Short-Acting Granulocyte Colony Stimulating Factors (SA-gCSF): Filgrastim (Neupogen®); Filgrastim-aafi (Nivestym™); Filgrastim-sndz (Zarxio®); Filgrastim-ayow (Releuko®); Tbo-Filgrastim (Granix®) (Subcutaneous/Intravenous)

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I. Length of Authorization

Coverage will be provided for 4 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

– Neupogen 300 mcg single-dose vial: 2 vials per 1 day – Neupogen 300 mcg single-dose prefilled syringe (SingleJect): 2 syringes per 1 day – Neupogen 480 mcg single-dose vial: 2 vials per 1 day – Neupogen 480 mcg single-dose prefilled syringe (SingleJect): 2 syringes per 1 day
– Nivestym 300 mcg single-dose vial: 2 vials per 1 day – Nivestym 300 mcg single-dose prefilled syringe: 2 syringes per 1 day – Nivestym 480 mcg single-dose vial: 2 vials per 1 day – Nivestym 480 mcg single-dose prefilled syringe: 2 syringes per 1 day
– Zarxio 300 mcg single-dose prefilled syringe: 2 syringes per 1 day – Zarxio 480 mcg single-dose prefilled syringe: 2 syringes per 1 day
– Releuko 300 mcg single-dose prefilled syringe: 2 syringes per 1 day – Releuko 480 mcg single-dose prefilled syringe: 2 syringes per 1 day – Releuko 300 mcg single-dose vial: 2 vials per 1 day – Releuko 480 mcg single-dose vial: 2 vials per 1 day
– Granix 300 mcg single-dose pre-filled syringe: 2 syringes per 1 day – Granix 300 mcg single-dose vial: 2 vials per 1 day – Granix 480 mcg single-dose pre-filled syringe: 2 syringes per 1 day – Granix 480 mcg single-dose vial: 2 vials per 1 day

B. Max Units (per dose and over time) [HCPCS Unit]:

Severe Chronic Neutropenia (Congenital Neutropenia):

- 1560 billable units per day

BMT or PBPC or H-ARS:

- 1200 billable units per day

All other indications:

- 600 billable units per day

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Zarxio is the preferred short-acting granulocyte colony-stimulating factor product and does not require prior authorization. • Patients must have failed, or have a contraindication, or intolerance to Zarxio prior to consideration of any other short-acting G-CSF product.

Bone Marrow Transplant (BMT) † ‡ Φ [1-4,6]

Peripheral Blood Progenitor Cell (PBPC) mobilization and transplant † ‡ Φ [1-3,6,19,30,33,35-37]

Prophylactic use in patients with solid tumors or non-myeloid malignancy † ‡ [1-7,9,10,12,13,15,17,27-29]

- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia❖ of > 20% **§**; **OR**
- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia❖ of 10% to 20% **§ AND** <u>one</u> or more of the patient-related risk factors **¥**; **OR**
- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia❖ of < 10% **§ AND** <u>two</u> or more of the patient-related risk factors **¥ ****

  ********Use in this setting is based on clinical judgment*

  <u>Note</u>: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.

Treatment of chemotherapy-induced febrile neutropenia ‡ [6,7,9,10,12,13,15,17,27-29]

- Patient has been on prophylactic therapy with filgrastim or tbo-filgrastim *(Note: therapy should not be used concomitantly with pegfilgrastim)*; **OR**
- Patient has not received prophylactic therapy with a granulocyte colony stimulating factor; **AND**
  - Patient has one or more of the following risk factors for developing infection-related complications:
    - Sepsis Syndrome
    - Age greater than 65 years

- Absolute neutrophil count [ANC] less than 100/mcL
- Duration of neutropenia expected to be greater than 10 days
- Pneumonia or other clinically documented infections
- Invasive fungal infection
- Hospitalization at the time of fever
- Prior episode of febrile neutropenia

Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy ‡ [6,7,9,10,12,13,15,17,27-29]

Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.

