

**Long-Acting Colony Stimulating Factors:**  
**Neulasta (pegfilgrastim)**  
**Fulphila (pegfilgrastim-jmdp)**  
**Udenyca (pegfilgrastim-cbqv)**  
**Ziextenzo (pegfilgrastim-bmez)**  
**Nyvepria (pegfilgrastim-apgf)**  
**Fylnetra (pegfilgrastim-pbbk)**  
**Ryzneuta (efbemalenograstim alfa-vuwx)**  
**Stimufend (pegfilgrastim-fpgk)**  
 Effective 07/01/2026

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical Benefit</b> <b>Pharmacy Benefit</b>	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
<b>Exceptions</b>	N/A		

### Overview

#### FDA-Approved Indication

- Cancer Receiving Myelosuppressive Chemotherapy: decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. (Neulasta, Fulphila, Udenyca, Ryzneuta, Ziextenzo)
- Hematopoietic Syndrome of Acute Radiation Syndrome: increase survival in patients acutely exposed to myelosuppressive doses of radiation (Neulasta/Neulasta Onpro, Stimufend, Udenyca/Udenyca Onbody ONLY)

#### Compendial Use

- Stem cell transplantation-related indications
- Prophylaxis for chemotherapy-induced febrile neutropenia in patients with solid tumors
- Radiation therapy/injury
- Hairy cell leukemia
- Chronic Myeloid Leukemia (CML), treatment of resistant neutropenia due to tyrosine kinases inhibitor therapy

Preferred Agents	Non-Preferred Agents
Neulasta, Neulasta Onpro	Ziextenzo
Fulphila	Udenyca, Udenyca Onbody
	Nyvepria

	Stimufend
	Fylnetra
	Ryzneuta

**Coverage Guidelines**

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

**OR**

Authorization may be granted for members when all of the following diagnosis-specific criteria are met:

**Prevention of neutropenia in cancer patients receiving myelosuppressive chemotherapy**

1. Used for prevention of neutropenia in cancer patients receiving myelosuppressive chemotherapy
2. The requested medication will not be used in combination with other colony stimulating factors within any chemotherapy cycle.
3. The member will not be receiving concurrent chemotherapy and radiation therapy.
4. The requested medication will not be administered with weekly chemotherapy regimens.
5. ONE of the following criteria is met:
  - a. The requested medication will be used for primary prophylaxis in members with a solid tumor or non-myeloid malignancies who have received, are currently receiving, or will be receiving myelosuppressive anti-cancer therapy that is expected to result in 20% or higher incidence of febrile neutropenia (FN) (*See Appendix A*) OR 10 – 19% risk of FN (*See Appendix B*).
  - b. The requested medication will be used for secondary prophylaxis in members with solid tumors or non-myeloid malignancies who experienced a febrile neutropenic complication or a dose-limiting neutropenic event (a nadir or day of treatment count impacting the planned dose of chemotherapy) from a prior cycle of similar chemotherapy, with the same dose and scheduled planned for the current cycle (for which primary prophylaxis was not received).
6. For Ziextenzo, Udenyca, Udenyca Onbody, Ryzneuta, Stimufend, Fylnetra and Nyvepria member has adverse reaction, intolerance or contraindication to Neulasta/Neulasta Onpro AND Fulphila

**All Other indications**

1. The member meets one of the following diagnoses:
  - a. Stem cell transplantation-related indications
  - b. Radiation therapy exposed to myelosuppressive doses of radiation therapy OR treatment of radiation injury
  - c. Hairy cell leukemia neutropenic fever following chemotherapy.
  - d. Chronic Myeloid Leukemia with resistant neutropenia due to tyrosine inhibitor therapy
- b. For Ziextenzo, Udenyca, Udenyca Onbody, Ryzneuta, Stimufend, Fylnetra and Nyvepria member has adverse reaction, intolerance or contraindication to Neulasta/Neulasta Onpro AND Fulphila

**Continuation of Therapy**

Reauthorization requests must meet all of the following criteria:

1. Member demonstrates a positive clinical response to therapy
2. For Ziextenzo, Udenyca, Udenyca Onbody, Ryzneuta, Stimufend, Fylnetra and Nyvepria: member has adverse reaction, intolerance or contraindication to Neulasta/Neulasta Onpro AND Fulphila



