Mass General Brigham
Health Plan

Long-Acting Colony Stimulating Factors:
Neulasta (pegfilgrastim)
Fulphila (pegfilgrastim-jmdp)
Udenyca (pegfilgrastim-cbqv)
Ziextenzo (pegfilgrastim-bmez)
Nyvepria (pegfilgrastim-apgf)
Rolvedon (eflapegrastim-xnst)
Fylnetra (pegfilgrastim-pbbk)
Stimufend (pegfilgrastim-fpgk)
Effective 01/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	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, 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
	Rolvedon
	Stimufend
	Fylnetra

Coverage Guidelines
Authorization may be reviewed for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted for members when ALL the following criteria are met:

Prevention of neutropenia in cancer patients receiving myelosuppressive chemotherapy

1. The requested medication will not be used in combination with other colony stimulating factors within any chemotherapy cycle.
2. The member will not be receiving concurrent chemotherapy and radiation therapy.
3. The requested medication will not be administered with weekly chemotherapy regimens.
4. 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).
5. For Ziextenzo, Udenyca, Udenyca Onbody, Rolvedon, 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, Rolvedon, Stimufend, Fylnetra and Nyvepria member has adverse reaction, intolerance or contraindication to Neulasta/Neulasta Onpro AND Fulphila

<u>Continuation of Therapy</u>
Reauthorization requests must meet all of the following criteria:

1. Initial criteria are met
2. Provider documentation of improvement of member's condition

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/ cyclophoaphamide/ etoposide) + bortezomib (VTD-PACE)
    b. DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophoaphamide/etoposide)

13. **Ovarian Cancer:** Topotecan or Docetaxel
14. **Pancreatic Cancer:** FOLFIRINOX (fluorouracil, leucovorin, irinotecan, oxaliplatin)
15. **Soft Tissue Sarcoma:**
    a. MAID (mesna, doxorubicin, ifosfammide, 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/m2) (hospitalized)
    d. AC (doxorubicin, cyclophosphamide) + sequential docetaxel (taxane portion only)
    e. AC + sequential docetaxel + trastuzumab
    f. A (doxorubicin) (75 mg/m2)
    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/m2 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. Neulasta (pegfilgrastim) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; February 2021.
2. Fulphila (pegfilgrastim-jmdb) [prescribing information]. Cambridge, MA: Biocon Biologics, Inc; June 2023.
3. Udenyca (pegfilgrastim-cbqv) [prescribing informaiton]. Redwood City, California: Coherus BioSciences, Inc: December 2023.
4. Ziextenzo (pegfilgrastim-bmez) [prescribing information]. Princeton, NJ: Sandoz Inc.; February 2024.
5. 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 Accessed September 27, 2024.
6. 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.
7. Nyvepria (pegfilgrastim-apgf) [prescribing information]. New York, NY: Pfizer Labs; March 2023.
8. Stimufend (pegfilgrastim-fpgk) [prescribing information]. Lake Zurich, IL: Fresenius Kabi; September 2023.
9. Fylnetra (pegfilgrastim-pbbk) [prescribing information]. Piscataway, NJ: Kashiv BioSciences, LLC; May 2022.
10. Rolvedon (eflapegrastim-xnst) [prescribing information]. Lake Forest, IL: Spectrum Pharmaceuticals Inc; November 2023.

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 Fylnetra 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.