Acute Myeloid Leukemia (AML) † ‡ Φ [1-4,8,14,35]

- Used in patients receiving induction/consolidation or re-induction chemotherapy; **OR**
- Used for relapsed or refractory disease

Bone Marrow Transplantation (BMT) failure or Engraftment Delay ‡ [25,26,30,33,35-37]

Severe Chronic Neutropenia † ‡ Φ [1-4,11]

- Patient must have an absolute neutrophil count (ANC) < 500/mm^3; **AND**
- Patient must have a diagnosis of one of the following:
  - Congenital neutropenia; **OR**
  - Cyclic neutropenia; **OR**
  - Idiopathic neutropenia

Myelodysplastic Syndromes (MDS) ‡ [6,38]

- Patient has symptomatic anemia with no del(5q) mutation; **AND**
- Patient has lower risk disease (*i.e., defined as IPSS-R [Very Low, Low, Intermediate]*); **AND**
- Patient has a serum erythropoietin level of ≤500 mUnits/mL; **AND**
- Used in combination with an erythropoiesis stimulating agent (ESA); **AND**
  - Patient has ring sideroblasts ≥15% (or ring sideroblasts ≥5% with an SF3B1 mutation); **AND**
    - Used following no response* to luspatercept; **OR**
  - Patient has ring sideroblasts <15% (or ring sideroblasts <5% with an SF3B1 mutation); **AND**
    - Used following no response* to ESAs alone (despite adequate iron stores); **OR**
    - Used following no response* to luspatercept

*** Note:** *No response defined as a lack of ≥1.5 gm/dL rise in hemoglobin OR lack of a decrease in RBC transfusion requirement (within 3-6 months if treated with luspatercept or 6-8 weeks if treated with ESAs)*

Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome [H-ARS]) † ‡ Φ [1-4,6,7,18]

Management of CAR T-cell related Toxicity ‡ [6]

- Patient has been receiving therapy with CAR T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, ciltacabtagene autoleucel, idecabtagene vicleucel, lisocabtagene maraleucel, tisagenlecleucel, etc.); **AND**
- Patient is experiencing neutropenia related to their therapy

Wilms Tumor (Nephroblastoma) ‡ [6]

- Patient has favorable histology disease; **AND**
- Used in combination with a cyclophosphamide-based chemotherapy regimen (i.e., Regimen M or I only)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

¥ Patient risk factors for febrile neutropenia: [7]
– Age >65 years receiving full dose intensity chemotherapy – Prior exposure to chemotherapy or radiation therapy – Persistent neutropenia (ANC ≤ 1000/mm3) – Bone marrow involvement by tumor – Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts) – Recent surgery and/or open wounds – Poor performance status – Renal dysfunction (creatinine clearance <50 mL/min) – Liver dysfunction (elevated bilirubin >2.0 mg/dL) – Chronic immunosuppression in the post-transplant setting, including organ transplant
❖Febrile neutropenia is defined as: [7]
– Temperature: a single temperature ≥38.3 °C orally or ≥38.0 °C over 1 hour; **AND** – Neutropenia: <500 neutrophils/mcL or <1,000 neutrophils/mcL and a predicted decline to ≤500 neutrophils/mcL over the next 48 hours
§ Expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Hematopoietic Growth Factors Clinical Practice Guideline at NCCN.org [7]

IV. Renewal Criteria [1-6]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: splenic rupture, acute respiratory distress syndrome (ARDS), serious allergic reactions/anaphylaxis, sickle cell crisis, glomerulonephritis, leukocytosis, capillary leak syndrome, potential for tumor growth stimulation of malignant cells, aortitis, alveolar hemorrhage and hemoptysis, thrombocytopenia, cutaneous vasculitis, MDS/AML (when used for congenital neutropenia or used in conjunction with chemotherapy and/or radiation for breast or lung cancer), etc.

