filgrastim

Commercial Medical Benefit Drug Policy

filgrastim, (Neupogen)
filgrastim-aafi (Nivestym)
filgrastim-ayow (Releuko)
filgrastim-sndz (Zarxio)
filgrastim-txid (Nypozi)

For oncology-related indications, medical necessity criteria can be found here: Blue Shield Oncology-Related Medication Policies.

For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's CarePro Provider Portal to submit your request.

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

Drug Details

USP Category: BLOOD PRODUCTS AND MODIFIERS
Mechanism of Action: Granulocyte colony-stimulating factor (G-CSF)
HCPCS:
J1442:Injection, filgrastim (g-csf), excludes biosimilars, 1 microgram
Q5101:Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram
Q5110:Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram
Q5125:Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram
Q5148:Injection, filgrastim-txid (nypozi), biosimilar, 1 microgram
How Supplied:
Neupogen / Nivestim / Releuko / Zarxio:
300 mcg/ml (single-dose vial)
480 mcg/1.6 ml (single-dose vial)
300 mcg/0.5 ml (single-dose prefilled syringe)
480 mcg/0.8 ml (single-dose prefilled syringe)

Nypozi:
300 mcg/0.5 ml (single-dose prefilled syringe)
480 mcg/0.8 ml (single-dose prefilled syringe)

Condition(s) listed in policy *(see coverage criteria for details)*

- Acute Exposure to Myelosuppressive Doses of Radiation

- Bone Marrow Transplantation
- Congenital Neutropenia (including Agranulocytosis), Cyclic Neutropenia or Idiopathic Neutropenia
- Drug-Induced Neutropenia
- Febrile Neutropenia
- HIV Patients on Myelosuppressive Therapy
- Peripheral Blood Stem Cell Mobilization

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Zarxio and Nivestym are 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.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Congenital Neutropenia (including Agranulocytosis), Cyclic Neutropenia or Idiopathic Neutropenia
Meets medical necessity if all the following are met:

1. For a non-preferred filgrastim product (Neupogen, Nypozi, or Releuko) request: Intolerance or contraindication with preferred filgrastim products (Nivestym and Zarxio) that is not expected with requested filgrastim product
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)
   b. 1 hospitalization for an infection within the past year

Covered Doses:
Initial: Up to 10 mcg/kg given subcutaneously once daily
Maintenance: Titrated dosing to maintain response (e.g. Absolute Neutrophil Count between 800/mm^3 – 1400/mm^3)

Coverage Period:
1 year

ICD-10:
D70.0, D70.4, D70.9

Drug-Induced Neutropenia
Meets medical necessity if all the following are met:
1. For a non-preferred filgrastim product (Neupogen, Nypozi, or Releuko) request: Intolerance or contraindication with preferred filgrastim products (Nivestym and Zarxio) that is not expected with requested filgrastim product
2. Neutropenia is caused by an identified drug
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 10 mcg/kg given subcutaneously once daily
Maintenance: Titrated dosing to maintain response (e.g. Absolute Neutrophil Count 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
Meets medical necessity if all the following are met:
1. For a non-preferred filgrastim product (Neupogen, Nypozi, or Releuko) request: Intolerance or contraindication with preferred filgrastim products (Nivestym and Zarxio) that is not expected with requested filgrastim product
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 given subcutaneously once daily
Maintenance: Titrated dosing to maintain response (e.g. Absolute Neutrophil Count 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
Meets medical necessity if all the following are met:
1. For a non-preferred filgrastim product (Neupogen, Nypozi, or Releuko) request: Intolerance or contraindication with preferred filgrastim products (Nivestym and Zarxio) that is not expected with requested filgrastim product

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 given subcutaneously once daily
Maintenance: Titrated dosing to maintain response (e.g., Absolute Neutrophil Count 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 with D70.2

Peripheral Blood Stem Cell Mobilization
Meets medical necessity if all the following are met:
1. For a non-preferred filgrastim product (Neupogen, Nypozi, or Releuko) request: Intolerance or contraindication with preferred filgrastim products (Nivestym and Zarxio) that is not expected with requested filgrastim product

Covered Doses:
Up to 12 mcg/kg given subcutaneously once daily

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

CPT:
38205, 38206

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

The following condition(s) DO NOT require Prior Authorization/Preservice if ALL its parameters are met, otherwise Prior Authorization/Preservice is required.

Acute Exposure to Myelosuppressive Doses of Radiation

Covered Doses:
Up to 10 mcg/kg given subcutaneously once daily

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

Bone Marrow Transplantation
1. For a non-preferred filgrastim product (Neupogen, Nypozi, or Releuko) request: Intolerance or contraindication with preferred filgrastim products (Nivestym and Zarxio) that is not expected with requested filgrastim product

Covered Doses:
Up to 10 mcg/kg given subcutaneously once daily

ICD-10:
Z94.81, or CPT: 38240, 38241

References

1. National Comprehensive Cancer Network. Acute Myeloid Leukemia (Version 2.2025). Available at http://www.nccn.org.
2. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 1.2025). Available at: www.nccn.org.
3. National Comprehensive Cancer Network. Hematopoietic Stem Cell Transplantation (Version 2.2025). Available at http://www.nccn.org.
4. National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 2.2025). Available at: www.nccn.org.
5. Neupogen (filgrastim). Prescribing Information. Thousand Oaks, CA: Amgen Inc.; 4/2023.
6. Nivestym (filgrastim-aafi) Prescribing Information. Pfizer, Inc., New York, NY: 2/2024.
7. Nypozi (filgrastim-txid) Prescribing Information. Tanvex BioPharma USA, Inc., San Diego, CA: 12/2024.
8. Releuko (filgrastim-ayow) [Prescribing Information]. Amneal Biosciences, LLC, Bridgewater, NJ: 4/2022.
9. Zarxio (filgrastim-sndz). Prescribing Information. Princeton, NJ: Sandoz Inc; 10/2024.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- For oncology-related indications, medical necessity criteria can be found here: Blue Shield Oncology-Related Medication Policies.
- For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's CarePro Provider Portal to submit your request.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee