Preferred filgrastim drugs	Place of Service
Filgrastim-sndz (Zarxio®) Filgrastim-aafi (Nivestym™)	Office Administration Outpatient Facility Administration Infusion Center Administration Home Infusion Administration Self-Administration - *May be covered under the pharmacy benefit* HCPCS: Zarxio: **Q5101** per 1 mcg Nivestym: **Q5110** per 1 mcg

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

- Acute exposure to myelosuppressive radiation
- Bone marrow transplantation
- Congenital neutropenia
- 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.

If covered under the Medical Benefit, please submit clinical information for prior authorization review via fax. **Please include medical rationale why medication cannot be home self-administered.**

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

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

Congenital neutropenia

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), or
    b. One 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. Recurring or persistent neutropenia in association with either one of the following:
    a. History of recurring infections (*e.g.* multiple episodes of infections requiring antibiotics), or
    b. One 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. Neutropenia is caused by an identified drug, **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:
D70.2

Febrile neutropenia

1. Initial absolute neutrophil count ANC ≤800/mm^3 or ANC ≤ 1000/mm^3 with expected neutropenia of > 5 days, **AND**
2. Patient has not received pegfilgrastim drugs (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. 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. Recurring or persistent neutropenia in association with either one 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:
D70.9

Myelodysplastic syndromes

1. 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**
        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. 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

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Zarxio® (filgrastim-sndz) 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

Bone marrow transplantation (CPT: 38240, 38241)

Covered Doses
Up to 10 mcg/kg SC per day

ICD-10:
Z94.81

CPT:
38240, 38241

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

1. Zarxio 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*

(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, Neupogen, Nivestym, Neupogen, 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:
300 mcg prefilled syringe
480 mcg prefilled syringe

Administration of doses less than 180 mcg (0.3 ml) is not recommended. A dose less than 0.3 ml cannot be accurately measured using the Zarxio 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.
- Zarxio® (filgrastim-sndz) [Prescribing Information]. Princeton, NJ: Sandoz Inc; 9/2022.

(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