Reference number(s)
2115-A

JURISDICTION SPECIFIC MEDICARE PART B

NEUPOGEN (filgrastim)
GRANIX (tbo-filgrastim)
NIVESTYM (filgrastim-aafi)
RELEUKO (filgrastim-ayow)
ZARXIO (filgrastim-sndz)

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. Prevention of febrile neutropenia due to myelosuppressive chemotherapy
B. Following induction or consolidation chemotherapy treatment in patients with acute myeloid leukemia
C. Patient's undergoing myeloablative chemotherapy followed by bone marrow transplantation
D. Mobilization of autologous hematopoietic progenitor cells into peripheral blood
E. Hematopoietic syndrome of acute radiation syndrome (H-ARS)
F. Severe chronic neutropenia (congenital, cyclic, or idiopathic)
G. Acquired immunodeficiency syndrome (AIDS) leukopenia in children
H. Leukopenia due to treatment with zidovudine or ganciclovir in AIDS patients
I. Neutropenia due to myelodysplastic syndrome (MDS)

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. EXCLUSIONS

The following are exclusions to therapy:
A. The medication will be administered by the member or the member's caregiver at home
B. The medication will be administered within 24 hours of chemotherapeutic medication
C. The medication will be administered concurrently with radiotherapy
D. The medication will be administered to increase chemotherapy dose intensity
E. The medication will be used for any of the following indications:
    1. Aplastic anemia
    2. Hairy cell leukemia
    3. Myeloid malignancy other than acute myeloid leukemia (AML)
    4. Drug-induced agranulocytosis
    5. Congenital agranulocytosis
    6. Alloimmune neonatal neutropenia
    7. Afebrile neutropenia

III. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. The member's current absolute neutrophil count (ANC)
B. The member's weight in kilograms
C. Dose and administration schedule of G-CSF
D. The indication for which the drug was given and accompanying symptomology (e.g., fever)
E. The member's response to treatment

IV. CRITERIA FOR APPROVAL

A. Prevention of neutropenia in cancer patients due to myelosuppressive chemotherapy
Authorization of 6 months may be granted for the prevention of febrile neutropenia in cancer patients receiving myelosuppressive chemotherapy for a non-myeloid malignancy.

B. Induction or consolidation chemotherapy in acute myeloid leukemia
Authorization of 6 months may be granted for reducing the time to neutrophil recovery and duration of fever following induction or consolidation chemotherapy treatment of members with acute myeloid leukemia.

C. Bone marrow transplantation in non-myeloid malignancies
Authorization of 6 months may be granted to reduce the duration of neutropenia and neutropenia-related sequelae in members with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation when the member's initial dose will not exceed 10 mcg/kg per day.

D. **Mobilization of hematopoietic progenitor cells in the autologous setting**
Authorization of 6 months may be granted for mobilization of autologous hematopoietic progenitor cells into peripheral blood when both of the following criteria are met:
1. The initial dose will not exceed 10 mcg/kg per day
2. The medication will be initiated at least 4 days before the first leukapheresis procedure and continued until the last leukapheresis

E. **Severe chronic neutropenia (congenital, cyclic, or idiopathic)**
Authorization of 6 months may be granted for treatment of severe chronic neutropenia including congenital, cyclic, or idiopathic neutropenia.

F. Acquired immunodeficiency syndrome (AIDS) leukopenia in children
Authorization of 6 months may be granted for the treatment of acquired immunodeficiency syndrome (AIDS) leukopenia in children

G. **Leukopenia due to treatment with zidovudine or ganciclovir**
Authorization of 6 months may be granted for the treatment of leukopenia due to treatment with zidovudine or ganciclovir in members with acquired immunodeficiency syndrome (AIDS)

H. **Neutropenia due to myelodysplastic syndrome (MDS)**
Authorization of 6 months may be granted for members who have severe neutropenia and recurrent infections with myelodysplastic syndrome

I. **Hematopoietic syndrome of acute radiation syndrome (H-ARS)**
Authorization of 6 months may be granted for acute exposure to myelosuppressive doses of radiation when the initial dose will not exceed 10 mcg/kg per day.

V. DOSAGE AND ADMINISTRATION

Filgrastim will be covered when it is not self/caregiver administered. When administered by the member or caregiver, the drug will be considered self-administered and not payable.

VI. REFERENCES

1. G-CSF LCD (L34002) Version R8. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed May 24, 2022.
2. Billing and Coding: G-CSF filgrastim (A57789) Version R1. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed August 30, 2022.
3. Neupogen [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2021.
4. Nivestym [package insert]. Lake Forest, IL: Hospira Inc.; November 2021.
5. Granix [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2019.
6. Zarxio [package insert]. Princeton, NJ: Sandoz Inc.; March 2021.
7. Releuko [package insert]. Piscataway, NJ: Kashiv Biosciences, LLC; February 2022.