Policy Title:	Fulphila (pegfilgrastim-jmdb) (subcutaneous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	04/19/2019, 09/18/2019, 12/18/19		
Revision Date:	04/19/2019, 09/18/2019		

Purpose: To support safe, effective and appropriate use of Fulphila (pegfilgrastim-jmdb).

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

Policy Statement:

Fulphila (pegfilgrastim-jmdb) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process. Neulasta (pegfilgrastim) or Udenyca (Pegfilgrastim-cbqv) are the preferred long acting colony stimulating factors.

Procedure:

Coverage of Fulphila will be reviewed prospectively via the prior authorization process based on criteria below.

Criteria:

- Patient must be using for prophylactic with non-myeloid malignancy:
  - Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 20% or greater *; OR
  - Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% or greater * AND one or more of the following co-morbidities:
    - Elderly patients (age >65)
    - History of recurrent febrile neutropenia from chemotherapy
    - Extensive prior exposure to chemotherapy
    - Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
    - Persistent neutropenia (ANC $\leq 1000/mm^3$)
    - Bone marrow involvement with tumor
    - Patient has a condition that can potentially increase the risk of serious infection (i.e. HIV/AIDS)
    - Infection/open wounds

- Recent surgery
- Poor performance status
- Poor renal function (creatinine clearance <50)
- Liver dysfunction (elevated bilirubin >2.0)
- Chronic immunosuppression in the post-transplant setting including organ transplant

- Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy; OR
- Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome); OR
- 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 Neulasta (pegfilgrastim) or Udenyca (Pegfilgrastim-cbqv) OR
- For patients that are currently on treatment with Fulphila (pegfilgrastim-jmdb) they can remain on treatment

Coverage durations: 4 months
*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

***** *Expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Myeloid Growth Factors Clinical Practice Guideline at NCCN.org*

Dosage/Administration:

Indication	**Dosing**	**Maximum Dosing (1 billable unit = 0.5 mg)**
All other indications*	<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
Acute Radiation Exposure	6 mg subcutaneously weekly x 2 doses (Use weight based dosing for pediatrics weighing < 45 kg)	12 billable units weekly x 2 doses

*Do not administer within 14 days before and 24 hours after administration of cytotoxic chemotherapy

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

References:

1. Fulphila [package insert]. Zurich, Switzerland; Mylan GmbH; September 2018. Accessed October 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) pegfilgrastim. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myeloid Growth Factors. Version 2.2018. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To

view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2018.

4. Russel N, Mesters R, Schubert J, et al. A phase 2 pilot study of pegfilgrastim and filgrastim for mobilizing peripheral blood progenitor cells in patients with non-Hodgkin's lymphoma receiving chemotherapy. Haematologica March 200893:405-412;doi:10.3324/haematol.11287
5. Isidori A, Tani M, Bonifazi F, et al. Phase II study of a single pegfilgrastim injection as an adjunct to chemotherapy to mobilize stem cells into the peripheral blood of pretreated lymphoma patients. Haematologica January 200590:225-231
6. Jagasia MH, Greer JP, Morgan DS, et al. Pegfilgrastim after high-dose chemotherapy and autologous peripheral blood stem cell transplant: phase II study. Bone Marrow Transplant. 2005 Jun;35(12):1165-9.
7. Bruns, Ingmar, et al. "A single dose of 6 or 12 mg of pegfilgrastim for peripheral blood progenitor cell mobilization results in similar yields of CD34+ progenitors in patients with multiple myeloma." Transfusion 46.2 (2006): 180-185.
8. 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.
9. Vanstraelen, Gaëtan, et al. "Pegfilgrastim compared with Filgrastim after autologous hematopoietic peripheral blood stem cell transplantation." Experimental hematology 34.3 (2006): 382-388.
10. 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.
11. 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.
12. 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.
13. 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.