INSTRUCTIONS FOR USE

This Policy Guideline is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates for health care services submitted on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450), or their electronic comparative. The information presented in this Policy Guideline is believed to be accurate and current as of the date of publication.

This Policy Guideline provides assistance in administering health benefits. All reviewers must first identify member eligibility, any federal or state regulatory requirements, Centers for Medicare and Medicaid Services (CMS) policy, the member specific benefit plan coverage, and individual provider contracts prior to use of this Policy Guideline. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document may differ greatly from the standard benefit plan upon which this Policy Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Policy Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

UnitedHealthcare follows Medicare coverage guidelines and regularly updates its Medicare Advantage Policy Guidelines to comply with changes in CMS policy. UnitedHealthcare encourages physicians and other healthcare professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Physicians and other healthcare professionals can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier. This Policy Guideline is provided for informational purposes. It does not constitute medical advice.

POLICY SUMMARY

Overview

Colony Stimulating Factors (CSF) are hematopoietic growth factors, which act on progenitor cells capable of forming either single differentiated (lineage-specific) cell types, such as the neutrophilic granulocyte, or forming several differentiated cell types (i.e., non-lineage-specific). G-CSFs regulate the production of neutrophils in the bone marrow. Neutrophils are essential in the body's fight against infections.

Filgrastim/Neupogen and Pegfilgrastim/Neulasta are G-CSFs that act on hematopoietic cells by binding to specific cell surface receptors thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

Filgrastim/Neupogen is a human granulocyte colony stimulating factor G-CSF produced by recombinant DNA technology.

Filgrastim-sndz/Zarxio® is the first biosimilar of reference biologic Neupogen (filgrastim).

Pegfilgrastim/Neulasta is a covalent conjugate of recombinant methionyl human G-CSF and monomethoxypolyethylene glycol.

Tbo-filgrastim/Granix® is a non-glycosylated recombinant methionyl human granulocyte colony-stimulating growth factor (r-metHuG-CSF) manufactured by recombinant DNA technology using the bacterium strain E coli K802.
Pegfilgrastim (Neulasta) (J2505) is approved for the following uses:

- To decrease the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs
- In mobilization of hematopoietic progenitor cells in the autologous setting as a single agent, following combination chemotherapy, or in combination with plerixafor when the transplant procedure is a covered benefit
- Used in hematopoietic cell transplant for supportive care in the post-transplant setting

Sargramostim/Leukine®

Granulocyte Macrophage Colony Stimulating Factor (GM-CSF) is an antineutropenic, hematopoietic growth factor, which supports survival, clonal expansion, and differentiation of hematopoietic progenitor cells. GM-CSF is also capable of activating mature granulocytes and macrophages. This drug is not a cancer chemotherapy agent.

The drug appears to elicit the pharmacologic effects usually produced by endogenous human GM-CSF. Endogenous GM-CSF is a multilineage colony-stimulating factor that principally affects the proliferation, differentiation, and activation of granulocytes and macrophages by inducing partially committed progenitor cells to divide and differentiate in the granulocyte-macrophage pathways.

Endogenous GM-CSF acts on various progenitor target cells by binding to GM-CSF specific receptors on their cell surfaces. Biosynthetic GM-CSF principally affects cells in the granulocyte-macrophage lineage. In patients receiving low doses of biosynthetic GM-CSF, the leukocyte response is composed principally of neutrophils; at higher concentrations, the leukocyte response also involves proliferation of monocytes and eosinophils.

**Indications**

Filgrastim (Neupogen) (J1442) is approved for the following uses:

- In mobilization of peripheral stem cells when the transplant procedure is a covered benefit [See the Policy Guideline titled Stem Cell Transplantation (NCD 110.23) (Formerly NCD 110.8.1)]
- For the prevention of infection, as manifest by febrile neutropenia in patients treated with cytotoxic chemotherapy, for which a high incidence of associated febrile neutropenia, can be anticipated in a given patient. In addition, to the regimen itself this may include the following factors:
  - Extensive prior chemotherapy/radiation therapy
  - Poor performance status
  - Prior episode of infection after chemotherapy in the absence of significant leukopenia
  - Prior significant leukopenia after chemotherapy in the absence of infection
- For AIDS leukopenia in children when not self-administered or administered by a care giver
- For amelioration of leukopenia in AIDS patients on AZT (zidovudine) when not self-administered or administered by a care giver
- For amelioration of leukopenia in AIDS patients with CMV chorioretinitis on Ganciclovir when not self-administered or administered by a care giver
- To decrease the incidence of neutropenia in patients with non-myeloid malignancies undergoing myeloablative chemotherapy, followed by bone marrow transplantation
- For febrile neutropenia, including congenital neutropenia, cyclic neutropenia, and idiopathic neutropenia
- To enhance neutrophil function in patients with myelodysplastic syndrome and a history of infection
- To enhance neutrophil function in patients with aplastic anemia
- To enhance neutrophil function in patients with drug induced and congenital agranulocytosis
- To enhance neutrophil function in patients with acute myeloid leukemia (AML)
- For treatment of drug induced neutropenia [e.g., the patient is receiving pentamidine (Pentam) for treatment of pneumocystis pneumonia and develops neutropenia]
- For treatment of mucositis following chemotherapy
- For treatment of neutropenia of pre-eclampsia

Pegfilgrastim (Neulasta) (J2505) is approved for the following uses:

- To decrease the incidence of infection, as manifested by febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive cancer drugs
- Prophylaxis of chemotherapy-induced febrile neutropenia or other neutropenic events compromising treatment in high-risk patients (greater than 20% risk of febrile neutropenia) with solid tumors and non-myeloid malignancies receiving:
  - Curative or adjuvant chemotherapy treatment
  - Chemotherapy to prolong survival and improve quality of life
  - Chemotherapy to manage symptoms and improve quality of life
- Harvesting of peripheral blood stem cells, prior to autologous stem-cell transplantation
- To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).
- Supportive care in the posttransplant setting

Tbo-filgrastim (Granix) (J1446) is approved for the following uses:

- To decrease the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia
- In mobilization of hematopoietic progenitor cells in the autologous setting as a single agent, following combination chemotherapy, or in combination with plerixafor when the transplant procedure is a covered benefit
- Used in hematopoietic cell transplant for supportive care in the post-transplant setting

Neupogen® (Filgrastim)/Neulasta® (Pegfilgrastim)/Sargramostim (Tbo-Filgrastim)
Filgrastim-sndz (Zarxio) (Q5101) is approved for the following use:

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
- For reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
- To reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation
- For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
- For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
- NCCN indications for Myelodysplastic Syndromes (MDS) for Treatment of lower risk disease associated with symptomatic anemia, no del(5q) with or without other cytogenetic abnormalities, serum erythropoietin levels ≤ 500 mU/mL, and ring sideroblasts ≥ 15%:
  - in combination with epoetin alpha or darbepoetin alpha as initial therapy,
  - in combination with lenalidomide and epoetin alpha or darbepoetin alpha if no response to erythropoietins alone,
  - consider in combination with epoetin alfa or darbepoetin alfa for lower risk disease associated with symptomatic anemia, serum erythropoietin levels ≤ 500 mU/mL, ring sideroblasts < 15%, and no response to epoetin or darbepoetin alone.

Sargramostim (Leukine) (J2820) is approved for the following uses:
Medicare will consider GM-CSF medically reasonable and necessary for the treatment of the following FDA approved indications when it is not self/caregiver administered:

- Primary neutropenia
  - Promotion of myeloid engraftment following bone marrow transplant (BMT)
  - For acceleration of myeloid recovery in patients with non-Hodgkin’s lymphomas, acute lymphoblastic leukemia, and Hodgkin’s disease undergoing autologous BMT
  - For acceleration of myeloid recovery in patients undergoing autologous or allogenic BMT following myeloablative chemotherapy for non-myeloid malignancies
  - For acceleration of myeloid recovery in patients undergoing allogenic BMT following myeloablative chemotherapy for myeloid malignancies
  - For treatment of failure or delay of myeloid engraftment following autologous or allogenic BMT, in the presence or absence of infection
- Enhancement of peripheral blood progenitor cell (PBPC) collection when the bone marrow transplant procedure itself is a covered benefit
- For acceleration of myeloid recovery in patients undergoing hematopoietic stem cell transplantation following myeloablative chemotherapy
- To reduce the duration of neutropenia, following induction chemotherapy treatment of adults with acute myelocytic leukemia (AML)

Medicare will consider GM-CSF medically reasonable and necessary for the treatment of the following off-label indications when it is not self/caregiver administered:

- Failure or delay of myeloid engraftment in patients who have undergone autologous or allogenic hematopoietic stem cell transplantation, in the presence or absence of infection
- To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe febrile neutropenia
- Acquired immunodeficiency syndrome (AIDS)-associated neutropenia caused by the disease (AIDS) itself or infection with opportunistic organisms (such as cytomegalovirus), or antiretroviral agents (zidovudine, ganciclovir)
- Intermittent administration of GM-CSF for a subset of patients with Myelodysplastic syndromes (MDS) who have severe neutropenia and recurrent infections

Limitations
General
Colony stimulating factors are not covered when:
- Self-administered
- Administered by a caregiver
- Administered in association with radiation therapy
- Routinely used for afebrile neutropenia
Limitations of Sargramostim/Leukine only (J2820)

- A physician is not to bill Medicare for a supply of GM-CSF given to the patient for self-administration at home. [See the Policy Guideline titled Self-Administered Drug(s) (SAD)]
- The following off-labeled uses of GM-CSF have not been shown to be safe and effective and are noncovered by Medicare:
  - Aplastic anemia
  - Hairy cell leukemia
  - Severe chronic neutropenia which includes congenital (Kostmann’s syndrome), idiopathic and cyclic
- Treatment of drug-induced neutropenia, except when associated with the use of antiretroviral agents is an off-labeled indication and noncovered by Medicare.
- There is no evidence that GM-CSF is an important benefit in patients with refractory or relapsed myeloid leukemia.
- Therapeutic initiation of GM-CSF does not add significantly to the antibiotic treatment outcome of established febrile neutropenia.
- CSFs should not be routinely used as adjunct therapy for the treatment of uncomplicated fever and neutropenia. Uncomplicated fever and neutropenia are defined as follows:
  - Fever of < 10 days in duration
  - No evidence of pneumonia, cellulitis, abscess, sinusitis, hypotension, multi-organ dysfunction, or invasive fungal infection, and
  - No uncontrolled malignancies
- There is inadequate data to support the use of GM-CSF for patients with afebrile neutropenia.
- GM-CSF is contraindicated in patients with excessive leukemic myeloid blasts in the bone marrow or peripheral blood (> 10%).
- In general, for previously untreated patients receiving a chemotherapy regimen, primary prophylactic administration of GM-CSF is not considered medically necessary.
- Due to the potential sensitivity of rapidly dividing hematopoietic cells, GM-CSF should not be administered simultaneously with cytotoxic chemotherapy or radiotherapy or within 24 hours preceding or following chemotherapy or radiotherapy.
- There is no evidence of benefit from the use of GM-CSF to increase chemotherapy dose-intensity.

Sargramostim/Leukine Documentation

- Medical record documentation maintained by the physician must clearly indicate:
  - The patient’s current absolute neutrophil count (ANC);
  - The patient’s weight in kilograms;
  - The administration and dosage of the GM-CSF;
  - The actual indication for which the drug was given and accompanying symptomology (e.g., fever); and
  - The patient’s response to the treatment.

This information is usually found in the history and physical or the office/progress notes. The ANC may be reported in the patient's laboratory report.

Dosing Information

Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarifications:
- For dates of service prior to 10/01/2015, refer to the archived version of this document, when applicable.
- See related Local Coverage Determinations.
HCPCS Code | Description |
--- | --- |
J2820 | Injection, sargramostim (GM-CSF), 50 mcg |
Q5101 | Injection, filgrastim (G-CSF), biosimilar, 1 microgram (Effective 07/01/2015) |

Modifier | Description |
--- | --- |
ZA | Novartis/Sandoz |

**DEFINITIONS**

**Off-Label Drug Use:** An off-label/unlabeled use of a drug is defined as a use for a non-FDA approved indication, that is, one that is not listed on the drug's official label/prescribing information. An indication is defined as a diagnosis, illness, injury, syndrome, condition, or other clinical parameter for which a drug may be given. Off-label use is further defined as giving the drug in a way that deviates significantly from the labeled prescribing information for a particular indication. This includes but is not necessarily limited to, dosage, route of administration, duration and frequency of administration, and population to whom the drug would be administered. Drugs used for indications other than those in the approved labeling may be covered under Medicare if it is determined that the use is medically accepted, taking into consideration the major drug compendia, authoritative medical literatures and/or accepted standards of medical practice. Determinations as to whether medication is reasonable and necessary for an individual patient are made on appeal on the same basis as all other such determinations (i.e., with support from the peer-reviewed literature, with the advice of medical consultants, with reference to accepted standards of medical practice, and in consideration of the medical circumstance of the individual case).

**Primary Prophylaxis:** Refers to administration of CSF during the first cycle of chemotherapy.

**Secondary Prophylaxis:** Refers to administration of CSF during subsequent cycles of chemotherapy.

**Severe Neutropenia:** Generally defined as an absolute neutrophil count of less than 500 cells per ml.

**Uncomplicated Fever and Neutropenia:**
- Fever of < 10 days in duration, and
- No evidence of pneumonia, cellulitis, abscess, sinusitis, hypotension, multi-organ dysfunction, or invasive fungal infection, and
- No uncontrolled malignancies.

**REFERENCES**

**CMS Local Coverage Determinations (LCDs)**

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**CMS Articles**

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**CMS Benefit Policy Manual**
Chapter 15; § 50 Drugs and Biologicals

**CMS Claims Processing Manual**
Chapter 17; § 10 Payment Rules for Drugs and Biologicals

**CMS Transmittals**
Transmittal 3259, Change Request 9152, Dated 05/15/2015 (Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) – July CY 2015 Update)
Transmittal 3361, Change Request 9310, Dated 09/25/2015 (October 2015 Update of the Ambulatory Surgical Center (ASC) Payment System)

**MLN Matters**
Article MM9152, Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) – July Calendar Year (CY) 2015 Update
Article MM9167, Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2015 Update
Article MM9310, October 2015 Update of the Ambulatory Surgical Center (ASC) Payment System

**GUIDELINE HISTORY/REVISION INFORMATION**

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| 12/14/2016 | • Annual Review
• Removed from body of policy due to expiration timeframe:
  o J1440: Injection, filgrastim (G-CSF), 300 mcg (Expired 12/31/2013-to report see J1442)
  o J1441: Injection, filgrastim (G-CSF), 480 mcg (Expired 12/31/2013- to report see J1442) |