Policy Title:	Long-Acting Granulocyte Colony Stimulating Factor (G-CSFs) Policy: Fulphila (pegfilgrastim-jmdb), Fylnetra (pegfilgrastim-pbbk) Neulasta (pegfilgrastim), Neulasta (pegfilgrastim) Onpro, Nyvepria (pegfilgrastim-apgf), Rolvedon (eflapegrastim-xnst), Stimufend (pegfilgrastim-fpgk), Udenyca (Pegfilgrastim-cbqv), Ziextenzo (pegfilgrastim-bmez)(subcutaneous) **NON-ONCOLOGY POLICY**		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	04/19/2019, 09/18/2019, 12/18/2019, 1/29/2020, 8/03/2020, 7/22/2021, 6/16/2022, 10/6/2022, 2/16/2023, 7/13/2023, 12/07/2023, 01/04/2024		

Purpose: To support safe, effective, and appropriate use of Long-Acting Granulocyte Colony Stimulating Factors.

Scope: Medicaid*, Commercial, Medicare-Medicaid Plan (MMP)
***Effective 8/1/2023: Medication is only available on the medical benefit**

Policy Statement:
Long-Acting Granulocyte Colony Stimulating Factors are covered under the Medical Benefit when used within the following guidelines for non-oncology indications. Use outside of these guidelines may result in non-payment unless approved under an exception process. Neulasta (pegfilgrastim), Neulasta Onpro (pegfilgrastim) or Udenyca (Pegfilgrastim-cbqv) are the preferred long-acting colony stimulating factors.
For oncology indications, please refer to Myeloid Growth Factors Policy.

Procedure:

Coverage of Long-Acting Granulocyte Colony Stimulating Factors will be reviewed prospectively via the prior authorization process based on criteria below.

Summary of Evidence:

Clinical trials evaluating the efficacy and safety of long-acting G-CSFs have demonstrated their effectiveness in reducing the incidence of febrile neutropenia in patients receiving myelosuppressive chemotherapy. These agents stimulate the production of neutrophils, thereby reducing the duration and severity of neutropenia and its associated complications. Clinical trials have shown redecutions in hospitalization and febrile neutropenia in addition to positive labratory outcomes. The most common adverse reaction reported is bone pain.

Criteria:

Patient has one of the following conditions:

- Bone marrow transplantation (BMT) failure or engraftment delay; OR
- Peripheral blood progenitor cell (PBPC) mobilization and transplant; AND

- For patients requesting Fulphila (pegfilgrastim-jmdb), Fylnetra (pegfilgrastim-pbbk), Rolvedon (eflapegrastim-xnst), Stimufend (pegfilgrastim-fpgk), Ziextenzo (pegfilgrastim-bmez) or Nyvepria (pegfilgrastim-apgf), they must have a documented failure, contraindication, or intolerance to Neulasta (pegfilgrastim), Neulasta (pegfilgrastim) Onpro, or Udenyca (Pegfilgrastim-cbqv); OR
- For patients that are currently on treatment with Fulphila (pegfilgrastim-jmdb), Fylnetra (pegfilgrastim-pbbk), Rolvedon (eflapegrastim-xnst), Stimufend (pegfilgrastim-fpgk), Ziextenzo (pegfilgrastim-bmez) or Nyvepria (pegfilgrastim-apgf) they can remain on treatment OR MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Coverage durations: 4 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Fulphila, Fylnetra, Neulasta, Neulasta Onpro, Nyvepria, Rolvedon, Stimufend, Udenyca, and Ziextenzo were reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Fulphilia, Fynetra, Neulasta, Neulasta Onpro, Nyvepria, Rolvedon, Stimufend, Udenyca, and Ziextenzo according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using these drugs for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosage/Administration:

Indication	**Dosing**	**Maximum Dosing (1 billable unit = 0.5 mg)**
BMT failure or engraftment delay PBPC mobilization and transplant	<10kg = 0.1mg/kg 10-20 kg = 1.5 mg 21-30 kg = 2.5 mg 31-44 kg = 4 mg 45 kg and up = 6 mg Dosed no more frequently than every 14 days.	12 billable units per 14 days for Fulphila, Nyvepria, Udenyca & Ziextenzo 1 billable unit per 14 days for Neulasta

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer

Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

HCPCS/CPT Code	Description
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5mg
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5mg
Q5122	Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5mg
J2506	Injection, pegfilgrastim, 6mg
Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg
Q5130	Injection, pegfilgrastim-pbbk (Fylnetra), biosimilar, 0.5mg
J1449	Injection, eflapergrastim-xnst (Rolvedon), 0.1mg
Q5122	Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5mg

References:

1. Fulphila [package insert]. Zurich, Switzerland; Mylan GmbH; October 2021. Accessed November 2023.
2. Neulasta [package insert]. Thousand Oaks, CA; Amgen Inc; March 2021. Accessed November 2023.
3. Udenyca [package insert]. Redwood City, California; Coherus Biosciences; March 2023. Accessed November 2023.
4. Ziextenzo [package insert]. Princeton, NJ; Sandoz, Inc; March 2021. Accessed November 2023.
5. Nyvepria [package insert]. Lake Forest, IL; Pfizer Oncology; June 2023. Accessed November 2023.
6. Fylnetra [package insert]. Bridgewater, NJ; Amneal Pharmaceuticals LLC; May 2022. Accessed November 2023.
7. Rolvedon [package insert]. Irvine, CA; Spectrum Pharmaceuticals, Inc; June 2023. Accessed November 2023.
8. Stimufend. [package insert]. Lake Zurich, IL; Fresenius Kabi; October 2023. Accessed November 2023.
9. Staber, P. B., et al. "Fixed-dose single administration of Pegfilgrastim vs daily Filgrastim in patients with haematological malignancies undergoing autologous peripheral blood stem cell transplantation." Bone marrow transplantation 35.9 (2005): 889-893.
10. Vanstraelen, Gaëtan, et al. "Pegfilgrastim compared with Filgrastim after autologous hematopoietic peripheral blood stem cell transplantation." Experimental hematology 34.3 (2006): 382-388.

11. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Human Granulocyte/Macrophage Colony Stimulating Factors (L34699). Centers for Medicare & Medicaid Services, Inc. Updated on 9/19/2018 with effective date 10/1/2018. Accessed October 2018.
12. First Coast Service Options, Inc. Local Coverage Determination (LCD): Pegfilgrastim (Neulasta®) (L33747). Centers for Medicare & Medicaid Services, Inc. Updated on 9/22/2017 with effective date 10/1/2017. Accessed October 2018.
13. Palmetto GBA. Local Coverage Determination: White Cell Colony Stimulating Factors (L37176). Centers for Medicare & Medicaid Services, Inc. Updated on 10/11/2018 with effective date 10/18/2018. Accessed October 2018.
14. National Government Services, Inc. Local Coverage Article: Filgrastim, Pegfilgrastim, Tbo-filgrastim, Filgrastim-sndz (e.g., Neupogen®, Neulasta™, Granix™, Zarxio™) - Related to LCD L33394 (A52408). Centers for Medicare & Medicaid Services, Inc. Updated on 10/13/2018 with effective date 10/01/2018. Accessed October 2018.