

Effective Date: 01/01/2016

Review Date:

## I. Initial Approval Criteria

Coverage for Neulasta® (pegfilgrastim) is provided in the following conditions:

Patient with non-myeloid malignancy†

- Patient is undergoing myelosuppressive chemotherapy and/or radiotherapy with an expected incidence of febrile neutropenia of 20% or greater‡; OR
- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% or greater ‡ AND one or more of the following co-morbidities:
  - Elderly patients (age 65 or older)
  - History of recurrent febrile neutropenia from chemotherapy
  - Extensive prior exposure to chemotherapy
  - Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
  - Pre-existing neutropenia ( $ANC \leq 1000/mm^3$ ) or bone marrow involvement with tumor
  - Patient has a condition that can potentially increase the risk of serious infection (i.e. HIV/AIDS) Infection/open wounds
  - Recent surgery
  - Poor performance status
  - Poor renal function
  - Liver dysfunction (elevated bilirubin)
- In all cases patients must weigh at least 45 kg to receive Neulasta®pegfilgrastim

Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy

## II. Renewal Criteria

Same as initial prior authorization policy criteria

## III. Length of Authorization

Coverage is provided for four months and may be renewed.

## Neulasta® Prior Authorization Criteria

### IV. Dosage/Administration

Indication	Dose
Neulasta – all indications	Up to 6mg every 14 days *Do not administer within 14 days before or 24 hours after administration of a cytotoxic chemotherapy *On-Body Injector may be administered on the same day as chemotherapy as long as the Neulasta is administered no less than 24 hours after administration of chemotherapy

### V. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Neulasta 6 mg prefilled syringe: 1 syringe per 14 days **B.**

#### Max Units (per dose and over time) [Medical Benefit]:

Neulasta (J2505)

**Male** 1 billable unit per 14 days

**Female** 1 billable unit per 14 days

### VI. Billing Code/Availability Information

Jcode:

- J2505 – Neulasta (Amgen) 6 mg injection: 1 billable unit = 6 mg

NDC:

- Neulasta 6 mg prefilled syringe – 55513-0190-xx (Amgen)
- Neulasta 6 mg prefilled syringe with On-body injector – 55513-192-xx (Amgen)

### VII. References

1. Neulasta [package insert]. Thousand Oaks, CA; Amgen Inc; December 2014. Accessed August 2015.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) pegfilgrastim. National Comprehensive Cancer Network, 2015. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are

### Neulasta® Prior Authorization Criteria

trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2015.

3. Palmetto GBA. Local Coverage Determination (LCD): White Cell Colony Stimulating Factors (L31799). Centers for Medicare & Medicaid Services, Inc. Updated on 5/22/2015 with effective date 7/1/2015. Accessed August 2015.
4. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Human Granulocyte/Macrophage Colony Stimulating Factors (L30306). Centers for Medicare & Medicaid Services, Inc. Updated on 7/20/2015 with effective date 8/1/2015. Accessed August 2015.
5. Cahaba Government Benefit Administrators, LLC. Local Coverage Determination (LCD): Drugs and Biologicals: Colony Stimulating Factors (L30026). Centers for Medicare & Medicaid Services, Inc. Updated on 04/14/2014 with effective date 01/01/2014. Accessed August 2015.
6. First Coast Service Options, Inc. Local Coverage Determination (LCD): Pegfilgrastim (Neulasta®) (L29254; L29463; L28967; L28946). Centers for Medicare & Medicaid Services, Inc. Updated on 07/01/2014 with effective date 03/27/2014. Accessed August 2015.
7. National Government Services, Inc. Local Coverage Article: Filgrastim, Pegfilgrastim, Tbofilgrastim (e.g., Neupogen®, Neulasta TM, Granix TM) - Related to LCD L25820 (A48208). Centers for Medicare & Medicaid Services, Inc. Updated on 08/29/2014 with effective date 09/01/2014. Accessed August 2015.

### Appendix 1 – Covered Diagnosis Codes

ICD-9 Codes	Diagnosis
<b>Neulasta</b>	
288.03	Drug induced neutropenia
V07.8	Other specified prophylactic or treatment measure
V42.82	Peripheral stem cells replaced by transplant
V59.02	Blood donors, stem cells
V58.11	Encounter for antineoplastic chemotherapy
ICD-9 Codes	Diagnosis

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V66.2	Convalescence following chemotherapy
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ICD-10	ICD-10 Description
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.2	Other drug-induced agranulocytosis
Z41.8	Encounter for other procedures for purposes other than remedying health state
Z51.11	Encounter for antineoplastic chemotherapy
Z51.89	Encounter for other specified aftercare
Z52.001	Unspecified donor, stem cells
Z52.011	Autologous donor, stem cells
Z52.091	Other blood donor, stem cells
Z94.84	Stem cells transplant status

### Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicarecoverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

#### Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 11(M)	NCD/LCD Document (s): L31799
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ICD-9 Codes	Diagnosis
140.0 - 173.89	MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - OTHER SPECIFIED MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF SKIN
174.0 - 204.92	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF FEMALE BREAST – UNSPECIFIED LYMPHOID LEUKEMIA, IN RELAPSE
205.00 - 205.02	ACUTE MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION – ACUTE MYELOID LEUKEMIA, IN RELAPSE

