

# **LCD for Human Granulocyte/Macrophage Colony Stimulating Factors (L30306)**

## **Contractor Information**

### **Contractor Name**

Wisconsin Physicians Service Insurance Corporation

### **Contractor Number**

00951, 00952, 00953, 00954, 52280, 05101, 05201, 05301, 05401, 05102, 05202, 05302, 05402

### **Contractor Type**

Carrier – MAC – FI

## **LCD Information**

### **LCD ID Number**

L30306

### **LCD Title**

Human Granulocyte/Macrophage Colony Stimulating Factors

### **Contractor's Determination Number**

INJ-019

### **AMA CPT / ADA CDT Copyright Statement**

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### **CMS National Coverage Policy**

Medicare Benefit Policy Manual: PUB 100-2 Chapter 15  
Medicare Claims Processing Manual: PUB 100-4 Chapter 17

### **Oversight Region**

Region V

### **Original Determination Effective Date**

For services performed on or after 09/15/2009

## **Original Determination Ending Date**

## **Revision Effective Date**

For services performed on or after 09/15/2009

## **Revision Ending Date**

## **Indications and Limitations of Coverage and/or Medical Necessity**

A. Human granulocyte colony-stimulating factors (Filgrastim and Pefilgrastim) are drugs that are produced by recombinant DNA technology with the use of bacteria and a human G-CSF gene. G-CSF regulates the production of neutrophils (a WBC) within the bone marrow (where blood cells are manufactured naturally in the body). Neutrophils are an essential in the body's fight against infections.

B. Granulocyte macrophage colony-stimulating factor (Sargramostim) is a recombinant human granulocyte-macrophage colony-stimulating factor produced by recombinant DNA technology in yeast. Granulocytes and macrophage cells (WBC's) are essential in the body's fight against infections.

C. Indications for Filgrastim (Neupogen) (J1440, J1441):

1. To decrease the incidence of infection as manifested by febrile neutropenia, for patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever (288.03)

2. Administration may be indicated for patients at high risk for chemotherapy-induced infectious complications. Such risk factors may include the following (V15.9) and should be documented in the patient record:

- a. Pre-existing neutropenia due to disease,
- b. Extensive prior chemotherapy
- c. Previous irradiation to the pelvis or other areas containing large amounts of bone marrow.
- d. A history of recurrent febrile neutropenia while receiving earlier chemotherapy of similar or lesser dose-intensity
- e. Conditions potentially enhancing the risk of serious infection.

3. To reduce the duration of neutropenia and neutropenia related clinical sequelae (febrile neutropenia) for patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplant. (V42.81).

4. Peripheral Blood Progenitor Cell (PBPC) Collection (V42.82)-For the mobilization of hematopoietic progenitor cells into the peripheral blood for leukapheresis collection. Mobilization allows for collection of increased progenitor cell numbers capable of engraftment compared with collection by leukapheresis without mobilization or bone marrow harvest. After myeloablative chemotherapy, the transplantation of an increased number of progenitor cells can lead to more rapid engraftment, decreasing the need for supportive care.

5. Severe chronic neutropenia: chronic administration to reduce the incidence and duration of sequelae of neutropenia (eg. fever, infections, and oropharyngeal ulcers) in symptomatic patients with congenital, cyclic or idiopathic neutropenia (288.00, 288.01, 288.02)

6. Patients with Acute Myeloid Leukemia (AML) (205.00, 205.02) receiving induction or consolidation chemotherapy

7. Acquired immunodeficiency syndrome (AIDS) patients with neutropenia caused by the disease itself or by opportunistic infections (042)

8. Severe aplastic anemia (284.89)

9. Hairy cell leukemia (202.40-202.48)

10. Myelodysplastic syndrome (238.72-238.76). It is not recommended for routine infection prophylaxis. Consider use if recurrent or resistant infections in neutropenic patients.

11. Drug induced or congenital agranulocytosis, alloimmune neonatal neutropenia (288.03 or 288.01).

D. Indications for Sargramostim (Leukine) (J2820):

1. To decrease the incidence of infection as manifested by febrile neutropenia, for patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever (288.03).

2. Acceleration of myeloid recovery in patients with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkin's disease undergoing autologous bone marrow transplantation (BMT).

Indicate this by coding the BMT (V42.81) and NHL (202.80-202.88) or ALL (204.00, 204.02) or Hodgkin's disease (201.40-201.98).

3. Bone Marrow Transplant failure or engraftment delay. For patients who have undergone allogeneic or autologous BMT in whom engraftment is delayed or has failed (996.85).

4. Induction chemotherapy in acute myelogenous leukemia (AML).

The acceleration of neutrophil recovery following induction of chemotherapy in the treatment of patients over the age of 55-years old with acute myelogenous leukemia. Safety and efficacy has not been established in AML patients less than 55 years of age. Use the ICD-9 code 288.03 to identify drug-induced neutropenia and the code 205.00 or 205.02 to indicate acute myelogenous leukemia.

5. Mobilization and following transplantation of autologous peripheral blood progenitor cells (V42.82). For mobilization of hematopoietic progenitor cells into peripheral blood collection by leukapheresis. After myeloablative chemotherapy, the transplantation of an increase number of progenitor cells can lead to rapid engraftment which may decrease the need for supportive care.

6. Myeloid reconstitution after allogeneic bone marrow transplant (BMT) (V42.81): For acceleration of myeloid recovery in patient's undergoing allogeneic BMT from human lymphocyte antigen (HLA) matched related donors. Safety and efficacy has been established in accelerating myeloid engraftment, reducing the incidence of bacteremia and other culture positive infections.

7. To increase WBC counts in patients with myelodysplastic syndromes (238.72-238.76).

8. Acquired Immunodeficiency Syndrome (AIDS) (042) patients receiving zidovudine.

9. To decrease nadir of leukopenia secondary to myelosuppressive chemotherapy and decrease myelosuppression in preleukemic patients (238.72-238.76).

10. To correct neutropenia in aplastic anemia patients (284.89).

11. Drug induced or congenital agranulocytosis, alloimmune neonatal neutropenia (288.03 or 288.01).

E. Indications for Pegfilgrastim (Neulasta): (J2505)

1. To decrease the incidence of infection, as manifested by febrile neutropenia, for patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of febrile neutropenia (288.03).

2. Administration may be indicated for patients at high risk for chemotherapy-induced infectious complications. Such risk factors may include the following (V15.9) and should be documented in the patient record:

- a. Pre-existing neutropenia due to disease,
- b. Extensive prior chemotherapy
- c. Previous irradiation to the pelvis or other areas containing large amounts of bone marrow.
- d. A history of recurrent febrile neutropenia while receiving earlier chemotherapy of similar or lesser dose-intensity
- e. Conditions potentially enhancing the risk of serious infection.

### Coding Information

**Bill Type Codes:**

**Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.**

12x	Hospital-inpatient or home health visits (Part B only)
13x	Hospital-outpatient (HHA-A also) (under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00)
14x	Non-Patient Laboratory Specimens
22x	SNF-inpatient or home health visits (Part B only)
23x	SNF-outpatient (HHA-A also)
71x	Clinic-rural health
73x	Clinic-independent provider based FQHC (eff 10/91)
85x	Special facility or ASC surgery-rural primary care hospital (eff 10/94)

**Revenue Codes:**

**Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

063X	Drugs requiring specific identification-general classification
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**CPT/HCPCS Codes**

J1440	INJECTION, FILGRASTIM (G-CSF), 300 MCG
J1441	INJECTION, FILGRASTIM (G-CSF), 480 MCG
J2505	INJECTION, PEGFILGRASTIM, 6 MG
J2820	INJECTION, SARGRAMOSTIM (GM-CSF), 50 MCG

**ICD-9 Codes that Support Medical Necessity**

Note: ICD-9 codes must be coded to the highest level of specificity.

042	HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
201.40 - 201.98	HODGKIN'S DISEASE LYMPHOCYTIC-HISTIOCYTIC PREDOMINANCE UNSPECIFIED SITE - HODGKIN'S DISEASE UNSPECIFIED TYPE INVOLVING LYMPH NODES OF MULTIPLE SITES
202.40 - 202.48	LEUKEMIC RETICULOENDOTHELIOSIS UNSPECIFIED SITE - LEUKEMIC RETICULOENDOTHELIOSIS INVOLVING LYMPH NODES OF MULTIPLE SITES
202.80 - 202.88	OTHER MALIGNANT LYMPHOMAS UNSPECIFIED SITE - OTHER MALIGNANT LYMPHOMAS INVOLVING LYMPH NODES OF MULTIPLE SITES
204.00	ACUTE LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
204.02	ACUTE LYMPHOID LEUKEMIA, IN RELAPSE
205.00	ACUTE MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
205.02	ACUTE MYELOID LEUKEMIA, IN RELAPSE
238.72	LOW GRADE MYELODYSPLASTIC SYNDROME LESIONS
238.73	HIGH GRADE MYELODYSPLASTIC SYNDROME LESIONS
238.74	MYELODYSPLASTIC SYNDROME WITH 5Q DELETION
238.75	MYELODYSPLASTIC SYNDROME, UNSPECIFIED

238.76	MYELOFIBROSIS WITH MYELOID METAPLASIA
284.89	OTHER SPECIFIED APLASTIC ANEMIAS
288.00	NEUTROPENIA, UNSPECIFIED
288.01	CONGENITAL NEUTROPENIA
288.02	CYCLIC NEUTROPENIA
288.03	DRUG INDUCED NEUTROPENIA
996.85	COMPLICATIONS OF TRANSPLANTED BONE MARROW
V15.9	UNSPECIFIED PERSONAL HISTORY PRESENTING HAZARDS TO HEALTH
V42.81	BONE MARROW REPLACED BY TRANSPLANT
V42.82	PERIPHERAL STEM CELLS REPLACED BY TRANSPLANT

### **Diagnoses that Support Medical Necessity**

### **ICD-9 Codes that DO NOT Support Medical Necessity**

Any ICD-9 code not listed above

### **ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation**

### **Diagnoses that DO NOT Support Medical Necessity**

## **General Information**

### **Documentation Requirements**

Medical necessity documentation for the use of these drugs must be clearly described in the patient's medical record, and be available, upon request, for verification and review. Documentation should not be submitted with each claim.

The medical record should indicate the patient is on a 14 day dose dense chemotherapy cycle.

### **Appendices**

### **Utilization Guidelines**

Coverage for this medication is based on the patient's condition, the appropriateness of the dose and route of administration, based on the clinical condition and the standard of medical practice regarding the effectiveness of the drug for the diagnosis and condition. The drug must be administered at a frequency that is supported in the medical literature.

Dose Dense chemotherapy treatment schedules will be allowed where literature supports its use, i.e. breast cancer. This off-label dosing schedule will allow patients to receive Neulasta outside of the warning that states Neulasta should not be administered 14 days before and 24 hours after chemotherapy.

### **Sources of Information and Basis for Decision**

Smith TJ, Khatcheressian K, Lyman GH, et al: "2006 Update of Recommendations for the Use of White Blood Cell Growth Factors: An Evidence-Based Clinical Practice Guideline", Journal of Clinical Oncology, Vol. 24, No 19 (July 1), 2006:pp. 3187-3205

National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology-Myeloid Growth Factors V.1.2009

ASCO Guidelines hematopoietic –colony stimulating growth factors

Drug Facts and Comparisons,  
Physicians' Desk Reference (PDR).  
Manufacture's package inserts,

### **Advisory Committee Meeting Notes**

Meeting Date:

Wisconsin: 01/16/2009

Illinois: 01/28/2009

Michigan: 01/07/2009

Minnesota: 01/22/2009

J-5 MAC (IA,KS,MO, NE) 02/12/2009

Jurisdictional Open meeting

12/17/08

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from hematology and oncology

### **Start Date of Comment Period**

02/12/2009

### **End Date of Comment Period**

07/05/2009

### **Start Date of Notice Period**

08/01/2009

**Revision History Number**

6

**Revision History Explanation**

07/24/2009 Revised draft and Released to Final. This policy replaces L19954, L19955, L19956, L19957

Removed contractor 05392 because it is joining with contractor number for W MO effective 08/01/2009 bw

09/16/2009 288.01 added to ICD-9 listing

**Reason for Change**

**Last Reviewed On Date**

07/01/2009

**Related Documents**

This LCD has no Related Documents.

**LCD Attachments**

**All Versions**

Updated on 09/16/2009 with effective dates 09/15/2009 - N/A

Updated on 07/24/2009 with effective dates 09/15/2009 - N/A