Pegfilgrastim (Neulasta®, Neulasta On-Body Injector®) **Pegfilgrastim-apgf (Nyvepria™)** **Pegfilgrastim-bmez (Ziextenzo™)** **Pegfilgrastim-cbqv (Udenyca®)** **Pegfilgrastim-fpgk (Stimufend®)** **Pegfilgrastim-jmdb (Fulphila®)** **Pegfilgrastim-pbbk (Fylnetra™)**	**Place of Service** **Home Infusion Administration** **Self-Administration** **Office Administration** **Outpatient Facility Infusion Administration** **Infusion Center Administration** **HCPCS** Neulasta: **J2506** per 0.5 mg Fulphila: **Q5108** per 0.5 mg Udenyca: **Q5111** per 0.5 mg Ziextenzo: **Q5120** per 0.5 mg Nyvepria: **Q5122** per 0.5 mg Stimufend: **Q5127** per 0.5 mg Fylnetra: **Q5130** per 0.5 mg

Conditions listed in policy *(see criteria for details)*

- Acute exposure to myelosuppressive radiation
- Bone marrow transplantation
- Non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia

AHFS therapeutic class: hematopoietic agents

Mechanism of action: colony stimulating factor

(1) Special Instructions and Pertinent Information

If covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

Fulphila, Fylnetra, Nyvepria, Stimufend, Udenyca and Ziextenzo are the preferred pegfilgrastim products. Request for Neulasta for members newly initiating pegfilgrastim therapy will require treatment failure or intolerance to all the preferred drugs or contraindication to all the preferred drugs for certain indications.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for pegfilgrastim must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acute exposure to myelosuppressive doses of radiation

Covered Doses
Up to two doses of 6 mg each, SC one week apart

Coverage Period
1 month

ICD-10:
T66.X

Bone marrow transplantation

1. If for Neulasta: Intolerable side effect with the preferred pegfilgrastim products, Fulphila, Fylnetra, Nyvepria, Stimufend, Udenyca and Ziextenzo, that is not expected with Neulasta, or contraindication to all preferred pegfilgrastim products

Covered Doses
Up to 6 mg SC x 1

Coverage Period
One dose

CPT:
38240, 38241

ICD-10:
Z48.290, Z52.011, Z94.81, Z94.84

Non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia

1. Drug is administered while patient is receiving myelosuppressive chemotherapy medications [J9000 series] **AND**
2. Drug is administered every 14 days or more, **AND**
3. Drug is not being used concurrently with long-acting or short-acting granulocyte colony stimulating factors (e.g. filgrastim or pegfilgrastim drugs), **AND**
4. If for Neulasta: Intolerable side effect with the preferred pegfilgrastim products, Fulphila, Fylnetra, Nyvepria, Stimufend, Udenyca and Ziextenzo, that is not expected with Neulasta, or contraindication to all preferred pegfilgrastim products

Covered Doses
One single 6 mg dose given subcutaneously per chemotherapy cycle

Coverage Period
Length of chemotherapy

ICD-10:
C00.0-C91.91, D00.00-D49.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice.
All requests for pegfilgrastim must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s):
Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Combination use of granulocyte-colony stimulating factor (G-CSF) drugs (e.g., Granix, Leukine, Neupogen, Nivestym, Zarxio, Fulphila, Udenyca) or using more than one G-CSF drug during a single chemotherapy cycle for neutropenia prophylaxis due to myelosuppressive chemotherapy
- Acute myeloid leukemia receiving induction or consolidation chemotherapy
- Peripheral blood progenitor cell collection and therapy
- Peginterferon induced neutropenia
- Severe chronic neutropenia remains to be proven
- Rescue therapy mid-cycle *(Neulasta® is not indicated for treatment of neutropenia)*

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

Neulasta

- 6 mg per 0.6 mL single-dose prefilled syringe
- 6 mg/0.6 mL solution in a single-dose prefilled syringe co-packaged with the On-body Injector. *A healthcare provider fills the On-body Injector with Neulasta using the co-packaged prefilled syringe. The On-body Injector is applied to the abdomen or back of arm. Approximately 27 hours after placed, Neulasta will be delivered over approximately 45 minutes.*

Fulphila

- 6 mg/0.6 mL single-dose prefilled syringe

Fylnetra

- 6 mg/0.6 mL single-dose prefilled syringe

Nyvepria

- 6 mg/0.6 mL single-dose prefilled syringe

Udenyca

- 6 mg/0.6 mL single-dose prefilled syringe

Ziextenzo

- 6 mg/0.6 mL single-dose prefilled syringe

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Fulphila® (pegfilgrastim-jmdb) [Prescribing Information]. Morgantown, WV: Mylan Pharmaceuticals Inc.; 3/2021.
- Fylnetra™ (pegfilgrastim-pbbk) [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; 5/2022.
- National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 2.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (Version 1.2023). Available at: www.nccn.org.
- Nyvepria™ (pegfilgrastim-apgf) [Prescribing Information]. New York, NY: Pfizer Inc.; 3/2023.
- Neulasta® (pegfilgrastim) [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; 2/2021.

- Stimufend® (pegfilgrastim-fpgk) [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; 9/2022.
- Udenyca® (pegfilgrastim-cbqv) [Prescribing Information]. Redwood City, CA: Coherus BioSciences, Inc.; 6/2021.
- Ziextenzo® (pegfilgrastim-bmez) [Prescribing Information]. Princeton, NJ: Sandoz, Inc.; 3/2021.

(7) Policy Update

Date of last review: 1Q2024

Date of next review: 1Q2025

Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee