blue of california

FILGRASTIM AGENTS

Applies To:
filgrastim (NEUPOGEN)
filgrastim-aafi (NIVESTIM)
filgrastim-ayow (RELEUKO)
filgrastim-sndz (ZARXIO)

Zarxio and Nivestym are the BSC preferred granulocyte colony-stimulating factor (G-CSF) drugs. For many indications, treatment failure, intolerance, or contraindication to Zarxio (filgrastim-sndz) is required for members newly initiating G-CSF therapy.

Diagnoses Considered for Coverage:

- Acute exposure to myelosuppressive radiation
- Congenital agranulocytosis
- Cyclic neutropenia
- Febrile neutropenia
- Idiopathic neutropenia
- Peripheral blood stem cell mobilization
- Prevention or treatment in cancer patients receiving myelosuppressive anticancer drugs
- Bone marrow transplantation
- HIV patients on myelosuppressive therapy – *support in DrugDex*
- Myelodysplastic syndromes – *off-label support in compendia*
- Drug-induced neutropenia – *off-label support in DrugDex*

Coverage Criteria:

1. **For prevention or reduction of neutropenia in patients receiving myelosuppressive chemotherapy:**

- Patient is receiving myelosuppressive chemotherapy, **and**
- Not being used in concurrently with peg-filgrastim (e.g. Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria) for prevention of neutropenia, **and**
- ***For Neupogen and Releuko request***: Intolerance or contraindication to Zarxio and Nivestym not expected with requested GCSF agent, **and**
- Dose does not exceed 10 mcg/kg per day for up to 14 days per chemo cycle

Coverage Duration: duration of chemotherapy treatment

2. **For diagnosis of prevention or reduction of acute radiation-induced**

neutropenia:

- Patient is currently receiving radiation therapy, **and**
- Not being used as part of a radiation regimen in combination with peg-filgrastim (e.g. Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria) for prevention of neutropenia, **and**
- Dose does not exceed FDA label maximum, and
- ***For Neupogen and Releuko:*** Intolerance or contraindication to Zarxio and Nivestym not expected with requested GCSF agent.

Coverage Duration: duration of radiation therapy

3. **For diagnosis of peripheral blood stem cell mobilization:**

- Dose does not exceed FDA label maximum, and
- ***For Neupogen and Releuko:*** Intolerance or contraindication to Zarxio and Nivestym not expected with requested GCSF agent.

Coverage Duration: up to 3 months

4. **For diagnosis of congenital neutropenia or agranulocytosis, cyclic neutropenia, or idiopathic neutropenia:**

- Dose does not exceed FDA label maximum, and
- ***For Neupogen and Releuko:*** Intolerance or contraindication to Zarxio and Nivestym not expected with requested GCSF agent, and
- One of the following:
- Patient has had multiple episodes of infections requiring antibiotics **or**
- Patient has been hospitalized for an infection within the past year.

Coverage Duration: 1 year

5. **For diagnosis of febrile neutropenia:**

- Absolute neutrophil count (ANC) ≤ 800 cells/mcl or absolute neutrophil count (ANC) ≤ 1000 cells/mcl and is expected to last at least 5 days, **and**
- Patient did not use peg-filgrastim (e.g. Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria) within the last 14 days for chemotherapy-induced neutropenia prophylaxis, **and**
- Dose does not exceed FDA label maximum, and
- ***For Neupogen and Releuko:*** Intolerance or contraindication to Zarxio and

Nivestym not expected with requested GCSF agent.

Coverage Duration: 2 months

6. **For diagnosis of drug-induced neutropenia:**

- Neutropenia is caused by an identified drug, **and**
- Absolute neutrophil count (ANC) ≤ 800 cells/mcl or absolute neutrophil count (ANC) ≤ 1000 cells/mcl and is expected to last at least 5 days, **and**
- Dose does not exceed FDA label maximum, and
- ***For Neupogen and Releuko:*** Intolerance or contraindication to Zarxio and Nivestym not expected with requested GCSF agent.

Coverage Duration: Up to length of therapy with drug causing neutropenia or up to one year (whichever is less)

7. **For diagnosis of drug-induced neutropenia in HIV patients receiving myelosuppressive drugs:**

- Absolute neutrophil count (ANC) ≤ 800 cells/mcl or absolute neutrophil count (ANC) ≤ 1000 cells/mcl and is expected to last at least 5 days, **and**
- Dose does not exceed FDA label maximum, and
- ***For Neupogen and Releuko:*** Intolerance or contraindication to Zarxio and Nivestym not expected with requested GCSF agent.

Coverage Duration: Up to length of therapy with drug causing neutropenia or up to one year (whichever is less)

8. **For bone marrow transplantation:**

- Dose does not exceed FDA label maximum, **and**
- ***For Neupogen and Releuko:*** Intolerance or contraindication to Zarxio and Nivestym not expected with requested GCSF agent.

Coverage Duration: Day 5 following transplant until ANC recovery

9. **For diagnosis of myelodysplastic syndrome (MDS), approve if:**

- Either one of the following:
  - Initial ANC ≤800/mm^3, **or**

- ANC ≤ 1000/mm^3 with expected neutropenia of > 5 days, **or**
- Being used in combination with an erythropoiesis-stimulating agent (e.g. Procrit or Aranesp) to improve symptoms of anemia **AND**
    - Hgb less than 10 gm/dl, **and**
    - EPO level less than or equal to 500 mU/mL

AND

- Dose does not exceed FDA label maximum, and
- ***For Neupogen and Releuko:*** Intolerance or contraindication to Zarxio and Nivestym not expected with requested GCSF agent.

Coverage Duration: one year

Coverage Duration: see specific criteria

References:

1. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Volume 4.2021). Available at: www.nccn.org.
2. National Comprehensive Cancer Network. Myelodysplastic Syndromes (Volume 3.2021). Available at: www.nccn.org.
3. Neupogen® (filgrastim) [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; 2/2021.
4. NivestymTM (filgrastim-aafi) [Prescribing Information]. New York, NY: Pfizer, Inc.; 4/2021.
5. Releuko® (filgrastim-ayow) [Prescribing Information]. Bridgewater, NJ: Pfizer, Inc.; 2/2022.

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