

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

DRUG NAME	Fulphila (pegfilgrastim-jmdb)
BILLING CODE	Q5108
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product includes Neulasta QUANTITY LIMIT— 12 mg per 28 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Fulphila (pegfilgrastim-jmdb) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

#### PREVENTION OF FEBRILE NEUTROPENIA

For **initial** authorization:

1. Member has a non-myeloid malignancy; AND
2. Medication will not be administered less than 14 days before OR less than 24 hours after chemotherapy; AND
3. Chart notes with length of chemotherapy cycle, the days of the cycle on which chemotherapy will be administered, and the day of the cycle on which the Fulphila will be administered, are submitted with prior authorization request; AND
4. Member has a documented history of febrile neutropenia (defined as an ANC < 1000/mm<sup>3</sup> and temperature > 38.2°C) following a previous course of chemotherapy and is receiving myelosuppressive chemotherapy; OR
5. Member is receiving myelosuppressive anti-cancer drugs associated with a high risk (> 20%, see Appendix for description) for incidence of febrile neutropenia; OR
6. Member is receiving myelosuppressive anti-cancer drugs associated with at intermediate risk (10-20%, see Appendix for description) for incidence of febrile neutropenia including **one** of the following:
  - a) Previous chemotherapy or radiation therapy;
  - b) Persistent neutropenia;
  - c) Bone marrow involvement with tumor;
  - d) Recent surgery and/or open wounds;
  - e) Liver dysfunction (bilirubin > 2.0);
  - f) Renal dysfunction (creatinine clearance < 50);
  - g) Age > 65 years receiving full chemotherapy dose intensity.
7. **Dosage allowed:** Up to 6 mg per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy.

*Note:* Fulphila is not indicated for hematopoietic syndrome of acute radiation syndrome.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***



For **reauthorization**:

1. Member must be in compliance with all other initial criteria.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

**CareSource considers Fulphila (pegfilgrastim-jmdb) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:**

- Hematopoietic syndrome of acute radiation syndrome
- Mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplant

DATE	ACTION/DESCRIPTION
07/25/2018	New policy for Fulphila (pegfilgrastim-jmdb) created.

References:

1. Fulphila [package insert]. Rockford, IL: Mylan Institutional LLC.; June 2018.
2. U.S. Food and Drug Administration. Media release. FDA approved first biosimilar to Nulasta to help reduce the risk of infection during cancer treatment. Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm609805.htm>. Accessed on July 25, 2018.
3. National Comprehensive Cancer Network. (2016). NCCN Drugs & Biologics Compendium™. Pegfilgrastim. Retrieved November 22, 2016 from the National Comprehensive Cancer Network.

Effective date: 10/26/2018

Revised date: 07/25/2018

## Appendix

### Chemotherapy Regimens with a High Risk for Febrile Neutropenia (>20%)

Cancer Type	Regimen
<b>Acute Lymphoblastic Leukemia (ALL)</b>	ALL induction regimens (see NCCN guidelines)
<b>Bladder Cancer</b>	MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) (neoadjuvant, adjuvant, metastatic)
<b>Breast Cancer</b>	Docetaxel + trastuzumab (metastatic or relapsed)
	Dose-dense AC followed by T (doxorubicin, cyclophosphamide, paclitaxel) (adjuvant)
	TAC (docetaxel, doxorubicin, cyclophosphamide) (adjuvant)
<b>Esophageal and Gastric Cancers</b>	Docetaxel/cisplatin/fluorouracil
<b>Hodgkin Lymphoma</b>	BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)
<b>Kidney Cancer</b>	Doxorubicin/gemcitabine
<b>Non-Hodgkin's Lymphoma</b>	ICE (ifosfamide, carboplatin, etoposide) (diffuse large B-cell lymphoma [DLBCL], peripheral T-cell lymphomas [PTCL], 2nd line)
	RICE (rituximab, ifosfamide, carboplatin, etoposide)
	CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab
	MINE (mesna, ifosfamide, novantrone, etoposide) (DLBCL, 2nd line, refractory)
	DHAP (dexamethasone, cisplatin, cytarabine)
	ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine (Ara-C)) (DLBCL, PTCL, 2nd line, recurrent)
	HyperCVAD + rituximab (cyclophosphamide, vincristine, doxorubicin, dexamethasone + rituximab)
<b>Melanoma</b>	Dacarbazine-based combination (dacarbazine, cisplatin, vinblastine) (advanced, metastatic, or recurrent)
	Dacarbazine-based combination with IL-2, interferon alpha (dacarbazine, cisplatin, vinblastine, IL-2, interferon alpha) (advanced, metastatic, or recurrent)
<b>Ovarian Cancer</b>	Topotecan
	Paclitaxel
	Docetaxel
<b>Soft Tissue Sarcoma</b>	MAID (mesna, doxorubicin, ifosfamide, dacarbazine)
	Doxorubicin
	Ifosfamide/doxorubicin
<b>Small Cell Lung Cancer</b>	topotecan
<b>Testicular cancer</b>	VeIP (vinblastine, ifosfamide, cisplatin)
	VIP (etoposide, ifosfamide, cisplatin)
	BEP (bleomycin, etoposide, cisplatin)

	TIP (paclitaxel, ifosfamide, cisplatin)
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National Comprehensive Cancer Network (NCCN): Myeloid Growth Factors, 2016.

Chemotherapy Regimens with an Intermediate Risk of Febrile Neutropenia (10% to 19%)

Cancer Histology	Regimen
<b>Occult primary - adenocarcinoma</b>	Gemcitabine/docetaxel
<b>Breast cancer</b>	Docetaxel every 21 days
	CMF classic (cyclophosphamide, methotrexate, fluorouracil) (adjuvant)
	AC (doxorubicin, cyclophosphamide) + sequential docetaxel (adjuvant) (taxane portion only)
	AC + sequential docetaxel + trastuzumab (adjuvant)
	FEC (fluorouracil, epirubicin, cyclophosphamide) + sequential docetaxel
	TC (docetaxel, cyclophosphamide)
<b>Cervical Cancer</b>	Cisplatin/topotecan (recurrent or metastatic)
	Paclitaxel/cisplatin
	Topotecan (recurrent or metastatic)
	Irinotecan (recurrent or metastatic)
<b>Colorectal</b>	FOLFOX (fluorouracil, leucovorin, oxaliplatin)
<b>Esophageal and Gastric Cancers</b>	Irinotecan/cisplatin
	Epirubicin/cisplatin/5-fluorouracil
	Epirubicin/cisplatin/capecitabine
<b>Multiple myeloma</b>	DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide)
	DT-PACE + bortezomib (VTD-PACE)
<b>Non-Hodgkin's lymphomas</b>	EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) (AIDS-related NHL, Burkitt lymphoma, recurrent, other NHL subtypes)
	EPOCH-IT chemotherapy (AIDS-related NHL, DLBCL, recurrent)
	GDP (gemcitabine, dexamethasone, cisplatin) (DLBCL, PTCL, 2nd line)
	GDP (gemcitabine, dexamethasone, cisplatin) + rituximab (DLBCL, 2nd line, Burkitt lymphoma, other NHL subtypes)
	FMR (fludarabine, mitoxantrone, rituximab)
	CHOP + rituximab (cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab) including regimens with pegylated liposomal doxorubicin or mitoxantrone substituted for doxorubicin
<b>Non-Small Cell Lung Cancer</b>	Cisplatin/paclitaxel (advanced/metastatic)
	Cisplatin/vinorelbine (adjuvant, advanced/metastatic)
	Cisplatin/docetaxel (adjuvant, advanced/metastatic)
	Cisplatin/etoposide (adjuvant, advanced/metastatic)

	Carboplatin/paclitaxel (adjuvant, advanced/metastatic)
	Docetaxel (advanced/metastatic)
<b>Ovarian Cancer</b>	Carboplatin/docetaxel
<b>Pancreatic Cancer</b>	FOLFIRINOX
<b>Prostate Cancer</b>	Cabazitaxel
<b>Small Cell Lung Cancer</b>	Etoposide/carboplatin
<b>Testicular Cancer</b>	Etoposide/cisplatin
<b>Uterine Sarcoma</b>	Docetaxel (advanced or metastatic)

National Comprehensive Cancer Network (NCCN): *Myeloid Growth Factors*, 2016.