Set. Rev 4194. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf>. Accessed September 12, 2021. 9. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual - Chapter 17: Drugs and Biologicals. Rev 10329. <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf>. Accessed September 12, 2021. 10. 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 6, 2021. 11. Centers for Medicare & Medicaid Services. Medicare-FFS Program. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-ops.pdf>. Accessed October 6, 2021. 12. NEUPOGEN® (filgrastim) prescribing information, Amgen.



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