Clinical Policy: Pegfilgrastim (Neulasta, Neulasta Onpro), Pegfilgrastim-jmdb (Fulphila), Pegfilgrastim-cbqv (Udenyca), Pegfilgrastim-bmez (Ziextenzo), Pegfilgrastim-apgf (Nyvepria), Pegfilgrastim-pbbk (Fylnetra)

Reference Number: DE.PHAR.296
Effective Date: 01.23
Last Review Date: 01.23
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Pegfilgrastim (Neulasta®, Neulasta® Onpro®) and its biosimilars, pegfilgrastim-jmdb (Fulphila™),pegfilgrastim-cbqv (Udenyca™), pegfilgrastim-bmez (Ziextenzo™), pegfilgrastim-apgf (Nyvepria™), and pegfilgrastim-pbbk (Fylnetra®) are leukocyte growth factors.

FDA Approved Indication(s)

Neulasta, Nyvepria, Fulphila, Fylnetra, 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 is 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, Nyvepria, Fulphila, Fylnetra, 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® that Neulasta, Neulasta Onpro, Nyvepria, Fulphila, Fylnetra, 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 (i.e., solid tumor and lymphoid malignancies);
2. Prescribed for use following myelosuppressive chemotherapy;
3. One of the following (a or b)
   a. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings *(see Appendix E)*;
   b. Both of the following (i and ii)

i. Failure of at least ONE preferred agent, unless one of the following (1, 2, or 3):
   1. Member has intolerance or contraindication;
   2. Documentation of member's inability to self-administer preferred agent due to both of the following (a and b):
      a) Lack of caregiver or support system for assistance with administration;
      b) Inadequate access to healthcare facility or home care interventions;
   3. Member requires ≥ 10 doses;

ii. One of the following (1, 2, or 3):
   1. Request is for Ziextenzo or Nyvepria;
   2. If request is for a biosimilar pegfilgrastim product other than Ziextenzo or Nyvepria (i.e., Fulphila, Fylnetra, Udenyca), member must have a failure of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;
   3. If request is for Neulasta or Neulasta Onpro, both of the following (a and b):
      a) Member must have a failure of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;
      b) If member is unable to use Ziextenzo or Nyvepria, member must use biosimilar pegfilgrastim products, unless clinically significant adverse effects are experienced or all are contraindicated;

**Prior authorization may be required for Ziextenzo or Nyvepria*

4. Confirmation that there is at least 12 days between pegfilgrastim dose and the next cycle of chemotherapy;
5. The requested medication will not be prescribed concurrently with other colony stimulating factors (e.g., filgrastim, Leukine®) within any chemotherapy cycle;
6. For members receiving palliative chemotherapy, provider attestation that chemotherapy dose reduction has been considered;
7. Dose does not exceed 6 mg (1 syringe) per 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. One of the following (a or b)
   a. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings *(see Appendix E)*;
   b. Both of the following (i and ii):
      i. Failure of at least ONE preferred agent, unless one of the following (1, 2, or 3):
         1. Member has intolerance or contraindication;
         2. Documentation of member's inability to self-administer due to both of the following (a and b):

a) Lack of caregiver or support system for assistance with administration;
b) Inadequate access to healthcare facility or home care interventions;

3. Member requires ≥ 10 doses;

ii. One of the following (1, 2, or 3):
1. Request is for Ziextenzo or Nyvepria;
2. If request is for a biosimilar pegfilgrastim product other than Ziextenzo or Nyvepria (i.e., Fulphila, Fylnetra, Udenyca), member must have a failure of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;
3. If request is for Neulasta or Neulasta Onpro, both of the following (a and b):
a) Member must have a failure of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;
b) If member is unable to use Ziextenzo or Nyvepria, member must use biosimilar pegfilgrastim products, unless clinically significant adverse effects are experienced or all are contraindicated;

**Prior authorization may be required for Ziextenzo or Nyvepria*

3. The requested medication will not be prescribed concurrently with other colony stimulating factors (e.g., filgrastim, Leukine) within any chemotherapy cycle;
4. 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, unless contraindicated, clinically significant adverse effects are experienced, or request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings *(see Appendix E)*;
**Prior authorization may be required for Leukine*
3. One of the following (a or b):
a. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings *(see Appendix E)*;
b. Both of the following (i and ii)
i. Failure of at least ONE preferred agent unless one of the following (1, 2, or 3):
1. Member has intolerance or contraindication;
2. Documentation of member's inability to self-administer due to both of the following (a and b):
a) Lack of caregiver or support system for assistance with administration;
b) Inadequate access to healthcare facility or home care interventions;
3. Member requires ≥ 10 doses;

ii. One of the following (1, 2, or 3):
1. Request is for Ziextenzo or Nyvepria;
2. If request is for a biosimilar pegfilgrastim product other than Ziextenzo or Nyvepria (i.e., Fulphila, Fylnetra, Udenyca), member must have a failure of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;
3. If request is for Neulasta or Neulasta Onpro, both of the following (a and b):
a) Member must have a failure of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;
b) If member is unable to use Ziextenzo or Nyvepria, member must use biosimilar pegfilgrastim products, unless clinically significant adverse effects are experienced or all are contraindicated;