## Limitations

1. Initial approvals and reauthorizations will be granted for 6 months.

## Appendix

### **APPENDIX A: Chemotherapy Regimens with an Incidence of Febrile Neutropenia of > 20%**

1. **Acute Lymphoblastic Leukemia:** ALL regimens as directed by treatment protocol (see NCCN guidelines)
2. **Bladder Cancer:**
  - a. Dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
  - b. CBDCa/Pac (carboplatin, paclitaxel)
3. **Bone Cancer**
  - a. VAI (vincristine, doxorubicin or dactinomycin, ifosfamide)
  - b. VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide)
  - c. Cisplatin/doxorubicin
  - d. VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin)
  - e. VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)
4. **Breast Cancer:**
  - a. Docetaxel + trastuzumab
  - b. Dose-dense AC (doxorubicin, cyclophosphamide) + paclitaxel (or dose dense paclitaxel)
  - c. TAC (docetaxel, doxorubicin, cyclophosphamide)
  - d. AT (doxorubicin, docetaxel)
  - e. Doc (docetaxel)
  - f. TC (docetaxel, cyclophosphamide)
  - g. TCH (docetaxel, carboplatin, trastuzumab)
5. **Colorectal Cancer:** FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, irinotecan)
6. **Esophageal and Gastric Cancers:** Docetaxel/cisplatin/fluorouracil
7. **Head and Neck Squamous Cell Carcinoma:** TPF (docetaxel, cisplatin, fluorouracil)
8. **Hodgkin Lymphoma:**
  - a. Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine)
  - b. Escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)
9. **Kidney Cancer:** Doxorubicin/gemcitabine
10. **Non-Hodgkin's Lymphoma:**
  - a. Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)
  - b. ICE (ifosfamide, carboplatin, etoposide)
  - c. Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab
  - d. MINE (mesna, ifosfamide, novantrone, etoposide)
  - e. DHAP (dexamethasone, cisplatin, cytarabine)
  - f. ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine (Ara-C))
  - g. HyperCVAD + rituximab (cyclophosphamide, vincristine, doxorubicin, dexamethasone + rituximab)
  - h. VAPEC-B (vincristine, doxorubicin, prednisolone, etoposide, cyclophosphamide, bleomycin)
11. **Melanoma:** Dacarbazine-based combination with IL-2, interferon alpha (dacarbazine, cisplatin, vinblastine, IL-2, interferon alpha)
12. **Multiple myeloma:**
  - a. DT-PACE (dexamethasone/ thalidomide/ cisplatin/ doxorubicin/ cyclophosphamide/ etoposide) + bortezomib (VTD-PACE)
  - b. DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide)



13. **Ovarian Cancer:** Topotecan or Docetaxel
14. **Pancreatic Cancer:** FOLFIRINOX (fluorouracil, leucovorin, irinotecan, oxaliplatin)
15. **Soft Tissue Sarcoma:**
  - a. MAID (mesna, doxorubicin, ifosfamide, dacarbazine)
  - b. Doxorubicin
  - c. Ifosfamide/doxorubicin
16. **Small Cell Lung Cancer:**
  - a. Top (topotecan)
  - b. CAV (cyclophosphamide, doxorubicin, vincristine)
17. **Testicular cancer:**
  - a. Velp (vinblastine, ifosfamide, cisplatin)
  - b. VIP (etoposide, ifosfamide, cisplatin)
  - c. TIP (paclitaxel, ifosfamide, cisplatin)

#### **APPENDIX B: Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 10% to 19%**

1. **Occult primary – adenocarcinoma:** Gemcitabine/docetaxel
2. **Breast cancer:**
  - a. Docetaxel
  - b. CMF classic (cyclophosphamide, methotrexate, fluorouracil)
  - c. CA (doxorubicin, cyclophosphamide) (60 mg/m<sup>2</sup>) (hospitalized)
  - d. AC (doxorubicin, cyclophosphamide) + sequential docetaxel (taxane portion only)
  - e. AC + sequential docetaxel + trastuzumab
  - f. A (doxorubicin) (75 mg/m<sup>2</sup>)
  - g. AC (doxorubicin, cyclophosphamide)
  - h. CapDoc (capecitabine, docetaxel)
  - i. Paclitaxel every 21 days
3. **Cervical Cancer:**
  - a. Irinotecan
  - b. Cisplatin/topotecan
  - c. Paclitaxel/cisplatin
  - d. Topotecan
4. **Colorectal:**
  - a. FL (fluorouracil, leucovorin)
  - b. CPT-11 (irinotecan) (350 mg/m<sup>2</sup> q 3 wk)
  - c. FOLFOX (fluorouracil, leucovorin, oxaliplatin)
5. **Esophageal and Gastric Cancers:**
  - a. Irinotecan/cisplatin
  - b. Epirubicin/cisplatin/fluorouracil
  - c. Epirubicin/cisplatin/capecitabine
6. **Non-Hodgkin's lymphomas:**
  - a. EPOCH-IT chemotherapy
  - b. GDP (gemcitabine, dexamethasone, cisplatin/carboplatin)
  - c. GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) + rituximab
  - d. FMR (fludarabine, mitoxantrone, rituximab)
  - e. CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin
  - f. CHOP + rituximab (cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab) including regimens with pegylated liposomal doxorubicin



