Medical Policy:

Colony Stimulating Factors: Fulphila™ (pegfilgrastim-jmdb)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.61	March 18, 2025	

Definitions

Fulphila is a colony stimulating factor that acts on hematopoietic cells by binding to specific cell surface receptors thereby stimulating proliferation, differentiation, commitment, and end cell functional activation

Length of Authorization

Coverage will be provided for six months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time)

- Acute radiation exposure
  - 12 billable units weekly for 2 doses
- All other indications:
  - 12 billable units per 14 days for all other indications

Guideline

I. Initial Approval Criteria

Fulphila *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

Neulasta and Udenyca are the preferred agents for Commercial, Medicaid, and Medicare members.

1. The patient has failed treatment with Neulasta **AND** Udenyca or they are contraindicated ††; **OR**
2. The patient is continuing previously established therapy with *Fulphila* for their current chemotherapy regimen; **AND**
3. A member does not have access to, or benefits for, home health services; **OR**
4. A member is expected to receive G-CSF for 5 consecutive days or more; **OR**
5. Fulphila is used in combination with one of the following chemotherapy regimens*:
   A. Bladder Cancer:
      i. Dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
   B. Breast Cancer:
      i. Dose dense AC followed by T (doxorubicin, cyclophosphamide, paclitaxel)
   C. Non-Hodgkin's Lymphoma:
      i. Dose dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone)

†† Commercial, Medicaid, AND Medicare members are subject to this step therapy

** Pegylated filgrastim is the only G-CSF product used in the published clinical trials for these regimens. The requesting provider should provide journal citations supporting this request for regimens other than those listed.*

Coverage for Fulphila™ (pegfilgrastim-jmdb) is provided in the following conditions:

Prophylactic use in patients with solid tumors or non-myeloid malignancy†

1. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia ❖ of greater than 20% §; **OR**
2. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia ❖of 10% to 20% § **AND** one or more patient-related risk factors ¥;
3. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia ❖ of <10% **AND** two or more patient related risk factors ¥ **

   ***Use in this setting is based on clinical judgment.*

   Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.

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

¥ Patient risk factors for febrile neutropenia
• Age >65 years receiving full dose intensity chemotherapy • Prior exposure to chemotherapy or radiation therapy • Persistent neutropenia (ANC ≤ 1000/mm3) • Bone marrow involvement by tumor • Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts) • Recent surgery and/or open wounds

- Poor performance status
- Renal dysfunction (creatinine clearance <50 mL/min)
- Liver dysfunction (elevated bilirubin >2.0 mg/dL)
- Chronic immunosuppression in the post-transplant setting, including organ transplant

❖ Febrile neutropenia is defined as:

- Temperature: a single temperature ≥38.3 °C orally or ≥38.0 °C over 1 hour; AND
- Neutropenia: <500 neutrophils/mcL or <1,000 neutrophils/mcL and a predicted decline to ≤500 neutrophils/mcL over the next 48 hours

Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy ‡

Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome) ‡

†FDA-labeled indication, ‡ Compendia recommended indication

§ 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

II. Renewal Criteria

Same as initial prior authorization policy criteria

III. Dosage/Administration

Indication	Dose
Acute radiation exposure	6 mg subcutaneously weekly for 2 doses (Use weight based dosing for pediatrics weight < 45 kg)
All other indications	6 mg subcutaneously once per chemotherapy cycle and dosed no more frequently than every 14 days (Use weight based dosing for pediatric patients weighing less than 45 kg)

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

Applicable Procedure Codes

Code	Description
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg

Applicable NDCs

Code	Description
67457-0833-06	Fulphila 6 mg prefilled syringe

ICD-10 Diagnoses

Code	Description
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.9	Neutropenia, unspecified
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs sequela
Z41.8	Encounter for other procedures for purposes other than remedying health state

Z48.290	Encounter for aftercare following bone marrow transplant
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy
Z51.89	Encounter for other specified aftercare
Z52.001	Unspecified donor, stem cells
Z52.011	Autologous donor, stem cells
ZZ52.091	Other blood donor, stem cells
Z94.81	Bone marrow transplant status
Z94.84	Stem cells transplant status

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/18/2025	Updated risk factors(patient co-morbidities) for febrile neutropenia. Added to criteria: Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of <10% AND two or more patient related risk factors ¥ ** Separated from criteria co-morbidities and created chart to reference, as well as defining febrile neutropenia.
EmblemHealth & ConnectiCare	3/21/2024	Annual Review: updated dosing chart
EmblemHealth & ConnectiCare	9/13/2023	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	4/07/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	1/1/2021	Extended coverage duration from 4 to 6 months
EmblemHealth & ConnectiCare	11/2/2020	Effective 01/01/2021, Member must fail trial of Neulasta AND Udenyca, prior to using Fulphila (Medicare members are subject to this step therapy).
EmblemHealth & ConnectiCare	11/20/2019	Neulasta and Udenyca are the preferred agents for Medicare members. (Step protocol not mandated for Medicare members).
EmblemHealth & ConnectiCare	12/18/2018	Added Step therapy to use Neulasta AND Udenyca prior to initiating Fulphila therapy.

References

1. Fulphila [package insert]. Mylan GmbH, Zurich, Switzerland. May 2019