blue california
Promise Health Plan

filgrastim

Medical Benefit Drug Policy

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

For oncology-related indications, coverage will be made based on medical necessity. Medical necessity determinations are made based on U.S. Food and Drug Administration (FDA) labeling, peer-reviewed medical literature, Medi-Cal coverage guidelines, and Centers for Medicare & Medicaid Services (CMS) approved compendia support (i.e., Clinical Pharmacology, National Comprehensive Cancer Network® (NCCN), American Hospital Formulary Service Drug Information, Thomson Micromedex DrugDex,® and Lexicomp®).

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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

Nivestym, Nypozi, Releuko, and Zarxio are the BSC preferred granulocyte colony-stimulating factor (G-CSF). For many indications, request for Neupogen for members newly initiating filgrastim therapy will require treatment failure or intolerance to all the preferred drugs or contraindication to all the preferred drugs for certain indications.

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

Acute Exposure to Myelosuppressive Doses of Radiation
Meets medical necessity if all the following are met:

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

Coverage Period:
As needed

ICD-10:

T66.X (X = any number)

Bone Marrow Transplantation

Meets medical necessity if all the following are met:

1. For request for Neupogen: Intolerable side effect with the preferred filgrastim products, Nivestym, Nypozi, Releuko, and Zarxio, that is not expected with Neupogen, or contraindication to all preferred drugs.

Covered Doses:

Up to 10 mcg/kg given subcutaneously once daily

Coverage Period:

6 months

ICD-10:

Z94.81, or CPT: 38240, 38241

Congenital Neutropenia (including Agranulocytosis), Cyclic Neutropenia or Idiopathic Neutropenia

Meets medical necessity if all the following are met:

1. 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
2. For request for Neupogen: Intolerable side effect with the preferred filgrastim products, Nivestym, Nypozi, Releuko, and Zarxio, that is not expected with Neupogen, or contraindication to all preferred drugs.

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. Neutropenia is caused by an identified drug

2. Initial absolute neutrophil count (ANC) ≤800/mm3 or ANC ≤ 1000/mm3 with expected neutropenia of > 5 days
3. For request for Neupogen: Intolerable side effect with the preferred filgrastim products, Nivestym, Nypozi, Releuko, and Zarxio, that is not expected with Neupogen, or contraindication to all preferred drugs.

Covered Doses:
Initial: Up to 10 mcg/kg given subcutaneously once daily
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
Meets medical necessity if all the following are met:
1. Initial Absolute Neutrophil Count (ANC) ≤800/mm^3 or ANC ≤ 1000/mm^3 with expected neutropenia of > 5 days
2. For request for Neupogen: Intolerable side effect with the preferred filgrastim products, Nivestym, Nypozi, Releuko, and Zarxio, that is not expected with Neupogen, or contraindication to all preferred drugs.

Covered Doses:
Initial: Up to 10 mcg/kg given subcutaneously once daily
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
Meets medical necessity if all the following are met:
1. Initial Absolute Neutrophil Count (ANC) ≤800/mm^3 or ANC ≤ 1000/mm^3 with expected neutropenia of > 5 days

2. For request for Neupogen: Intolerable side effect with the preferred filgrastim products, Nivestym, Nypozi, Releuko, and Zarxio, that is not expected with Neupogen, or contraindication to all preferred drugs.

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

Peripheral Blood Stem Cell Mobilization
Meets medical necessity if all the following are met:
1. For request for Neupogen: Intolerable side effect with the preferred filgrastim products, Nivestym, Nypozi, Releuko, and Zarxio, that is not expected with Neupogen, or contraindication to all preferred drugs.

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

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, coverage will be made based on medical necessity

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