- g. CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin
- h. Bendamustine
- 7. **Non-Small Cell Lung Cancer:**
  - a. Cisplatin/paclitaxel
  - b. Cisplatin/vinorelbine
  - c. Cisplatin/docetaxel
  - d. Cisplatin/etoposide
  - e. Carboplatin/paclitaxel
  - f. Docetaxel
- 8. **Ovarian cancer:** Carboplatin/docetaxel
- 9. **Prostate cancer:** Cabazitaxel
- 10. **Small Cell Lung Cancer:** Etoposide/carboplatin
- 11. **Testicular Cancer:**
  - i. BEP (bleomycin, etoposide, cisplatin)
  - ii. Etoposide/cisplatin
- 12. **Uterine sarcoma:** Docetaxel

## References

1. Fulphila (pegfilgrastim-jmdb) [prescribing information]. Cambridge, MA: Biocon Biologics, Inc; June 2023.
2. Fynetra (pegfilgrastim-pbbk) [prescribing information]. Piscataway, NJ: Kashiv BioSciences, LLC; May 2022.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors. Version 3.2024.  
[https://www.nccn.org/professionals/physician\\_gls/pdf/growthfactors.pdf](https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf) Accessed September 27, 2024.
4. Neulasta (pegfilgrastim) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; February 2021.
5. Nyvepria (pegfilgrastim-apgf) [prescribing information]. New York, NY: Pfizer Labs; March 2023.
6. Udenyca (pegfilgrastim-cbqv) [prescribing information]. Redwood City, California: Coherus BioSciences, Inc; December 2023.
7. Ryzneuta (efbemalenograstim alfa-vuxw) [prescribing information]. Singapore: Evive Biotechnology PTE LTD; November 2023.
8. Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the use of white blood cell growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol*. 2015;33(28):3199-3212.
9. Stimufend (pegfilgrastim-fpgk) [prescribing information]. Lake Zurich, IL: Fresenius Kabi; September 2023.
10. Ziextenzo (pegfilgrastim-bmez) [prescribing information]. Princeton, NJ: Sandoz Inc.; February 2024.

## Review History

01/20/2021 – Created and Reviewed P&T; switched from CVS template to custom template; added overview; added preferred products. Nyvepria added. Effective 03/01/21.

11/17/2021 – Reviewed and Updated for Nov P&T; effective 1/1/2022 preferred agents will be Neulasta and Udenyca; non-preferred agents will be Fulphila, Udenyca, and Nyvepria. Effective 1/1/22.

02/08/2023 – Reviewed and Updated for Feb P&T; added new drugs Stimufend, Rolvedon, and Fynetra to criteria as non-preferred agents. Non-preferred agents require prior use of preferred agents (Neulasta and Ziextenzo). Effective 5/1/2023



06/14/2023 – Reviewed and updated for Jun P&T; Updated preferred products to Fulphila and Neulasta. Ziextenzo moved to non-preferred along with Udenyca, Nyvepria, Rolvedon, Stimufend, and Fylnetra. Effective 9/1/23.

10/09/2024 – Reviewed and updated for October P&T. Added Udenyca Onbody to the policy as a nonpreferred product. Clarified that Neulasta Onpro is a preferred agent. Effective 1/1/2025.

09/10/2025 – Reviewed and updated for September P&T. Added Ryzneuta to the policy as a nonpreferred product. Effective 12/1/2025.

10/08/2025 – Reviewed at October P&T. Updated policy to indicate it no longer applies to the medical benefit. Updated reauthorization criteria for nonpreferred agents to require trial and failure with Fulphila and Neulasta/Onpro. Effective 01/01/2026.

04/15/2026 – Reviewed and updated at April P&T. Removed Rolvedon from the policy, as agent is moving to nonformulary status. Updated language for members new to the Plan. Effective 07/01/2026.

