Non-Preferred Filgrastim Drugs

Filgrastim, (Neupogen®)

Filgrastim-ayow (Releuko®)

Place of Service
Hospital Administration
Office Administration
Specialty Pharmacy
Home Infusion Administration
Outpatient Facility Administration
Infusion Center Administration
Self-Administration - *May be covered under the pharmacy benefit*

HCPCS
Neupogen: **J1442** per 1 mcg
Releuko: **Q5125** per 1 mcg

Conditions listed in policy *(see criteria for details)*

- Acute exposure to myelosuppressive radiation
- Bone marrow transplantation
- Congenital agranulocytosis
- Cyclic neutropenia
- Drug-induced neutropenia
- Febrile neutropenia
- HIV patients on myelosuppressive therapy
- Idiopathic neutropenia
- Myelodysplastic syndromes
- Peripheral blood stem cell mobilization
- Prevention or treatment in cancer patients receiving myelosuppressive anticancer agents

AHFS therapeutic class: Hematopoietic agents

Mechanism of action: Granulocyte colony-stimulating factor (G-CSF)

(1) Special Instructions and Pertinent Information

If member has a Prescription Benefit, please refer cases to Pharmacy Services for prior authorization.

To submit under the Medical Benefit, please submit clinical information for prior authorization review via fax including **medical rationale why patient cannot home self-administer.**

Filgrastim may be obtained and billed by a specialty pharmacy.

Starting 1/1/2024 and after, Zarxio and Nivestym will be the BSC preferred granulocyte colony-stimulating factor (G-CSF). For many indications, treatment failure, intolerance or contraindication to Zarxio and Nivestym will be required for members newly initiating G-CSF therapy.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for filgrastim for conditions NOT LISTED in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Bone marrow transplantation

1. Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product

Covered Doses
Up to 10 mcg/kg SC per day

Coverage Period
6 months

ICD-10: Z94.81

CPT: 38240, 38241

Congenital agranulocytosis

1. Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product, **AND**
2. Recurring or persistent neutropenia in association with either of the following:
    a. History of recurring infections (*e.g.* multiple episodes of infections requiring antibiotics), or
    b. 1 hospitalization for an infection within the past year

Covered Doses
Initial: Up to 10 mcg/kg SC per day
Maintenance: Titrated dosing to maintain response (e.g. ANC between $800/mm^3$ – $1400/mm^3$)

Coverage Period
1 year

ICD-10:
D70.0

Cyclic neutropenia

1. Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product, **AND**
2. Recurring or persistent neutropenia in association with either of the following:
    a. A history of recurring infections (*e.g.* multiple episodes of infections requiring antibiotics), or
    b. 1 hospitalization for an infection within the past year

Covered Doses
Initial: Up to 10 mcg/kg SC per day
Maintenance: Titrated dosing to maintain response (e.g. ANC between 800/mm^3 – 1400/mm^3)

Coverage Period
1 year

ICD-10:
D70.4

Drug-induced neutropenia

1. Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product, **AND**
2. Neutropenia is caused by an identified drug, **AND**
3. Initial absolute neutrophil count ANC ≤800/mm^3 or ANC ≤ 1000/mm^3 with expected neutropenia of > 5 days

Covered Doses
Initial: Up to 10mcg/kg SC per day
Maintenance: Titrated dosing to maintain response (e.g. ANC between 800/mm^3 – 1400/mm^3)

Coverage Period
Up to the length of therapy that the drug causing neutropenia is prescribed or up to one year (whichever is less)

ICD-10:
D70.2

Febrile neutropenia

1. Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product, **AND**
2. Initial absolute neutrophil count ANC ≤800/mm^3 or ANC ≤ 1000/mm^3 with expected neutropenia of > 5 days, **AND**
3. Patient has not received pegfilgrastim (e.g. Neulasta, Fulphila, Udenyca) for neutropenia prophylaxis in the past 14 days

Covered Doses
Initial: Up to 10 mcg/kg SC per day

Maintenance: Titrated dosing to maintain response (e.g. ANC between 800/mm^3 – 1400/mm^3)

Coverage Period
Up to 2 months

ICD-10:
D70.9 with R50.81

HIV patients on myelosuppressive therapy

1. Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product, **AND**
2. Initial absolute neutrophil count ANC ≤800/mm^3 or ANC ≤ 1000/mm^3 with expected neutropenia of > 5 days

Covered Doses
Initial: Up to 10 mcg/kg SC per day
Maintenance: Titrated dosing to maintain response (e.g., ANC between 800/mm^3 – 1400/mm^3)

Coverage Period
Up to the length of therapy that the drug causing neutropenia is prescribed or up to one year (whichever is less)

ICD-10:
B20 plus D70.2

Idiopathic neutropenia

1. Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product, **AND**
2. Recurring or persistent neutropenia in association with of the following:
    a. a history of recurring infections (*e.g.,* multiple episodes of infections requiring antibiotics), **OR**
    b. 1 hospitalization for an infection within the past year

Covered Doses
Initial: Up to 10 mcg/kg SC per day
Maintenance: Titrated dosing to maintain response (e.g. ANC between 800/mm^3 – 1400/mm^3)

Coverage Period
1 year

ICD-10:
D70.9

Myelodysplastic syndromes

1. Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product, **AND**
2. Either of the following:
    a. Initial absolute neutrophil count ANC ≤800/mm^3 or ANC ≤ 1000/mm^3 with expected neutropenia of > 5 days, **OR**
    b. Being used in combination with an erythropoiesis-stimulating agent [ESA] (e.g., Procrit or Aranesp) to improve symptoms of anemia, AND both the following:
        i. Hgb < 10 gm/dl, **and**
        ii. EPO level ≤ 500 mU/mL

Covered Doses
Up to 10 mcg/kg SC per day

Coverage Period
Indefinite

ICD-10:
D46.0, D46.1, D46.2-D46.22, D46.4, D46.9, D46.A-D46.C, D46.Z

Peripheral blood stem cell mobilization

1. Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product, **AND**
2. Drug is NOT covered under a transplant case rate

Covered Doses
Up to 12 mcg/kg SC per day

Coverage Period
Up to 3 months
Reauthorization requires continued response to therapy

ICD-10:
Z48.290, Z52.001, Z52.011, Z52.091, Z94.81, Z94.84

CPT:
38205, 38206

Prevention or treatment in cancer patients receiving myelosuppressive anticancer agents (J9000 series codes)

1. Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product, **AND**

2. Drug is not being used concurrently with long-acting or short-acting granulocyte colony stimulating factors (e.g. filgrastim or pegfilgrastim drugs)

Covered Doses
Up to 10 mcg/kg SC per day

Coverage Period
Up to the length of the chemotherapy treatment that or up to one year (whichever is less).

ICD-10:
C00.0-C91.91, C92.0x, C92.2x-C92.6x, C92.Ax, C93.00, C93.02, C94.00, C94.02, C94.20, C94.22, D00.00-D49.9, D70.1
**Does NOT include C92.10, C92.11, C92.12*

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for filgrastim for conditions NOT LISTED in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acute exposure to myelosuppressive doses of radiation

Covered Doses
Up to 10 mcg/kg SC per day

ICD-10: (X = any number)
T66.X

(4) This Medication is NOT medically necessary for the following condition(s):
Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Auto Immune Disorders
- Burn Patients
- Chronic Infections
- ANC > 1000/mm^3
- Combination use of granulocyte-colony stimulating factor (G-CSF) drugs (e.g., Granix, Leukine, Nivestym, Zarxio, Neulasta, Fulphila, Udenyca) or using more than one G-CSF drug during a single chemotherapy cycle for neutropenia prophylaxis due to myelosuppressive chemotherapy

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How Supplied:

Vials

- 300 mcg/mL in a single-dose vial
- 480 mcg/1.6 mL in a single-dose vial

Prefilled Syringes

- 300 mcg/0.5 mL in a single-dose prefilled syringe
- 480 mcg/0.8 mL in a single-dose prefilled syringe

For Nivestym, administration of doses less than 180 mcg (0.3ml) using the prefilled syringe is not recommended. A dose less than 0.3 ml cannot be accurately measured using the Nivestym prefilled syringe.

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 2.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 1.2023). Available at: www.nccn.org.
- Neupogen® (filgrastim) [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; 4/2023.
- Nivestym™ (filgrastim-aafi) [Prescribing Information]. New York, NY: Pfizer, Inc.; 3/2023.
- Releuko® (filgrastim-ayow) [Prescribing Information]. Bridgewater, NJ: Amneal Biosciences, LLC; 2/2022.

(7) Policy Update

Date of last revision: 1Q2024
Date of next review: 3Q2024
Changes from previous policy version:

- No clinical change to policy following revision.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee