Long-Acting Granulocyte Colony Stimulating Factors (LA-G-CSF):
Fulphila®; Fylnetra®; Neulasta®; Nyvepria™; Pegfilgrastim-fpgk; Rolvedon®; Ryzneuta®; Stimufend®; Udenyca®; Ziextenzo®
(Subcutaneous)

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I. Length of Authorization [1-9,16-21]

Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, Fylnetra, and Stimufend/Pegfilgrastim-fpgk

- Initial: Prior authorization validity will be provided initially for 4 months, unless otherwise specified.
  - Bone marrow transplantation (BMT) failure or engraftment delay: Prior authorization validity will be provided for 1 dose only.
  - Peripheral blood progenitor cell (PBPC) mobilization and transplant: Prior authorization validity will be provided for 1 dose only.
  - Acute exposure to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS]): Prior authorization validity will be provided for 2 doses only.
- Renewal: Prior authorization validity may be renewed every 4 months thereafter, unless otherwise specified:
  - Prior authorization validity may NOT be renewed for the following indications:
    - ❖ Bone marrow transplantation (BMT) failure or engraftment delay
    - ❖ Peripheral blood progenitor cell (PBPC) mobilization and transplant
    - ❖ Acute exposure to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS])

Rolvedon, Ryzneuta

- Initial: Prior authorization validity will be provided initially for 4 months, unless otherwise specified.
  - Acute exposure to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS]): Prior authorization validity will be provided for 2 doses only.
- Renewal: Prior authorization validity may be renewed every 4 months thereafter, unless otherwise specified:
  - Acute exposure to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS]): Prior authorization validity may not be renewed.

II. Dosing Limits

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

Drug Name	Indication	Billable Units
Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, Fylnetra, and Stimufend/Pegfilgrastim-fpgk	Acute Radiation Exposure	12 billable units weekly x 2 doses
	BMT failure or engraftment delay/ PBPC mobilization and transplant	12 billable units x 1 dose
	All other indications	12 billable units per 14 days
Rolvedon	Acute Radiation Exposure	132 billable units weekly x 2 doses
	All other indications	132 billable units per 14 days
Ryzneuta	Acute Radiation Exposure	40 billable units weekly x 2 doses
	All other indications	40 billable units per 14 days

III. Initial Approval Criteria [1-9]

Prior authorization validity is provided in the following conditions:

Nyvepria and Fulphila are the preferred long-acting granulocyte colony-stimulating factor products.

- Patients must have failed, or have a contraindication, or intolerance to Nyvepria AND Fulphila prior to consideration of any other long-acting G-CSF product.

- Patient is at least 18 years of age *(Rolvedon and Ryzneuta ONLY)*; **AND**

Prophylactic use in patients with solid tumors or non-myeloid malignancy † ‡ [1-12,22,24-32]

- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia❖ of > 20% **§**; **OR**

- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia❖ of 10% to 20% **§ AND** one or more patient-related risk factors **¥**; **OR**
- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia❖ of <10% **§ AND** two or more patient-related risk factors **¥ ****

  *****Use in this setting is based on clinical judgment.***

  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 experience a neutropenic complication from a prior cycle of the same chemotherapy ‡ [11,12]

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 [1,3,4,6,7,11,12,31,32]

Bone marrow transplantation (BMT) failure or engraftment delay ‡ [16-21] *(Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, Fylnetra, and Stimufend/Pegfilgrastim-fpgk ONLY)*

Peripheral blood progenitor cell (PBPC) mobilization and transplant ‡ [11] *(Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, Fylnetra, and Stimufend/Pegfilgrastim-fpgk ONLY)*

Wilms Tumor (Nephroblastoma) ‡ [11] *(Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, Fylnetra, and Stimufend/Pegfilgrastim-fpgk ONLY)*

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

Pediatric Aggressive Mature B-Cell Lymphomas ‡ [11,38] *(Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, Fylnetra, and Stimufend/Pegfilgrastim-fpgk ONLY)*

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

¥ Patient risk factors for febrile neutropenia [12]
• Age >65 years receiving full dose intensity chemotherapy • Prior exposure to chemotherapy or radiation therapy • Persistent neutropenia • Bone marrow involvement by tumor • Human immunodeficiency virus (HIV) infection • 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
❖ Febrile neutropenia is defined as: [12]
– 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
§ Examples of incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the National Comprehensive Cancer Network (NCCN) Hematopoietic Growth Factors Clinical Practice Guideline at NCCN.org [12]

IV. Renewal Criteria [1-9]

Prior authorization validity may be renewed based upon the following criteria:

Nyvepria and Fulphila are the preferred long-acting granulocyte colony-stimulating factor products.

- Patients must have failed, or have a contraindication, or intolerance to Nyvepria AND Fulphila prior to consideration of any other long-acting G-CSF product.

- 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**
- Duration of authorization has not been exceeded *(refer to Section I)*; **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 in patients with breast and lung cancer, etc.

V. Dosage/Administration [1-9,12,16-21]

Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, Fylnetra, and Stimufend/Pegfilgrastim-fpgk

Indication	Dose
Acute Radiation Exposure (Hematopoietic Acute Radiation Syndrome)	• Administer 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	Administer 6 mg subcutaneously for 1 dose only
All other indications	• Administer 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
NOTE: • Do not administer within 14 days before and 24 hours after administration of cytotoxic chemotherapy. • Use of the pre-filled syringe products may be self-administered or administered by a caregiver or healthcare professional. • A healthcare provider must fill the on-body injector with Neulasta or Udenyca using the prefilled syringe and then apply the on-body injector to the patient's skin (abdomen or back of arm). • On-body Injectors may be applied on the same day as chemotherapy as long as the Neulasta or Udenyca 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.	

