



## Medical Pharmacy Drug Prior Authorization Criteria

<b>Drug Trade Name:</b>	See Below	<b>Drug Generic Name:</b>	Pegfilgrastim
<b>J Code:</b>	See Below	<b>1 billable unit =</b>	0.5 mg
<b>Original Date of Review:</b>	12/7/2022	<b>Last Reviewed:</b>	12/03/2025
<b>Revision Date History</b>	12/7/2022, 3/15/2023, 12/13/2023, 6/12/2024, 12/11/2024		

**Drug Trade Name (J Code):** Neulasta® (J2506), Fulphila® (Q5108), Udenyca® (Q5111), Ziextenzo® (Q5120), Nyvepria™ (Q5122), Stimufend® (Q5127), Fylnetra® (Q5130)

Pegfilgrastim is a colony stimulating factor that acts on hematopoietic cells by binding to specific cell surface receptors thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

**Criteria:**

- **Length of authorization:**
  - 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.
- **Age: see below for product specific requirements**
- **Diagnoses [including ICD-10 codes]: see below**
- **Quantity Limit:**
  - Neulasta® 6 mg prefilled syringe: 1 syringe per 14 days
  - Neulasta® Onpro kit: 1 kit per 14 days
  - Fulphila® 6 mg prefilled syringe: 1 syringe per 14 days
  - Stimufend® 6mg prefilled syringe: 1 syringe per 14 days
  - Udenyca® 6 mg prefilled syringe: 1 syringe per 14 days
  - Udenyca® 6 mg Onbody kit: 1 kit per 14 days
  - Udenyca® 6mg prefilled autoinjector: 1 pen per 14 days
  - Ziextenzo® 6 mg prefilled syringe: 1 syringe per 14 days
  - Nyvepria™ 6 mg prefilled syringe: 1 syringe per 14 days
  - Fylnetra® 6 mg prefilled syringe: 1 syringe per 14 days
- **Maximum Units:**

Indication	Billable Units
Acute radiation exposure	12 billable units weekly x 2 doses
BMT failure or engraftment delay/PBPC mobilization and transplant	12 billable units weekly x 1 dose
All other indications	12 billable units per 14 days

- **Initial Approval Criteria**
  - **Indication Specific Criteria**
    - **Prophylactic use in patients with solid tumors or non-myeloid malignancy**
      - Patient is undergoing treatment regimen that the National Comprehensive Cancer Network recommends inclusion of Pegfilgrastim as standard of care.
      - 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  $\leq$  1000/mm<sup>3</sup>)
        - 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 experience 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])**
    - **Bone marrow transplantation (BMT) failure or engraftment delay**
    - **Peripheral blood progenitor cell (PBPC) mobilization and transplant**
    - **Wilms Tumor (Nephroblastoma)**
- **Renewal Criteria**
  - 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 universal criteria; **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.

- **Dosage/Administration**

<b>Pegfilgrastim</b>	
<b>Indication</b>	<b>Dose</b>
Prophylactic use in patients with non-myeloid malignancy Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy	<ul style="list-style-type: none"> <li>• 6 mg subcutaneously once per chemotherapy cycle and dosed no more frequently than every 14 days</li> <li>• For pediatric patients weighing &lt;45 kg:               <ul style="list-style-type: none"> <li>○ &lt;10 kg = 0.1 mg/kg</li> <li>○ 10-20 kg = 1.5 mg</li> <li>○ 21-30 kg = 2.5 mg</li> <li>○ 31-44 kg = 4 mg</li> </ul> </li> </ul>
Acute Radiation Exposure (Hematopoietic Acute Radiation Syndrome)	<ul style="list-style-type: none"> <li>• 6 mg subcutaneously weekly x 2 doses</li> <li>• For pediatric patients weighing &lt;45 kg:               <ul style="list-style-type: none"> <li>○ &lt;10 kg = 0.1 mg/kg</li> <li>○ 10-20 kg = 1.5 mg</li> <li>○ 21-30 kg = 2.5 mg</li> <li>○ 31-44 kg = 4 mg</li> </ul> </li> </ul>
BMT failure or engraftment delay PBPC mobilization and transplant	<ul style="list-style-type: none"> <li>• 6 mg subcutaneously for 1 dose only</li> </ul>

**NDC:**

- Neulasta® 6 mg prefilled syringe: 55513-0190-01
- Neulasta® 6 mg prefilled syringe Onpro Kit: 55513-0192-01
- Fulphila® 6 mg prefilled single-dose syringe: 67457-0833-06
- Udenyca® 6 mg prefilled single-dose syringe: 70114-0101-01
- Udenyca® 6mg prefilled syringe Onbody kit: 70114-0130-01
- Udenyca® 6mg prefilled autoinjector: 70114-0120-01
- Ziextenzo® 6 mg single-dose prefilled syringe: 61314-0866-01
- Nyvepria™ 6 mg single-dose prefilled syringe: 00069-0324-01
- Fylnetra® 6 mg single-dose prefilled syringe: 70121-1627-01
- Stimufend® 6 mg single-dose prefilled syringe: 65219-0371-10

**References:**

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4. Ziextenzo® [package insert]. Princeton, NJ; Sandoz, Inc; March 2021. Accessed March 2022.

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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
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