

LEUKINE (sargramostim, GM-CSF)

Diagnoses Considered for Coverage:

- Prophylaxis in patients with acute myelogenous leukemia (AML) following chemotherapy
- Prophylaxis in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy
- Bone Marrow Transplantation
- High-risk neuroblastoma
- Peripheral blood stem cell mobilization
- Prevention or reduction of acute radiation-induced neutropenia
- Aplastic Anemia
- Drug-induced Neutropenia
- Febrile Neutropenia
- HIV patients on Myelosuppressive Drugs
- Myelodysplastic Syndromes

Coverage Criteria:

For diagnosis of chemotherapy-induced or BMT related neutropenia:

1. Dose is appropriate for diagnosis, **and**
2. Intolerance or contraindication with preferred filgrastim products (Zarxio and Nivestym) that is not expected with requested filgrastim product, **and**
3. Diagnosis is one of the following:
 - To prevent neutropenia and shorten neutropenic time in patients receiving myelosuppressive chemotherapy, **or**
 - To mobilize peripheral blood stem cells for collection, **or**
 - To accelerate myeloid recovery and engraftment after bone marrow transplantation (BMT).

Coverage Duration:

Chemotherapy-induced: 14 days

BMT related: up to 2 months

For diagnosis of high-risk neuroblastoma:

1. Patient has received prior first-line therapy, **and**
2. Used in combination with Unituxin (dinutuximab) or Danyelza (naxitamab-ggk), **and**
3. Dose does not 250 mcg/m² subcutaneously daily for 5 doses starting 5 days prior to the day 1 Danyelza (naxitamab-ggk) infusion followed by 500 mcg/m² subcutaneously daily on days 1, 2, 3, 4, and 5 repeated each cycle in combination with Danyelza (naxitamab-ggk).

Coverage Duration: one year

For a diagnosis of myelodysplastic syndrome, aplastic anemia, febrile neutropenia, drug-induced neutropenia or HIV patients on myelosuppressive medications:

1. Intolerance or contraindication with preferred filgrastim products (e.g., Zarxio and Nivestym) that is not expected with requested filgrastim product, and
2. One of the following:
 - Absolute neutrophil count (ANC) $\leq 800/\text{mm}^3$, or
 - Absolute neutrophil count (ANC) $\leq 1000/\text{mm}^3$ with expected neutropenia of > 5 days.

Coverage Duration:

Febrile neutropenia: 2 months

Myelodysplastic syndrome: 3 months; Reauth requires continued response to therapy

Aplastic anemia: up to 3 months

Drug-induced neutropenia or HIV patients on myelosuppressive medications: Up to length of therapy with drug causing neutropenia or up to 1 year (whichever is less). Reauthorization requires continuation of drug therapy causing neutropenia.

For prevention or reduction of acute radiation-induced neutropenia:

1. Patient is currently receiving radiation therapy, and
2. Intolerance or contraindication with preferred filgrastim products (e.g., Zarxio and Nivestym) that is not expected with requested filgrastim product, and
3. Dose does not exceed 7 mcg/kg per day.

Coverage Duration: through duration of radiation therapy

Coverage Criteria: see above

Effective Date: 04/03/2024