

**Contractor's Policy Number**

96-06-R2

**Contractor Name**

CareFirst of Maryland Inc., Medicare Part A

**Contractor Number**

00190

**Contractor Type**

Fiscal Intermediary

**LMRP Title**

Granulocyte Colony Stimulating Factors-Neupogen™ and Neulasta™

**AMA CPT Copyright Statement**

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**CMS National Coverage Policy**

- Establishment of national policy supercedes all previous contractor policy statements, including Local Medical Policy coverage guidelines.
- Title XVIII of the Social Security Act, section 1862 (a) (7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, section 1862 (a) (1) (A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

**Primary Geographic Jurisdiction**

Maryland

Washington, DC

**Secondary Geographic Jurisdiction**

Alabama, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, Washington state, and Wyoming

**CMS Region**

Region III

**CMS Consortium**

Northeast

**Original Policy Effective Date**

10/12/1996

**Original Policy Ending Date**

NA

**Revision Effective Date**

01/01/2003

**Revision Ending Date**

12/31/2002

**LMRP Description**

Filgrastim (Neupogen™) is a human granulocyte colony stimulating factor (G-CSF) produced by recombinant DNA technology. G-CSF stimulates the production of neutrophils within the bone marrow. Pegfilgrastim (tradename Neulasta™) is the same molecule with a covalent bond to a polyethylene glycol

molecule, and has the same effect on the bone marrow. Both are effective in accelerating the recovery of neutrophil counts following myelosuppressive chemotherapy.

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

Neupogen™ is indicated:

- 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 clinically significant incidence of febrile neutropenia.
- For reducing the time to neutrophil recovery and duration of fever, following induction of consolidation chemotherapy treatment of adults with AML.
- To reduce the duration of neutropenia in patients undergoing myeloablative chemotherapy followed by marrow transplantation for a nonmyeloid malignancy.
- To mobilize hematopoietic progenitor cells for collection by leukapheresis for engraftment after myeloablative chemotherapy.
- To reduce the incidence and duration of sequelae of neutropenia in symptomatic patients with severe chronic neutropenia.
- To reduce the neutropenia of AIDs in children.
- To reduce the neutropenia of AIDs patients treated with AZT.
- To reduce the neutropenia of AIDs patients treated with ganciclovir for CMV chororetinitis.

Neulasta™ is indicated 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 clinically significant incidence of febrile neutropenia.

## **CPT/HCPCS Section & Benefit Category**

HCPCS Level II Codes

### **Type of Bill Code**

13X, 21X, 22X, 23X, 72X, 83X

### **Revenue Codes**

636

### **CPT/HCPCS Codes**

C9119	Pegfilgrastim, per 1 mg
J1440	Filgrastim 300 mcg
J1441	Filgrastim 480 mcg

### **Not Otherwise Classified (NOC)**

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

42	Human immunodeficiency virus [HIV] Use this code (042) only for AIDs neutropenia in children
238.7	Neoplasm of uncertain behavior of other and unspecified sites and tissues, other lymphatic and hematopoietic tissues Note: Use this code (238.7) for myelodysplastic syndrome
284.0	Constitutional aplastic anemia
284.8	Other specified aplastic anemias
284.9	Aplastic anemia, unspecified
288.0	Agranulocytosis
288.9	Unspecified disease of white blood cells
V42.81	Organ or tissue replaced by transplant, other specified organ or tissue, bone marrow
V42.82	Organ or tissue replaced by transplant, other specified organ or tissue, peripheral stem cells
V42.9	Organ or tissue replaced by transplant, other unspecified

organ or tissue

V59.9

Donors unspecified organ or tissue

Use V59.8 when patient is being primed for autologous

stem cells

V66.2

Convalescence and palliative care, following

chemotherapy

V66.5

Convalescence and palliative care, following other

treatment

Use V66.5 when the patient has neutropenia secondary to the use of AZT or ganciclovir

### **Diagnosis that Support Medical Necessity**

As listed in the "ICD-9 Codes that support Medical Necessity" section of this policy.

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

Any diagnosis codes not listed in the "ICD-9 Codes that support Medical Necessity" section of this policy.

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

Conditions not listed in the "ICD-9 Codes that support Medical Necessity" section of this policy.

### **Reasons for Denial**

- The medical record does not document that the service described by the HCPCS code was provided.
- The service was provided for an indication not listed in the "ICD-9 Codes that support Medical Necessity" section of this policy.
- The service does not follow the guidelines of this policy.
- The documentation in the medical record does not support the medical necessity of providing this service.

### **Non-covered ICD-9 Code(s)**

Any diagnosis code not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

### **Non-covered Diagnosis**

Conditions not listed in the "ICD-9 Codes that support Medical Necessity" section of this policy.

### **Coding Guidelines**

- Diagnosis (es) must be present on the submitted claim, and be coded to the highest level of specificity to accurately represent the patient's condition.
- The service(s) should be reported using the appropriate HCPCS code(s)
- Refer to the Correct Coding Initiative for "bundling" information

### **Documentation Requirements**

- Documentation supporting the medical necessity for this procedure should be legible, maintained in the patient's medical record, and available to Medicare upon request.
- Appropriate HCPCS codes should be used when reporting this service.
- An appropriate diagnosis code should be submitted on the claim. The patient's medical record should indicate the signs/symptoms supporting the diagnosis, as well as functional impairments.
- Documentation of dosage of drug administered should be included with the claim.

### **Utilization Guidelines**

When used for cytotoxic therapy induced neutropenia, Neupogen™ should be discontinued when the absolute neutrophil count reaches 10,000 or after two weeks of daily therapy.

### **Other Comments**

"Least costly alternative" provisions apply when there is a significant disparity between the overall costs of using two medications which are clinically equivalent.

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

TrailBlazer Health Enterprises, Inc.

CareFirst , INC., Medical Policy Committee

Neupogen™ package insert

Neulasta™ package insert

## **Advisory Committee Notes**

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 the appropriate specialty (ies).

Advisory Committee meeting date:

## **Start Date of Comment Period**

## **End Date of Comment Period**

## **Start Date of Notice Period**

09/12/1996

## **Revision History**

<u>Number</u>	<u>Date</u>	<u>Changes</u>
99-06-R2	01/01/2003	Annual CPT/HCPCS updates. Addition of C9119,

addition of

99-06-R1      07/22/2002  
format.

Added

ICD-9

removal of J3490 from policy due to

new code. CPT descriptors changed to short descriptor.

Changed title. Adapted policy to CMS

Added information concerning Neulasta™.

indications. Updated HCPCS codes. Added

codes.

**THIS BULLETIN SHOULD BE SHARED WITH ALL HEALTH CARE PRACTITIONERS AND MANAGERIAL MEMBERS OF THE PROVIDER/SUPPLIER STAFF. BULLETINS ISSUED AFTER OCTOBER 1,1999 ARE AVAILBABLE AT NO-COST FROM OUR WEBSITE AT [www.marylandmedicare.com](http://www.marylandmedicare.com)**

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