CareSource

PHARMACY POLICY STATEMENT **Indiana 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 **NOT** MEDICALLY NECESSARY	Click Here

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^3 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.
11/08/2019	Appendix updated to the most recent NCCN guidelines chemotherapy regimens.

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: 04/01/2020
Revised date: 11/08/2019

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Appendix

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

This list is not comprehensive. There are other regimens that have a high risk for the development of febrile neutropenia. See NCCN guidelines for treatment by cancer site for details.

Cancer Type	Regimen
Acute Lymphoblastic Leukemia (ALL)	ALL induction regimens (see NCCN guidelines)
Bladder Cancer	Dose-dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
Bone Cancer	VAI (vincristine, doxorubicin or dactinomycin, ifosfamide)
	VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide)
	VIDE (vincristine, ifosfamide. doxorubicin or dactinomycin, etoposide)
Breast Cancer	Dose-dense AC followed by T (doxorubicin, cyclophosphamide, paclitaxel)
	TAC (docetaxel, doxorubicin, cyclophosphamide)
	TC (docetaxel, cyclophosphamide)
	TCH (docetaxel, carboplatin, trastuzumab)
Head and Neck Squamous Cell Carcinoma	TPF (docetaxel, cisplatin, 5-fluorouracil)
Hodgkin Lymphoma	Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine)
	Escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)
Kidney Cancer	Doxorubicin/gemcitabine
Non-Hodgkin's Lymphoma	Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)
	ICE (ifosfamide, carboplatin, etoposide)
	Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone)
	MINE (mesna, ifosfamide, mitoxantrone, etoposide)
	DHAP (dexamethasone, cisplatin, cytarabine)
	ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine)
	HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone)
Melanoma	Dacarbazine-based combination with IL-2, interferon alpha (dacarbazine, cisplatin, vinblastine, IL-2, interferon alpha)
Multiple Myeloma	DT-PACE (dexamethasone/thalidomide/ cisplatin/doxorubicin/cyclophosphamide/etoposide) ± bortezomib (VTD-PACE)
	Dacarbazine-based combination with IL-2, interferon alpha (dacarbazine, cisplatin, vinblastine, IL-2, interferon alpha)
Ovarian Cancer	Topotecan
	Docetaxel
Soft Tissue Sarcoma	MAID (mesna, doxorubicin, ifosfammide, dacarbazine)

	Doxorubicin
	Ifosfamide/doxorubicin
Small Cell Lung Cancer	Topotecan
Testicular cancer	VelP (vinblastine, ifosfamide, cisplatin)
	VIP (etoposide, ifosfamide, cisplatin)
	TIP (paclitaxel, ifosfamide, cisplatin)

National Comprehensive Cancer Network (NCCN): Hematopoietic Growth Factors, 2019.

Chemotherapy Regimens with an Intermediate Risk of Febrile Neutropenia (10% - 20%)

Cancer Histology	**Regimen**
Occult primary - Adenocarcinoma	Gemcitabine/docetaxel
Bone Cancer	Cisplatin/doxorubicin
	VDC (vincristine, doxorubicin or dactinomycin, cyclophosphamide)
Breast cancer	Docetaxel
	AC (doxorubicin, cyclophosphamide) + sequential docetaxel (taxane portion only)
	Paclitaxel every 21 days
Cervical Cancer	Cisplatin/topotecan
	Paclitaxel/cisplatin
	Topotecan
	Irinotecan
Colorectal	FOLFOX (fluorouracil, leucovorin, oxaliplatin)
Esophageal and Gastric Cancers	Irinotecan/cisplatin
	Epirubicin/cisplatin/5-fluorouracil
	Epirubicin/cisplatin/capecitabine
Non-Hodgkin's lymphomas	GDP (gemcitabine, dexamethasone, cisplatin/carboplatin)
	CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin
Non-Small Cell Lung Cancer	Cisplatin/paclitaxel
	Cisplatin/vinorelbine
	Cisplatin/docetaxel
	Cisplatin/etoposide
	Carboplatin/paclitaxel
	Docetaxel
Ovarian Cancer	Carboplatin/docetaxel
Pancreatic Cancer	FOLFIRINOX

Prostate Cancer	Cabazitaxel
Small Cell Lung Cancer	Etoposide/carboplatin
Testicular Cancer	Etoposide/cisplatin
	BEP (bleomycin, etoposide, cisplatin)
Uterine Sarcoma	Docetaxel

National Comprehensive Cancer Network (NCCN): Hematopoietic Growth Factors, 2019.