

**Clinical Policy: Pegfilgrastim (Neulasta, Neulasta OnPro), Pegfilgrastim-jmdb (Fulphila), Pegfilgrastim-pbbk (Fylnetra), Pegfilgrastim-apgf (Nyvepria), Eflapegrastim-xnst (Rolvedon), Pegfilgrastim-fpgk (Stimufend), Pegfilgrastim-cbqv (Udenyca), Pegfilgrastim-bmez (Ziextenzo),**

Reference Number: IL.PHAR.296

Effective Date: 1.1.20

Last Review Date: 11.28.22

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

## **Description**

### **Description**

Pegfilgrastim (Neulasta<sup>®</sup>, Neulasta<sup>®</sup> Onpro<sup>®</sup>) and its biosimilars, pegfilgrastim-jmdb (Fulphila<sup>™</sup>), pegfilgrastim-pbbk (Fylnetra<sup>®</sup>), pegfilgrastim-apgf (Nyvepria<sup>™</sup>), eflapegrastim-xnst (Rolvedon<sup>™</sup>), pegfilgrastim-fpgk (Stimufend<sup>®</sup>), pegfilgrastim-cbqv (Udenyca<sup>™</sup>), and pegfilgrastim-bmez (Ziextenzo<sup>™</sup>) are leukocyte growth factors.

### **FDA Approved Indication(s)**

Neulasta, Neulasta Onpro, Fulphila, Fylnetra, Nyvepria, Stimufend, Rolvedon, Udenyca, and Ziextenzo are indicated to 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 (FN).

Neulasta and Udenyca are also indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome).

Limitation(s) of use: Neulasta, , Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend, Udenyca, and Ziextenzo are not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Neulasta, Neulasta Onpro, Fulphila, Nyvepria, Rolvedon, Stimufend, Udenyca, and Ziextenzo are **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Chemotherapy-Induced Neutropenia (must meet all):**

1. Diagnosis of non-myeloid malignancy (solid tumor or lymphoid malignancies);
2. Prescribed for use following myelosuppressive chemotherapy;

**CLINICAL POLICY** Pegfilgrastim, Pegfilgrastim-jmdb, Pegfilgrastim-cbqv, Pegfilgrastim-bmez, Pegfilgrastin-apgf, Pegfilgrastim-jmdb, Pegfilgrastim-pbbk, Pegfilgrastim-apgf, Eflapegrastim-xnst, Pegfilgrastim-fpgk, Pegfilgrastim-cbqv, Pegfilgrastim-bmez



3. For members receiving palliative chemotherapy, provider attestation that chemotherapy dose reduction has been considered;
4. Member has intolerance or contraindication to Neupogen;
5. Confirmation that there is at least 12 days between pegfilgrastim dose and the next cycle of chemotherapy;
6. Dose does not exceed 6 mg (1 syringe) per chemotherapy cycle;
7. Requested medication will not be prescribed concurrently with other colony stimulating factors within chemotherapy cycle.

**Approval duration:**

**Medicaid** – 6 months

**B. Acute Radiation Syndrome (must meet all):**

1. Prescribed for use following suspected or confirmed acute exposure to myelosuppressive doses of radiation;
2. Request is not for Neulasta Onpro;
3. Failure of ONE of the following, unless contraindicated or clinically significant adverse effects are experienced: Neupogen, Leukine;
- 4.
5. Dose does not exceed two 6 mg doses administered one week apart.

**Approval duration:**

**Medicaid** – 6 months

**C. Bone Marrow Transplantation (off-label) (must meet all):**

1. Prescribed for one of the following (a or b):
  - a. Supportive care post autologous hematopoietic cell transplantation;
  - b. Mobilization of peripheral-blood progenitor cells prior to autologous transplantation;
2. Failure of Leukine<sup>®</sup>, unless contraindicated or clinically significant adverse effects are experienced;
3. Member has intolerance or contraindication to Neupogen;
4. Request meets one of the following (a or b):
  - a. Dose does not exceed 6 mg/dose;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration:**

**Medicaid** – 6 months

**D. Wilms Tumor (off-label) (must meet all):**

1. Diagnosis of Wilms tumor (nephroblastoma);
2. Request is for supportive care for member receiving a regimen of cyclophosphamide and etoposide, or cyclophosphamide, doxorubicin, and vincristine in Regimen M and Regimen I (*see Appendix C*);
3. Member has intolerance or contraindication to Neupogen;
4. Request meets one of the following (a or b):

**CLINICAL POLICY** Pegfilgrastim, Pegfilgrastim-jmdb, Pegfilgrastim-cbqv, Pegfilgrastim-bmez, Pegfilgrastin-apgf, Pegfilgrastim-jmdb, Pegfilgrastim-pbbk, Pegfilgrastim-apgf, Eflapegrastim-xnst, Pegfilgrastim-fpgk, Pegfilgrastim-cbqv, Pegfilgrastim-bmez



- a. Dose does not exceed 6 mg (1 syringe) per chemotherapy cycle;
- b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approved duration:**

**Medicaid**– 6 months

**E. Other diagnoses/indications**

1. One of the following (a or b):
  - a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (i or ii):
    - i. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
    - ii. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
  - b. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.
2. Member has intolerance or contraindication to Neupogen

**II. Continued Therapy**

**A. All Indications in Section I** (must meet all):

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. Member has intolerance or contraindication to Neupogen;
4. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
  - a. Chemotherapy-induced neutropenia: 6 mg administered once per chemotherapy cycle;
  - b. Acute radiation syndrome: two 6 mg doses administered one week apart;
  - c. Bone marrow transplantation: 6 mg/dose or dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration:**

**Medicaid** – 6 months

**B. Other diagnoses/indications** (must meet 1 or 2):

**CLINICAL POLICY** Pegfilgrastim, Pegfilgrastim-jmdb, Pegfilgrastim-cbqv, Pegfilgrastim-bmez, Pegfilgrastin-apgf, Pegfilgrastim-jmdb, Pegfilgrastim-pbbk, Pegfilgrastim-apgf, Eflapegrastim-xnst, Pegfilgrastim-fpgk, Pegfilgrastim-cbqv, Pegfilgrastim-bmez



1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 6 months (whichever is less);** or
2. One of the following (a or b):
  - a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (i or ii):
    - i. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
    - ii. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
  - b. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.
3. Member has intolerance or contraindication to Neupogen

### **III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

### **IV. Appendices/General Information**

#### *Appendix A: Abbreviation/Acronym Key*

ANC: absolute neutrophil count	FDA: Food and Drug Administration
ASCO: American Society of Clinical Oncology	FN: febrile neutropenia
CSFs: colony-stimulating factors	NCCN: National Comprehensive Cancer Network

#### *Appendix B: Contraindications/Boxed Warnings*

- Contraindication(s): history of serious allergic reactions to human granulocyte colony-stimulating factors such as eflapegrastim, pegfilgrastim or filgrastim products
- Boxed warning(s): none reported

#### *Appendix C: General Information*

- Neutropenia is defined as an absolute neutrophil count (ANC) of < 500 neutrophils/mcL or an ANC of < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours. Neutropenia can progress to FN, defined as a single temperature of ≥ 38.8 C orally or ≥ 38.0 C over 1 hour.
- The development of FN is a common dose-limiting toxicity of many chemotherapy regimens. This risk is directly related to the intensity of the chemotherapy regimen. Chemotherapy regimens that have an incidence of FN greater than 20% in clinical trials in chemotherapy naïve patients are considered by the National Comprehensive Cancer Network (NCCN) panel at high risk. Prophylaxis with myeloid growth factors is

**CLINICAL POLICY** Pegfilgrastim, Pegfilgrastim-jmdb, Pegfilgrastim-cbqv, Pegfilgrastim-bmez, Pegfilgrastin-apgf, Pegfilgrastim-jmdb, Pegfilgrastim-pbbk, Pegfilgrastim-apgf, Eflapegrastim-xnst, Pegfilgrastim-fpgk, Pegfilgrastim-cbqv, Pegfilgrastim-bmez



recommended at this level of risk (category 1 recommendation). NCCN Compendium recommend prophylaxis be considered in intermediate-risk (10-20% overall risk of FN) patients (category 2A recommendation). In addition to chemotherapy regimens, other risk factors such as: treatment-related, patient related, cancer-related, and co-morbidities have also been associated with an increased risk of FN. Therefore, the type of chemotherapy regimen is only one component of the risk assessment.

- Harvesting of peripheral blood stem cells prior to autologous stem-cell transplantation has a recommendation of Class IIa in DRUGDEX.
- The NCCN Compendium recommends Neulasta for supportive care post autologous hematopoietic cell transplant (category 2A).
- According to the ASCO, 2006 Clinical Practice Guideline for the Use of White Blood Cell Growth Factors, dose reduction or delay remains an appropriate strategy for the palliative treatment of cancer, as there is no evidence that dose maintenance or escalation improves clinically important outcomes in this setting. The 2015 updates to this guideline found no new data supporting the use of colony-stimulating factors (CSFs) to maintain dose-intensity in the treatment of metastatic disease, and the review found no demonstrable benefit in the use of myeloid growth factors to in patients with metastatic lung, small-cell lung, colorectal, hormone-refractory prostate, or breast cancer. To date, there have been no improvements in disease-free or OS reported for any common cancer with the use of CSFs to maintain dose-intensity, instead of dose reduction. The ASCO Panel recognizes that there may be individual patients who will not tolerate effective doses of chemotherapy without CSFs. Medical Oncologists making the decision to use prophylactic MGFs, or not, may need to consider not only the optimal chemotherapy regimen, but also the individual member risk factors and the intention of treatment; that is, curative, prolongation of life, or symptom control and palliation.
- Chemotherapy regimens used in the treatment of Wilms Tumor for which filgrastim supportive care may be considered:
  - Regimen M: 9 doses of vincristine, 5 doses of dactinomycin, 5 doses of doxorubicin (cumulative dose 150 mg/m<sup>2</sup>), 4 courses of 5 daily doses of cyclophosphamide, and 4 courses of 5 daily doses of etoposide over 24 weeks. Dactinomycin and doxorubicin are given together, and cyclophosphamide and etoposide are given together.
  - Regimen I: 9 doses of vincristine, 4 doses of doxorubicin (cumulative dose 180 mg/m<sup>2</sup>), 7 courses of 3 to 5 daily doses of cyclophosphamide, and 3 courses of 5 daily doses of etoposide. Doxorubicin and 3 daily doses of cyclophosphamide are given together, and 5 daily doses of cyclophosphamide and etoposide are given together.

**V. Dosage and Administration**

Drug Name	Indication	Dosing Regimen	Maximum Dose
Pegfilgrastim (Neulasta), pegfilgrastim-jmdb	Myelosuppressive chemotherapy	6 mg administered SC once per chemotherapy cycle. Do not administer between 14 days before and 24 hours after	6 mg/dose

**CLINICAL POLICY** Pegfilgrastim, Pegfilgrastim-jmdb, Pegfilgrastim-cbqv, Pegfilgrastim-bmez, Pegfilgrastin-apgf, Pegfilgrastim-jmdb, Pegfilgrastim-pbbk, Pegfilgrastim-apgf, Eflapegrastim-xnst, Pegfilgrastim-fpgk, Pegfilgrastim-cbqv, Pegfilgrastim-bmez



Drug Name	Indication	Dosing Regimen	Maximum Dose
(Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastin-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv pegfilgrastim-cbqv (Udenyca), pegfilgrastim-bmez (Ziextenzo)		administration of cytotoxic chemotherapy.  Weight based dosing for pediatric patients < 45 kg	
Pegfilgrastim (Neulasta), pegfilgrastim-cbqv (Udenyca)	Members acutely exposed to myelosuppressive doses of radiation	Two doses, 6 mg each, administered SC one week apart. Administer the first dose as soon as possible after suspected or confirmed exposure to myelosuppressive doses of radiation, and a second dose one week after  Weight based dosing for pediatric patients < 45 kg	6 mg/dose
Eflapegrastim-xnst (Rolvedon)	Myelosuppressive chemotherapy	13.2 mg administered SC once per chemotherapy cycle. Do not administer between 14 days before and 24 hours after administration of cytotoxic chemotherapy.	13.2 mg/dose

**VI. Product Availability**

Drug Name	Availability
Pegfilgrastim (Neulasta)	<ul style="list-style-type: none"> <li>Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only</li> <li>Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe co-packaged with the on-body injector</li> </ul>
Pegfilgrastim-jmdb (Fulphila)	<ul style="list-style-type: none"> <li>Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only</li> </ul>

**CLINICAL POLICY** Pegfilgrastim, Pegfilgrastim-jmdb, Pegfilgrastim-cbqv, Pegfilgrastim-bmez, Pegfilgrastin-apgf, Pegfilgrastim-jmdb, Pegfilgrastim-pbbk, Pegfilgrastim-apgf, Eflapegrastim-xnst, Pegfilgrastim-fpgk, Pegfilgrastim-cbqv, Pegfilgrastim-bmez



Drug Name	Availability
Pegfilgrastim-cbqv (Udenyca)	<ul style="list-style-type: none"> <li>Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only</li> </ul>
Pegfilgrastim-bmez (Ziextenzo)	<ul style="list-style-type: none"> <li>Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only</li> </ul>
Pegfilgrastim-pbbk (Fylnetra)	<ul style="list-style-type: none"> <li>Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only</li> </ul>
Pegfilgrastin-apgf (Nyvepria)	<ul style="list-style-type: none"> <li>Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only</li> </ul>
Pegfilgrastim-fpgk (Stimufend)	<ul style="list-style-type: none"> <li>Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only</li> </ul>

**VII. References**

1. Neulasta Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; February 2021. Available at [www.neulasta.com](http://www.neulasta.com). Accessed April 1, 2021.
2. National Comprehensive Cancer Network. Hematopoietic Growth Factors Version 2.2021. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/growthfactors.pdf](https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf). Accessed April 27, 2022.
3. Pegfilgrastim. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed April 1, 2021.
4. Fulphila Prescribing Information. Zurich, Switzerland: Mylan GmbH; March 2021. Available at: [www.fulphila.com](http://www.fulphila.com). Accessed April 27, 2022.
5. Fylnetra Prescribing Information. Piscataway, NJ: Kashiv BioSciences, LLC; May 2022. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/761084s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761084s000lbl.pdf). Accessed June 14, 2022.
6. Nyvepria Prescribing Information. Lake Forest, IL: Hospira, Inc.; April 2021. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/761111lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761111lbl.pdf). Accessed April 27, 2022.
7. Rolvedon. Prescribing Information. Irvine, CA: Spectrum Pharmaceuticals, Inc.; September 2022. Available at: [www.rolvedon.com](http://www.rolvedon.com). Accessed September 26, 2022.
8. Stimufend Prescribing Information. Lake Zurich, IL: Fresenius Kabi, LLC; September 2022. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/761173s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761173s000lbl.pdf). Accessed September 13, 2022.
9. DRUGDEX<sup>®</sup> System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed April 1, 2021.
10. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed April 1, 2021.
11. Fulphila Prescribing Information. Zurich, Switzerland: Mylan GmbH; March 2021. Available at: [www.fulphila.com](http://www.fulphila.com). Accessed April 1, 2021.
12. Udenyca Prescribing Information. Redwood City, CA: Coherus BioSciences, Inc.; September 2019. Available at: [www.udenyca.com](http://www.udenyca.com). Accessed April 1, 2021.