Rolvedon

Indication	Dose
Prophylactic use in patients with solid tumors or non-myeloid malignancy Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy	• Administer 13.2 mg subcutaneously once per chemotherapy cycle approximately 24 hours after cytotoxic chemotherapy
Acute Radiation Exposure (Hematopoietic Acute Radiation Syndrome)	• Administer 13.2 mg subcutaneously weekly x 2 doses

NOTE:
• Do not administer within 14 days before and 24 hours after administration of cytotoxic chemotherapy. • Rolvedon may be self-administered or administered by a caregiver or healthcare professional.

Ryzneuta

Indication	Dose
Prophylactic use in patients with solid tumors or non-myeloid malignancy Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy	• Administer 20 mg subcutaneously once per chemotherapy cycle at least 24 hours after cytotoxic chemotherapy.
Acute Radiation Exposure (Hematopoietic Acute Radiation Syndrome)	• Administer 20 mg subcutaneously weekly x 2 doses
NOTE: • Do not administer within 14 days before and 24 hours after administration of cytotoxic chemotherapy. • Ryzneuta is administered subcutaneously via a single-dose prefilled syringe by a healthcare professional.	

VI. Billing Code/Availability Information

HCPCS Code(s):

- J2506 – Injection, pegfilgrastim, excludes biosimilar, 0.5 mg; 1 billable unit = 0.5 mg *(Neulasta only)*
- 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
- Q5127 – Injection, pegfilgrastim-fpgk, biosimilar, (Stimufend), 0.5 mg; 1 billable unit = 0.5 mg *(Includes unbranded biologic[§])*
- Q5130 – Injection, pegfilgrastim-pbbk, biosimilar, (Fylnetra), 0.5 mg; 1 billable unit = 0.5 mg
- J1449 – Injection, eflapegrastim-xnst, 0.1 mg; 1 billable unit = 0.1 mg *(Rolvedon only)*
- J9361 – Injection, efbemalenograstim alfa-vuxw, 0.5 mg; 1 billable unit = 0.5 mg *(Ryzneuta only)*

NDC(s):

- Neulasta 6 mg single-dose prefilled syringe: 55513-0190-xx
- Neulasta 6 mg single-dose prefilled syringe Onpro Kit: 55513-0192-xx
- Fulphila 6 mg single-dose prefilled syringe: 83257-0005-xx
- Fulphila 6 mg single-dose prefilled syringe: 67457-0833-xx
- Udenyca 6 mg single-dose prefilled syringe: 70114-0101-xx

- Udenyca 6mg single-dose prefilled syringe: 69448-0025-xx
- Udenyca 6 mg single-dose prefilled autoinjector: 70114-0120-xx
- Udenyca 6 mg single-dose prefilled autoinjector: 69448-0026-xx
- Udenyca 6 mg single-dose prefilled syringe ONBODY kit: 70114-0130-xx
- Udenyca 6 mg single-dose prefilled syringe ONBODY kit: 69448-0027-xx
- Ziextenzo 6 mg single-dose prefilled syringe: 61314-0866-xx
- Nyvepria 6 mg single-dose prefilled syringe: 00069-0324-xx
- Fylnetra 6 mg single-dose prefilled syringe: 70121-1627-xx
- Stimufend 6 mg single-dose prefilled syringe: 65219-0371-xx
- Pegfilgrastim-fpgk 6 mg single-dose prefilled syringe: xxxxx-xxxx-xx *(Unbranded biologic of Stimufend[§])*
- Rolvedon 13.2 mg single-dose prefilled syringe: 76961-0101-xx
- Ryzneuta 20 mg/mL prefilled syringe: 72893-0016-xx

[§]*An unbranded biologic is the same as the brand biologic and uses the same cell-line as the brand-name reference biologic.*

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, Fylnetra, & Stimufend/Pegfilgrastim-fpgk

ICD-10	ICD-10 Description
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
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C83.30	Diffuse large B-cell lymphoma unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb

ICD-10	ICD-10 Description
C83.36	Diffuse large B-cell lymphoma intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma extranodal and solid organ sites
C83.70	Burkitt lymphoma, unspecified site
C83.71	Burkitt lymphoma, lymph nodes of head, face, and neck
C83.72	Burkitt lymphoma, intrathoracic lymph nodes
C83.73	Burkitt lymphoma, intra-abdominal lymph nodes
C83.74	Burkitt lymphoma, lymph nodes of axilla and upper limb
C83.75	Burkitt lymphoma, lymph nodes of inguinal region and lower limb
C83.76	Burkitt lymphoma, intrapelvic lymph nodes
C83.77	Burkitt lymphoma, spleen
C83.78	Burkitt lymphoma, lymph nodes of multiple sites
C83.79	Burkitt lymphoma, extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
D61.810	Antineoplastic chemotherapy induced pancytopenia
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

ICD-10	ICD-10 Description
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
Z51.89	Encounter for other specified aftercare
Z52.011	Autologous donor, stem cells
Z52.091	Other blood 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

Rolvedon & Ryzneuta

ICD-10	ICD-10 Description
D61.810	Antineoplastic chemotherapy induced pancytopenia
D61.811	Other drug-induced pancytopenia
D61.818	Other pancytopenia
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
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy
Z51.89	Encounter for other specified aftercare
Z76.89	Persons encountering health services in other specified circumstances

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local

Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
J, M	A56748	Palmetto GBA
J, M	A54682	Palmetto GBA

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.
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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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