Colony Stimulating Factors – Pegfilgrastim:
Neulasta®; Fulphila™; Udenyca®; Ziextenzo™; Nyvepria™
(Subcutaneous)

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I. Length of Authorization[1-5,10-14]

- Bone marrow transplantation (BMT) failure or engraftment delay: Coverage will be provided for 1 dose only and may not be renewed.
- Peripheral blood progenitor cell (PBPC) mobilization and transplant: Coverage will be provided for 1 dose only and may not be renewed.
- All other indications: Coverage will be provided for four months and may be renewed unless otherwise specified.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Neulasta 6 mg prefilled syringe: 1 syringe per 14 days
- Fulphila 6 mg prefilled syringe: 1 syringe per 14 days
- Udenyca 6 mg prefilled syringe: 1 syringe per 14 days
- Ziextenzo 6 mg prefilled syringe: 1 syringe per 14 days
- Nyvepria 6 mg prefilled syringe: 1 syringe per 14 days

B. Max Units (per dose and over time) [HCPCS Unit]:

	Neulasta (J2505)	Fulphila (Q5108)	Udenyca (Q5111)	Ziextenzo (Q5120)	Nyvepria (Q5122)
Acute Radiation Exposure	1 billable unit weekly x 2 doses	12 billable units weekly x 2 doses	12 billable units weekly x 2 doses	12 billable units weekly x 2 doses	12 billable units weekly x 2 doses
BMT failure or engraftment delay/ PBPC mobilization and transplant	1 billable unit x 1 dose	12 billable units x 1 dose	12 billable units x 1 dose	12 billable units x 1 dose	12 billable units x 1 dose

All other indications	1 billable unit per 14 days	12 billable units per 14 days	12 billable units per 14 days	12 billable units per 14 days	12 billable units per 14 days

III. Initial Approval Criteria [1-10,18,19]

Coverage is provided in the following conditions:

Site of care specialty infusion program requirements are met (refer to Moda Site of Care Policy).
Ziextenzo and Udenyca are the preferred long-acting granulocyte colony-stimulating factor products. • Patients must have failed, or have a contraindication, or intolerance to Ziextenzo AND Udenyca prior to consideration of any other long-acting G-CSF product.

Prophylactic use in patients with non-myeloid malignancy †

- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia* of greater than 20% §; **OR**
- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia* of 10% to 20% § **AND** one or more of the following co-morbidities:
  - Age >65 years receiving full dose intensity chemotherapy
  - Extensive prior exposure to chemotherapy
  - Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
  - Persistent neutropenia (ANC ≤ 1000/mm^3)
  - Bone marrow involvement by tumor
  - Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts)
  - Recent surgery and/or open wounds
  - Poor performance status
  - Renal dysfunction (creatinine clearance <50 mL/min)
  - Liver dysfunction (elevated bilirubin >2.0 mg/dL)
  - Chronic immunosuppression in the post-transplant setting, including organ transplant

  Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.

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

Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.

Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS]) † Φ

Bone marrow transplantation (BMT) failure or engraftment delay ‡

Peripheral blood progenitor cell (PBPC) mobilization and transplant ‡

Wilms Tumor (Nephroblastoma) [7] ‡

- Patient has favoralbe histology disease; **AND**
- Used in combination with a cyclophosphamide-based chemotherapy regimen (i.e., Regimen M or I only)

† FDA-labeled indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

*Febrile neutropenia is defined as:
– Temperature: a single temperature ≥38.3 °C orally or ≥38.0 °C over 1 hour; **AND** – Neutropenia: <500 neutrophils/mcL or <1,000 neutrophils/mcL and a predicted decline to ≤500 neutrophils/mcL over the next 48 hours
§ Expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Hematopoietic Growth Factors Clinical Practice Guideline at NCCN.org

IV. Renewal Criteria [1-10,18,19]

Note: Coverage for use in BMT failure or engraftment delay and PBPC mobilization and transplant may NOT be renewed.

Coverage for all other indications can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: splenic rupture, acute respiratory distress syndrome (ARDS), serious allergic reactions/anaphylaxis, sickle cell crisis, glomerulonephritis, leukocytosis, thrombocytopenia, capillary leak syndrome, potential for tumor growth stimulation of malignant cells, aortitis, myelodysplastic syndrome and acute myeloid leukemia, etc.

V. Dosage/Administration [1-10,13-19]

Indication	Dose

Prophylactic use in patients with non-myeloid malignancy Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy	• 6 mg subcutaneously once per chemotherapy cycle and dosed no more frequently than every 14 days • For pediatric patients weighing <45 kg: – <10 kg = 0.1 mg/kg – 10-20 kg = 1.5 mg – 21-30 kg = 2.5 mg – 31-44 kg = 4 mg
Acute Radiation Exposure (Hematopoietic Acute Radiation Syndrome)	• 6 mg subcutaneously weekly x 2 doses • For pediatric patients weighing <45 kg: – <10 kg = 0.1 mg/kg – 10-20 kg = 1.5 mg – 21-30 kg = 2.5 mg – 31-44 kg = 4 mg
BMT failure or engraftment delay PBPC mobilization and transplant	6 mg subcutaneously for 1 dose only

*Do not administer within 14 days before and 24 hours after administration of cytotoxic chemotherapy.
*Onpro On-body Injector may be applied on the same day as chemotherapy as long as the Neulasta is administered no less than 24 hours after administration of chemotherapy. Not recommended for use in patients with acute radiation exposure or in pediatric patients.

VI. Billing Code/Availability Information

HCPCS Code:

- J2505 – Injection, pegfilgrastim, 6 mg; 1 billable unit = 6 mg
- Q5108 – Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg: 1 billable unit = 0.5 mg
- Q5111 – Injection, Pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg; 1 billable unit = 0.5 mg
- Q5120 – Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg: 1 billable unit = 0.5 mg
- Q5122 – Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5 mg: 1 billable unit = 0.5 mg

NDC:

- Neulasta 6 mg prefilled syringe: 55513-0190-xx
- Neulasta 6 mg prefilled syringe Onpro Kit: 55513-0192-xx
- Fulphila 6 mg prefilled single-dose syringe: 67457-0833-xx
- Udenyca 6 mg prefilled single-dose syringe: 70114-0101-xx
- Ziextenzo 6 mg single-dose prefilled syringe: 61314-0866-xx
- Nyvepria 6 mg single-dose prefilled syringe: 00069-0324-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D61.81	Pancytopenia
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.9	Neutropenia, unspecified
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs sequela
T66.XXXA	Radiation sickness, unspecified, initial encounter
T66.XXXD	Radiation sickness, unspecified, subsequent encounter
T66.XXXS	Radiation sickness, unspecified, sequela
W88.1	Exposure to radioactive isotopes
W88.8	Exposure to other ionizing radiation
Z41.8	Encounter for other procedures for purposes other than remedying health state
Z48.290	Encounter for aftercare following bone marrow transplant
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy

ICD-10	ICD-10 Description
Z51.89	Encounter for other specified aftercare
Z52.011	Autologous donor, stem cells
Z76.89	Persons encountering health services in other specified circumstances
Z94.81	Bone marrow transplant status
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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-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/LCA):

Jurisdiction(s): 6, K	**NCD/LCD/LCA Document (s):** A52408
https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A52408&bc=gAAAAAAAAAAA&	

Jurisdiction(s): N	**NCD/LCD/LCA Document (s):** A57725
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57725&bc=gAAAAAAAAAAA	

Jurisdiction(s): J, M	**NCD/LCD/LCA Document (s):** A56748
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56748&bc=gAAAAAAAAAAA	

Jurisdiction(s): J, M	**NCD/LCD/LCA Document (s):** A54682
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A54682&bc=gAAAAAAAAAAA	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC