PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Pegfilgrastim (Fulphila, Neulasta, Nyvepria, Udenyca, Ziextenzo, Stimufend, Fylentra)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Pegfilgrastim is a colony stimulating factor with a prolonged duration of effect that boosts the production and activation of neutrophils in individuals who are immunosuppressed as a result of myelosuppressive chemotherapy or exposure to myelosuppressive does of radiation.

It was initially approved by the FDA in 2002 as Neulasta. Since then, the FDA has approved the following biosimilars: Udenyca (2018), Fulphila (2018), Ziextenzo (2019), Nyvepria (2020), Stimufend (2022), and Fylentra (2022). All of the biosimilar pegfilgrastim products share the indication for prevention of febrile neutropenia due to myelosuppressive chemotherapy; however, only Neulasta is approved to increase survival in patients acutely exposed to radiation.

Pegfilgrastim will be considered for coverage when the following criteria are met:

Hematopoietic Syndrome of Acute Radiation Syndrome (ARS) – Neulasta Only

For **initial** authorization:

1. Medication is prescribed by a physician with expertise in treating acute radiation syndrome; AND
2. Member has documented suspected or confirmed exposure to radiation levels greater than 2 Gray (Gy).
   Note: The member's absorbed radiation level can be estimated based on information provided by public health authorities, biodosimetry, or clinical findings such as time to onset of vomiting.
3. **Dosage allowed/Quantity limit:**
   a) **Adults:** Two 6 mg doses administered one week apart (2 units per 28 days)

If all the above requirements are met, the medication will be approved for 14 days.

For **reauthorization**:

1. Neulasta will not be reauthorized for the same radiation phase after 2 allowed doses. If another round of radiation therapy is needed in the future, the initial authorization criteria will be applied.

Prevention of Febrile Neutropenia

All oncology treatments, including supportive therapies such as pegfilgrastim, must be submitted to Eviti Connect for review via the NantHealth Eviti Connect portal. For additional information and details, please refer to the CareSource policy statement "Oncology Treatment Regimen Review."

Dosage allowed/Quantity limit: Up to 6 mg per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy (2 units per 28 days).

CareSource considers pegfilgrastim not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
5/27/2022	New policy for pegfilgrastim products. NantHealth link added for prevention of febrile neutropenia.
7/9/2024	Annual Review. No updates.

References:

1. Nyvepria [package insert]. New York, NY: Pfizer Inc; 2020. Accessed May 27, 2022.
2. Ziextenzo [package insert]. Princeton, NJ: Sandoz Inc; 2019 Accessed May 27, 2022.
3. NCCN Guidelines for Hematopoietic Growth Factors, Version 1.2022, Pages MGF-1 through MGF-D.
4. National Comprehensive Cancer Network. (2022). NCCN Drugs & Biologics Compendium™. Pegfilgrastim. Retrieved May 27, 2022. from the National Comprehensive Cancer Network.
5. Neulasta. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed May 27, 2022.
6. Neulasta [package insert]. Thousand Oaks, CA: Amgen Inc; 2016. Accessed March 15, 2017.
7. Neulasta. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed March 15, 2017.
8. Udenyca [prescribing information]. Redwood City, CA: Coherus BioSciences, Inc.; September 2019.
9. NCCN Guidelines for Hematopoietic Growth Factors, Version 1.2020, Pages MGF-1 through MGF-C.
10. Fulphila [package insert]. Rockford, IL: Mylan Institutional LLC.; June 2018.
    U.S. Food and Drug Administration. Media release. FDA approved first biosimilar to Nulasta to help reduce the risk of infection during cancer treatment. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm609805.htm. Accessed on July 25, 2018.

Effective date: 10/01/2024
Revised date: 07/09/2024