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205.10	CHRONIC MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
205.12	CHRONIC MYELOID LEUKEMIA, IN RELAPSE
209.00 - 209.36	MALIGNANT CARCINOID TUMOR OF THE SMALL INTESTINE, UNSPECIFIED PORTION - MERKEL CELL CARCINOMA OF OTHER
<b>ICD-9 Codes</b>	<b>Diagnosis</b>
	SITES
209.70 - 209.79	SECONDARY NEUROENDOCRINE TUMOR, UNSPECIFIED SITE - SECONDARY NEUROENDOCRINE TUMOR OF OTHER SITES
230.0 - 238.9	CARCINOMA IN SITU OF LIP ORAL CAVITY AND PHARYNX - NEOPLASM OF UNCERTAIN BEHAVIOR SITE UNSPECIFIED
239.81	NEOPLASMS OF UNSPECIFIED NATURE, RETINA AND CHOROID
239.89	NEOPLASMS OF UNSPECIFIED NATURE, OTHER SPECIFIED SITES
285.3	ANTINEOPLASTIC CHEMOTHERAPY INDUCED ANEMIA
288.00 - 288.09	NEUTROPENIA, UNSPECIFIED - OTHER NEUTROPENIA
714.1	FELTY'S SYNDROME
V42.81	BONE MARROW REPLACED BY TRANSPLANT
V42.82	PERIPHERAL STEM CELLS REPLACED BY TRANSPLANT
V58.11	ENCOUNTER FOR ANTINEOPLASTIC CHEMOTHERAPY
V58.12	ENCOUNTER FOR IMMUNOTHERAPY FOR NEOPLASTIC CONDITION
V59.3	BONE MARROW DONORS

Jurisdiction(s): 5,8	NCD/LCD Document (s): L30306
<b>ICD-9 Codes</b>	<b>Diagnosis</b>
288.03	DRUG INDUCED NEUTROPENIA
V07.8	OTHER SPECIFIED PROPHYLACTIC OR TREATMENT MEASURE
V15.9	UNSPECIFIED PERSONAL HISTORY PRESENTING HAZARDS TO HEALTH

### Neulasta® Prior Authorization Criteria

Jurisdiction(s): 10(J)	NCD/LCD Document (s): L30026
ICD-9 Codes	Diagnosis
288.00 - 288.04	NEUTROPENIA, UNSPECIFIED - NEUTROPENIA DUE TO INFECTION
288.09	OTHER NEUTROPENIA
288.50	LEUKOCYTOPENIA, UNSPECIFIED
288.51	LYMPHOCYTOPENIA
288.59	OTHER DECREASED WHITE BLOOD CELL COUNT
V07.8	OTHER SPECIFIED PROPHYLACTIC OR TREATMENT MEASURE
V66.2	CONVALESCENCE FOLLOWING CHEMOTHERAPY

Jurisdiction(s): 6, K	NCD/LCD Document (s): A48208
ICD-9 Codes	Diagnosis
284.11	ANTINEOPLASTIC CHEMOTHERAPY INDUCED PANCYTOPENIA
288.03	DRUG INDUCED NEUTROPENIA
V07.8	OTHER SPECIFIED PROPHYLACTIC OR TREATMENT MEASURE
V15.9	UNSPECIFIED PERSONAL HISTORY PRESENTING HAZARDS TO HEALTH
V42.82	PERIPHERAL STEM CELLS REPLACED BY TRANSPLANT
V58.11	ENCOUNTER FOR ANTINEOPLASTIC CHEMOTHERAPY
V58.12	ENCOUNTER FOR IMMUNOTHERAPY FOR NEOPLASTIC CONDITION
V66.2	CONVALESCENCE FOLLOWING CHEMOTHERAPY

Jurisdiction(s): 9 (N)	NCD/LCD Document (s): L29254; L29463; L28967; L28946
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ICD-9 Codes	Diagnosis
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140.0 - 149.9	MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE LIP AND ORAL CAVITY
150.0 - 159.9	MALIGNANT NEOPLASM OF CERVICAL ESOPHAGUS - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE DIGESTIVE ORGANS AND PERITONEUM
160.0 - 165.9	MALIGNANT NEOPLASM OF NASAL CAVITIES - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE RESPIRATORY SYSTEM
170.0 - 176.9	MALIGNANT NEOPLASM OF BONES OF SKULL AND FACE EXCEPT MANDIBLE - KAPOS'I'S SARCOMA UNSPECIFIED SITE
179 - 189.9	MALIGNANT NEOPLASM OF UTERUS-PART UNS - MALIGNANT NEOPLASM OF URINARY ORGAN SITE UNSPECIFIED
190.0 - 199.2	MALIGNANT NEOPLASM OF EYEBALL EXCEPT CONJUNCTIVA CORNEA RETINA AND CHOROID - MALIGNANT NEOPLASM ASSOCIATED WITH TRANSPLANT ORGAN
200.00 - 200.88	RETICULOSARCOMA UNSPECIFIED SITE - OTHER NAMED VARIANTS OF LYMPHOSARCOMA AND RETICULOSARCOMA INVOLVING LYMPH NODES OF MULTIPLE SITES

ICD-9 Codes	Diagnosis
201.00 - 201.98	HODGKIN'S PARAGRANULOMA UNSPECIFIED SITE - HODGKIN'S DISEASE UNSPECIFIED TYPE INVOLVING LYMPH NODES OF MULTIPLE SITES
202.00 - 202.08	NODULAR LYMPHOMA UNSPECIFIED SITE - NODULAR LYMPHOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
202.10 - 202.18	MYCOSIS FUNGOIDES UNSPECIFIED SITE - MYCOSIS FUNGOIDES INVOLVING LYMPH NODES OF MULTIPLE SITES
202.20 - 202.28	SEZARY'S DISEASE UNSPECIFIED SITE - SEZARY'S DISEASE INVOLVING LYMPH NODES OF MULTIPLE SITES
202.30 - 202.38	MALIGNANT HISTIOCYTOSIS UNSPECIFIED SITE - MALIGNANT HISTIOCYTOSIS INVOLVING LYMPH NODES OF MULTIPLE SITES
202.40 - 202.48	LEUKEMIC RETICULOENDOTHELIOSIS UNSPECIFIED SITE - LEUKEMIC RETICULOENDOTHELIOSIS INVOLVING LYMPH NODES OF MULTIPLE SITES

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202.50 - 202.58	LETTERER-SIWE DISEASE UNSPECIFIED SITE - LETTERER-SIWE DISEASE INVOLVING LYMPH NODES OF MULTIPLE SITES
202.60 - 202.68	MALIGNANT MAST CELL TUMORS UNSPECIFIED SITE - MALIGNANT MAST CELL TUMORS INVOLVING LYMPH NODES OF MULTIPLE SITES
202.70 - 202.78	PERIPHERAL T CELL LYMPHOMA, UNSPECIFIED SITE, EXTRANODAL AND SOLID ORGAN SITES - PERIPHERAL T CELL LYMPHOMA, LYMPH NODES OF MULTIPLE SITES
202.80 - 202.88	OTHER MALIGNANT LYMPHOMAS UNSPECIFIED SITE - OTHER MALIGNANT LYMPHOMAS INVOLVING LYMPH NODES OF MULTIPLE SITES
203.00 - 203.82	MULTIPLE MYELOMA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER IMMUNOPROLIFERATIVE NEOPLASMS, IN RELAPSE
204.00 - 204.02	ACUTE LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - ACUTE LYMPHOID LEUKEMIA, IN RELAPSE
204.10 - 204.12	CHRONIC LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - CHRONIC LYMPHOID LEUKEMIA, IN RELAPSE
204.20 - 204.22	SUBACUTE LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - SUBACUTE LYMPHOID LEUKEMIA, IN RELAPSE
204.80 - 204.82	OTHER LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER LYMPHOID LEUKEMIA, IN RELAPSE
<b>ICD-9 Codes</b>	<b>Diagnosis</b>
209.31	MERKEL CELL CARCINOMA OF THE FACE
209.32	MERKEL CELL CARCINOMA OF THE SCALP AND NECK
209.33	MERKEL CELL CARCINOMA OF THE UPPER LIMB
209.34	MERKEL CELL CARCINOMA OF THE LOWER LIMB
209.35	MERKEL CELL CARCINOMA OF THE TRUNK
209.36	MERKEL CELL CARCINOMA OF OTHER SITES



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209.75	SECONDARY MERKEL CELL CARCINOMA
273.3	MACROGLOBULINEMIA
995.20	UNSPECIFIED ADVERSE EFFECT OF UNSPECIFIED DRUG, MEDICINAL AND BIOLOGICAL SUBSTANCE
995.29	UNSPECIFIED ADVERSE EFFECT OF OTHER DRUG, MEDICINAL AND BIOLOGICAL SUBSTANCE
V07.8	OTHER SPECIFIED PROPHYLACTIC OR TREATMENT MEASURE
V66.2	CONVALESCENCE FOLLOWING CHEMOTHERAPY

### Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
E	CA, HI, NV, AS, GU, CNMI	Noridian Administrative Services (NAS)
F	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Administrative Services (NAS)
5	KS, NE, IA, MO	Wisconsin Physicians Service (WPS)
6	MN, WI, IL	National Government Services (NGS)
H	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions
8	MI, IN	Wisconsin Physicians Service (WPS)
9 (N)	FL, PR, VI	First Coast Service Options
10 (J)	TN, GA, AL	Cahaba Government Benefit Administrators
11 (M)	NC, SC, VA, WV	Palmetto GBA
12 (L)	DE, MD, PA, NJ, DC	Novitas Solutions
K	NY, CT, MA, RI, VT, ME, NH	National Government Services (NGS)
15	KY, OH	CGS Administrators, LLC