**CLINICAL POLICY** Pegfilgrastim, Pegfilgrastim-jmdb, Pegfilgrastim-cbqv, Pegfilgrastim-bmez, Pegfilgrastin-apgf, Pegfilgrastim-jmdb, Pegfilgrastim-pbbk, Pegfilgrastim-apgf, Eflapegrastim-xnst, Pegfilgrastim-fpgk, Pegfilgrastim-cbqv, Pegfilgrastim-bmez



13. Smith TJ, Khatcheressian J, Lyman GH, et al. 2006 Update of recommendations for the use of white blood cell growth factors: an evidence-based clinical practice guideline. JCO 2006 July. 24(19): 3187-3205.
14. Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology clinical practice guideline update. 2015 October. JCO 33(28): 3199-3212.
15. Ziextenzo Prescribing Information. Princeton, NJ: Sandoz Inc.; March 2021. Available at: [www.ziextenzo.com](http://www.ziextenzo.com). Accessed April 1, 2021.
16. Nyvepria Prescribing Information. Lake Forest, IL: Hospira, Inc.; June 2020. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/761111bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761111bl.pdf). Accessed April 27, 2022.
17. National Comprehensive Cancer Network. Wilms Tumor (Nephroblastoma) 1.2021. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/wilms\\_tumor.pdf](https://www.nccn.org/professionals/physician_gls/pdf/wilms_tumor.pdf). Accessed April 27, 2022.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2506	Injection, pegfilgrastim, 6 mg
Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg
Q5122	Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5 mg
J3590	Unclassified biologics

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created, adapted CP.PHAR.296 Pegfilgrastim (Neulasta Fulphila Udenyca) policy.	12.11.19	1.7.20
3Q 2020 annual review: no significant changes; references reviewed and updated.	7.10.20	7.22.20
1Q 2021 annual review and added Nyvepria. References updated.	2.3.2021	
Changes: Added Confirmation that there is at least 12 days between pegfilgrastim dose and the next cycle of chemotherapy; added to continues therapy section- Member has intolerance or contraindication to Neupogen;	4.23.2021	



**CLINICAL POLICY** Pegfilgrastim, Pegfilgrastim-jmdb, Pegfilgrastim-cbqv, Pegfilgrastim-bmez, Pegfilgrastin-apgf, Pegfilgrastim-jmdb, Pegfilgrastim-pbbk, Pegfilgrastim-apgf, Eflapegrastim-xnst, Pegfilgrastim-fpgk, Pegfilgrastim-cbqv, Pegfilgrastim-bmez



Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed: Other diagnoses/indications: modified redirect language to align with criteria sets by indication that include redirection	6.3.21	
3Q 2021 annual review: added NCCN compendium supported off-label use in Wilms tumor; added HCPCS code for Nyvepria; references reviewed and updated	9.8.21	
1Q 2022 review: Updated HCPCS code for Neulasta	3.11.22	
3Q2022 annual review: : added requirement that requested medication will not be prescribed concurrently with other colony stimulating factors within any chemotherapy cycle; clarified non-myeloid malignancy refers to solid tumor and lymphoid malignancies;	06.22.22	
RT4: added <b>Fylnetra</b> , Stimufend and Rolvedon to policy; template changes applied to other diagnoses/indications and continued therapy section.	11.28.22	
RT4: added new indication of hematopoietic subsyndrome of acute radiation syndrome to Udenyca; added that request is not for Neulasta OnPro for acute radiation syndrome.	1.19.23	

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

**CLINICAL POLICY** Pegfilgrastim, Pegfilgrastim-jmdb, Pegfilgrastim-cbqv, Pegfilgrastim-bmez, Pegfilgrastin-apgf, Pegfilgrastim-jmdb, Pegfilgrastim-pbbk, Pegfilgrastim-apgf, Eflapegrastim-xnst, Pegfilgrastim-fpgk, Pegfilgrastim-cbqv, Pegfilgrastim-bmez



discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.