**Prior authorization may be required for Ziextenzo or Nyvepria*

4. The requested medication will not be prescribed concurrently with other colony stimulating factors (e.g., filgrastim, Leukine) within any chemotherapy cycle;
5. Request meets one of the following (a or b):
a. Dose does not exceed 6 mg (1 syringe) per 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 D*);
3. One of the following (a or b):
a. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings *(see Appendix E*);
b. Both of the following (i and ii):
i. Failure of at least ONE preferred agent unless one of the following (1, 2, or 3):
1. Member has intolerance or contraindication;
2. Documentation of member's inability to self-administer due to both of the following (a and b):
a) Lack of caregiver or support system for assistance with administration;
b) Inadequate access to healthcare facility or home care interventions;
3. Member requires ≥ 10 doses;
ii. One of the following (1, 2, or 3):
1. Request is for Ziextenzo or Nyvepria;
2. If request is for a biosimilar pegfilgrastim product other than Ziextenzo or Nyvepria (i.e., Fulphila, Fylnetra, Udenyca), member must have a failure

of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;

3. If request is for Neulasta or Neulasta Onpro, both of the following (a and b):
   a) Member must have a failure of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;
   b) If member is unable to use Ziextenzo or Nyvepria, member must use biosimilar pegfilgrastim products, unless clinically significant adverse effects are experienced or all are contraindicated;

**Prior authorization may be required for Ziextenzo or Nyvepria*

4. The requested medication will not be prescribed concurrently with other colony stimulating factors (e.g., filgrastim, Leukine) within any chemotherapy cycle;
5. Request meets one of the following (a or b):
   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 (must meet 1 and 2):
1. One of the following (a or b):
   a. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings *(see Appendix E)*;
   b. Both of the following (i and ii):
      i. Failure of at least ONE preferred agent unless one of the following (1, 2, or 3):
         1. Member has intolerance or contraindication;
         2. Documentation of member's inability to self-administer due to both of the following (a and b):
            a) Lack of caregiver or support system for assistance with administration;
            b) Inadequate access to healthcare facility or home care interventions;
         3. Member requires ≥ 10 doses;
      ii. One of the following (1, 2, or 3):
         1. Request is for Ziextenzo or Nyvepria;
         2. If request is for a biosimilar pegfilgrastim product other than Ziextenzo or Nyvepria (i.e., Fulphila, Fylnetra, Udenyca), member must have a failure of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;
         3. If request is for Neulasta or Neulasta Onpro, both of the following (a and b):
            a) Member must have a failure of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;

b) If member is unable to use Ziextenzo or Nyvepria, member must use biosimilar pegfilgrastim products, unless clinically significant adverse effects are experienced or all are contraindicated;
**Prior authorization may be required for Ziextenzo or Nyvepria*

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. One of the following (a or b):
   a. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings *(see Appendix E)*;
   b. Both of the following (i and ii):
      i. Failure of at least ONE preferred agent, unless one of the following (1, 2, or 3):
         1. Member has intolerance or contraindication;
         2. Documentation of member's inability to self-administer due to both of the following (a and b):
            a) Lack of caregiver or support system for assistance with administration;
            b) Inadequate access to healthcare facility or home care interventions;
         3. Member requires ≥ 10 doses;
      ii. One of the following (1, 2, or 3):
         1. Request is for Ziextenzo or Nyvepria;
         2. If request is for a biosimilar pegfilgrastim product other than Ziextenzo or Nyvepria (i.e., Fulphila, Fylnetra, Udenyca), member must have a failure of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;
         3. If request is for Neulasta or Neulasta Onpro, both of the following (a and b):
            a) Member must have a failure of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;
            b) If member is unable to use Ziextenzo or Nyvepria, member must use biosimilar pegfilgrastim products, unless clinically significant adverse effects are experienced or all are contraindicated;
            **Prior authorization may be required for Ziextenzo or Nyvepria*
4. The requested medication will not be prescribed concurrently with other colony stimulating factors (e.g., filgrastim, Leukine®) within any chemotherapy cycle;
5. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):

a. Chemotherapy-induced neutropenia, Wilms tumor: 6 mg (1 syringe) administered once per chemotherapy cycle;
b. Acute radiation syndrome: two 6 mg doses administered one week apart;
c. Bone marrow transplantation: 6 mg (1 syringe) per 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 and 2)**:**
1. One of the following (a or b):
   a. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings *(see Appendix E*);
   b. Both of the following (i and ii):
      i. Failure of at least ONE preferred agent unless one of the following (1, 2, or 3):
         1. Member has intolerance or contraindication;
         2. Documentation of member's inability to self-administer due to both of the following (a and b):
            a) Lack of caregiver or support system for assistance with administration;
            b) Inadequate access to healthcare facility or home care interventions;
         3. Member requires ≥ 10 doses;
      ii. One of the following (1, 2, or 3):
         1. Request is for Ziextenzo or Nyvepria;
         2. If request is for a biosimilar pegfilgrastim product other than Ziextenzo or Nyvepria (i.e., Fulphila, Fylnetra, Udenyca), member must have a failure of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;
         3. If request is for Neulasta or Neulasta Onpro, both of the following (a and b):
            a) Member must have a failure of both Ziextenzo and Nyvepria, unless contraindicated or clinically significant adverse effects are experienced;
            b) If member is unable to use Ziextenzo or Nyvepria, member must use biosimilar pegfilgrastim products, unless clinically significant adverse effects are experienced or all are contraindicated;

**Prior authorization may be required for Ziextenzo or Nyvepria*

2. One of the following (a or b):
   a. 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
   b. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NO T 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 policy – CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Neupogen® (filgrastim), Zarxio® (filgrastim-sndz), Granix® (tbo-filgrastim), Nivestym® (filgrastim-aafi)	**Supportive care post autologous hematopoietic cell transplantation** 10 mcg/kg IV or SC infusion QD **Mobilization of peripheral-blood progenitor cells prior to autologous transplantation** 10 mcg/kg SC bolus or continuous infusion QD	10 mcg/kg/day 10 mcg/kg/day
Leukine® (sargramostim)	**Supportive care post autologous hematopoietic cell transplantation** 250 mcg/m^2/day IV **Mobilization of peripheral-blood progenitor cells prior to autologous transplantation** 250 mcg/m^2/day IV or SC QD	500 mcg/m^2/day 250 mcg/m^2/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

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

Appendix D: 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 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 pegfilgrastim and its biosimilars for supportive care post autologous hematopoietic cell transplant and treatment for hematopoietic cell mobilization for autologous donors in combination with plerixafor, both category 2A recommendations.
- 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/m2), 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/m2), 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.

Appendix E: States with Regulations against Redirections in Cancer

State	Step Therapy Prohibited?	Notes
FL	Yes	For stage 4 metastatic cancer and associated conditions.
GA	Yes	For stage 4 metastatic cancer. Redirection does not refer to review of medical necessity or clinical appropriateness.
IA	Yes	For standard of care stage 4 cancer drug use, supported by peer-reviewed, evidence-based literature, and approved by FDA.
LA	Yes	For stage 4 advanced, metastatic cancer or associated conditions. Exception if "clinically equivalent therapy, contains identical active ingredient(s), and proven to have same efficacy.
NV	Yes	Stage 3 and stage 4 cancer patients for a prescription drug to treat the cancer or any symptom thereof of the covered person
OH	Yes	**Applies to Commercial and HIM requests only** For stage 4 metastatic cancer and associated conditions
PA	Yes	For stage 4 advanced, metastatic cancer
TN	Yes	For advanced metastatic cancer and associated conditions
TX	Yes	For stage 4 advanced, metastatic cancer and associated conditions

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Pegfilgrastim (Neulasta), pegfilgrastim-jmdb (Fulphila), pegfilgrastim-cbqv (Udenyca), pegfilgrastim-bmez (Ziextenzo), pegfilgrastin-apgf (Nyvepria), pegfilgrastim-pbbk (Fylnetra)	Myelosuppressive chemotherapy	6 mg administered SC once per chemotherapy cycle. Do not administer between 14 days before and 24 hours after administration of cytotoxic chemotherapy. Weight based dosing for pediatric patients < 45 kg	6 mg/dose
Pegfilgrastim (Neulasta)	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	6 mg/dose

Drug Name	Indication	Dosing Regimen	Maximum Dose
		doses of radiation, and a second dose one week after Weight based dosing for pediatric patients < 45 kg	

VI. Product Availability

Drug Name	Availability
Pegfilgrastim (Neulasta)	• Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only • Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe co-packaged with the on-body injector
Pegfilgrastin-apgf (Nyvepria)	• Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only
Pegfilgrastim-jmdb (Fulphila)	• Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only
Pegfilgrastim-pbbk (Fylnetra)	• Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only
Pegfilgrastim-cbqv (Udenyca)	• Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only
Pegfilgrastim-bmez (Ziextenzo)	• Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only

VII. References

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14. Fylnetra Prescribing Information. Piscataway, NJ: Kashiv BioSciences, LLC; May 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761084s000lbl.pdf. Accessed June 14, 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-todate sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2506	Injection, pegfilgrastim, excludes biosimilar, 0.5 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
Policy created	09.22	11.22

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 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.