V. Dosage/Administration [1-5]

Indication	Dose
BMT/PBPC/H-ARS	10 mcg/kg daily for up to 14 days
Congenital Neutropenia	6 mcg/kg twice daily
All other indications	5 mcg/kg daily for up to 14 days

VI. Billing Code/Availability Information

HCPCS Code(s):

- J1442 – Injection, filgrastim (g-csf), excludes biosimilars, 1 mcg: 1 billable unit = 1 mcg
- Q5110 – Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 mcg: 1 billable unit = 1 mcg
- Q5101 – Injection, filgrastim-sndz, biosimilar, (Zarxio), 1 mcg: 1 billable unit = 1 mcg
- J1447 – Injection, tbo-filgrastim (Granix), 1 mcg: 1 billable unit = 1 mcg
- Q5125 – Injection, filgrastim-ayow, biosimilar, (Releuko), 1 mcg; 1 billable unit = 1 mcg

NDC(s):

• Neupogen 300 mcg single-dose vial: 55513-0530-xx • Neupogen 300 mcg single-dose prefilled syringe (SingleJect): 55513-0924-xx • Neupogen 480 mcg single-dose vial: 55513-0546-xx • Neupogen 480 mcg single-dose prefilled syringe (SingleJect): 55513-0209-xx
• Nivestym 300 mcg single-dose vial: 00069-0293-xx • Nivestym 300 mcg single-dose prefilled syringe: 00069-0291-xx • Nivestym 480 mcg single-dose vial: 00069-0294-xx • Nivestym 480 mcg single-dose prefilled syringe: 00069-0292-xx
• Zarxio 300 mcg single-dose prefilled syringe: 61314-0318-xx • Zarxio 480 mcg single-dose prefilled syringe: 61314-0326-xx
• Releuko 300 mcg single-dose prefilled syringe: 70121-1568-xx • Releuko 480 mcg single-dose prefilled syringe: 70121-1570-xx • Releuko 300 mcg single-dose vial: 70121-1569-xx • Releuko 480 mcg single-dose vial: 70121-1571-xx
• Granix 300 mcg single-dose prefilled syringe: 63459-0910-xx

- Granix 480 mcg single-dose prefilled syringe: 63459-0912-xx
- Granix 300 mcg single-dose vial: 63459-0918-xx
- Granix 480 mcg single-dose vial: 63459-0920-xx

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C92.00	Myeloid leukemia not having achieved remission
C92.01	Acute myeloblastic leukemia, in remission
C92.02	Myeloid leukemia in relapse
C92.50	Acute myelomonocytic leukemia not having achieved remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.52	Acute myelomonocytic leukemia in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality in remission
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia in relapse
C93.00	Acute monoblastic/monocytic leukemia not having achieved remission
C93.01	Acute monoblastic/monocytic leukemia, in remission
C93.02	Acute monoblastic/monocytic leukemia in relapse

ICD-10	ICD-10 Description
C93.10	Chronic myelomonocytic leukemia, not having achieved remission
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.4	Refractory anemia, unspecified
D46.9	Myelodysplastic syndrome, unspecified
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.Z	Other myelodysplastic syndrome
D61.810	Antineoplastic chemotherapy induced pancytopenia
D70.0	Congenital agranulocytosis
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.2	Other drug-induced agranulocytosis
D70.4	Cyclic neutropenia
D70.9	Neutropenia, unspecified
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs sequela
T66.XXXA	Radiation sickness, unspecified, initial encounter
T66.XXXD	Radiation sickness, unspecified, subsequent encounter
T66.XXXS	Radiation sickness, unspecified, sequela
T80.82XA	Complication of immune effector cellular therapy, initial encounter
T80.82XS	Complication of immune effector cellular therapy, sequela
T80.89XA	Other complications following infusion, transfusion and therapeutic injection, initial encounter
T80.89XS	Other complications following infusion, transfusion and therapeutic injection, sequela
W88.1	Exposure to radioactive isotopes
W88.8	Exposure to other ionizing radiation
Z41.8	Encounter for other procedures for purposes other than remedying health state
Z48.290	Encounter for aftercare following bone marrow transplant
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy
Z51.89	Encounter for other specified aftercare

ICD-10	ICD-10 Description
Z52.001	Unspecified donor, stem cells
Z52.011	Autologous donor, stem cells
Z52.091	Other blood donor, stem cells
Z76.89	Persons encountering health services in other specified circumstances
Z94.81	Bone marrow transplant status
Z94.84	Stem cells transplant status

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
J, M	A56748	Palmetto GBA

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC