

Policy Title:	Fulphila (pegfilgrastim-jmdb)		
Policy Number:	000666	Department:	PHA
Effective Date:	07/01/2019		
Review Date:	04/19/2019		
Revision Date:	04/19/2019		

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

Scope: Medicaid, Exchange, Integrity

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 Coverage for Medicaid and Exchange:

- 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 or older)
 - 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
 - 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).

Criteria Coverage for Integrity:

- 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 or older)
 - 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
 - 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.

Coverage durations: 4 months

§ 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

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 one of the above listed resources. 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 codes are:

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

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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 2008;93:405-412;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 2005;90:225-231
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.