MEDICAL MUTUAL®

Drug Policy

Policy:	**201827-MRX**	**Initial Effective Date: 10/30/2014**
Code(s):	**HCPCS J2506, Q5108, Q5111, Q5120, Q5122, Q5127, Q5130, J1449, J3590**	**Annual Review Date: 04/17/2025**
SUBJECT:	**Long-Acting Granulocyte Colony Stimulating Factors – Pegfilgrastim, Eflapegrastim, Efbemalenograstim alfa** - **Neulasta® (Pegfilgrastim)** - **Fulphila™ (pegfilgrastim-jmdb)** - **Nyvepria™ (pegfilgrastim-apgf)** - **Udenyca™ (pegfilgrastim-cbqv)** - **Ziextenzo (pegfilgrastim-bmez)** - **Fylnetra (pegfilgrastim-pbbk)** - **Stimufend (pegfilgrastim-fpgk)** - **Rolvedon (eflapegrastim-xnst)** - **Ryzneuta (efbemalenograstim alfa);** - **Pegfligrastim-fpgk**	**Last Revised Date: 05/21/2025**

Subject to: ☐Site of Care
☐Medication

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

POLICY STATEMENT

This policy involves the use of pegfilgrastim products. Prior authorization is recommended for medical benefit coverage of pegfilgrastim products. Approval is recommended for those who meet the conditions of coverage in the **Initial Approval and Renewal Criteria, Preferred Drug (when applicable), Dosing/Administration, Length of Authorization, and Site of Care (when applicable)** for the diagnosis provided. The requirement that the patient meet the Criteria and Preferred Drug for coverage of the requested medication applies to the initial authorization only. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy.

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

- 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.
- Acute exposure to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS]): Coverage will be provided for 2 doses 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

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]

Coverage is provided in the following conditions:

- **If the request is for Nyvepria, Udenyca, Ziextenzo, Fylnetra, Stimufend, Rolvedon, Ryzneuta, or pegfligrastim- fpgk, the patient had an inadequate response, or has a contraindication or intolerance to Neulasta or Fulphila; AND**
- Patient is at least 18 years of age *(Rolvedon and Ryzneuta ONLY)*; **AND**

Prophylactic use in patients with solid tumors or non-myeloid malignancy † ‡ [1-12,22,24-30]

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

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

  <u>Note</u>: 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 ‡ [16-20] *(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)

† 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 (ANC ≤ 1000/mm3) • 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
❖ 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
§ 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 [12]

IV. Renewal Criteria [1-9,16-21]

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

- **If the request is for Nyvepria, Udenyca, Ziextenzo, Fylnetra, Stimufend, Rolvedon, Ryzneuta, or pegfligrastim- fpgk, the patient had an inadequate response, or has a contraindication or intolerance to Neulasta or Fulphila; AND**
- 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 in patients with breast and lung cancer, etc.; **AND**

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

- Coverage may not be renewed

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

- Coverage may not be renewed

Acute exposure to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS])

- Coverage may not be renewed

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

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

Indication	Dose
Prophylactic use in patients with non-myeloid malignancy Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy	• 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

Wilms Tumor (Nephroblastoma)	– 31-44 kg = 4 mg
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
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 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 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
- Udenyca 6 mg single-dose prefilled syringe: 70114-0101-xx
- Udenyca 6 mg single-dose prefilled autoinjector: 70114-0120-xx
- Udenyca 6 mg single-dose prefilled syringe ONBODY kit: 70114-0130-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: 73491-0627-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 1 – Covered Diagnosis Codes

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

ICD-10	ICD-10 Description
D61.810	Antineoplastic chemotherapy induced 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
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

ICD-10	ICD-10 Description
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,	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	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drugs provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for HCPCS Codes J2506, Q5108, Q5111, Q5120, Q5122, Q5127, Q5130, J1449, J3590