Policy Title:	Long Acting Granulocyte Colony Stimulating Factor (G-CSFs) Policy: Fulphila (pegfilgrastim-jmdb), Neulasta(pegfilgrastim), Nyvepria (pegfilgrastim-apgf), 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, 7/29/2021		
Revision Date:	04/19/2019, 09/18/2019, 1/29/2020, 8/03/2020, 7/29/2021		

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

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

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 Onpro (pegfilgrastim) or Ziextenzo (pegfilgrastim-bmez) 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.

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
- Patients must have a documented failure, contraindication, or intolerance to Zarxio (filgrastim-sndz); AND
- Patients must have a documented failure, contraindication, or intolerance to Neulasta Onpro (pegfilgrastim) or Ziextenzo (pegfilgrastim-bmez); OR
- For patients that are currently on treatment with Fulphila (pegfilgrastim-jmdb), Udenyca (Pegfilgrastim-cbqv) 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
*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

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
J2505	Injection, pegfilgrastim, 6mg
Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg

References:

1. Fulphila [package insert]. Zurich, Switzerland; Mylan GmbH; March 2021. Accessed July 2021.
2. Neulasta [package insert]. Thousand Oaks, CA; Amgen Inc; March 2021. Accessed July 2021.
3. Udenyca [package insert]. Redwood City, California; Coherus Biosciences; June 2021. Accessed July 2021.
4. Ziextenzo [package insert]. Princeton, NJ; Sandoz, Inc; March 2021. Accessed July 2021.
5. Nyvepria [package insert]. Lake Forest, IL; Pfizer Oncology; April 2021. Accessed July 2021.
6. 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.
7. Vanstraelen, Gaëtan, et al. "Pegfilgrastim compared with Filgrastim after autologous hematopoietic peripheral blood stem cell transplantation." Experimental hematology 34.3 (2006): 382-388.
8. 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.
9. 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.
10. 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.
11. 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.