



Colony Stimulating Factors
TBO-Filgrastim (Granix®)
Sargramostim (Leukine®)
Pegfilgrastim (Neulasta®)

Policy Number: M-0026

Revision: 2

Last Update 6/4/2014

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

Coverage Guidelines:

Sargramostim

FDA:

1. Allogeneic bone marrow transplantation, Myeloid reconstitution in HLA-matched related donors.
2. Autologous bone marrow transplant, Myeloid reconstitution following transplant in patients with non-Hodgkin's lymphoma, Hodgkin's disease, and acute lymphoblastic lymphoma.
3. Bone marrow transplant, Delay or failure of myeloid engraftment.
4. Febrile neutropenia, In acute myelogenous leukemia following induction chemotherapy; Prophylaxis.
5. Harvesting of peripheral blood stem cells.
6. Peripheral blood stem cell graft, Autologous, myeloid reconstitution following transplant in patients mobilized with granulocyte macrophage colony stimulating factor.

Off-labeled:

1. Crohn's disease
2. Febrile neutropenia, In non-myeloid malignancies following myelosuppressive chemotherapy; Prophylaxis
3. Malignant melanoma
4. Myelodysplastic syndrome
5. Neutropenic disorder - Sepsis of the newborn
6. Pulmonary alveolar proteinosis



7. Wound care

Pegfilgrastim

FDA:

1. Febrile neutropenia, In patients with non-myeloid malignancies ; Prophylaxis.

Off Labeled:

1. Harvesting of peripheral blood stem cells, Prior to autologous stem-cell transplantation

Tbo-filgrastim

FDA:

1. Chemotherapy-induced neutropenia

Coding Information:

HCPCS Code(s)

J1446	INJECTION, TBO-FILGRASTIM, 5 MCG
J2505	INJECTION, PEGFILGRASTIM, 6 MG
J2820	INJECTION, SARGRAMOSTIM (GM-CSF), 50 MCG

ICD-9 Code(s) for Sargramostim J2820

042	HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
202.00- 202.90	NODULAR LYMPHOMA UNSPECIFIED SITE - OTHER AND UNSPECIFIED MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE UNSPECIFIED SITE
203.00	MULTIPLE MYELOMA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
203.02	MULTIPLE MYELOMA, IN RELAPSE
205.00	ACUTE MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
205.02	ACUTE MYELOID LEUKEMIA, IN RELAPSE
238.71- 238.77	ESSENTIAL THROMBOCYTHEMIA - POST-TRANSPLANT LYMPHOPROLIFERATIVE DISORDER (PTLD)
238.79	OTHER LYMPHATIC AND HEMATOPOIETIC TISSUES
288.00- 288.04	NEUTROPENIA, UNSPECIFIED - NEUTROPENIA DUE TO INFECTION
288.09	OTHER NEUTROPENIA



288.50	LEUKOCYTOPENIA, UNSPECIFIED
288.51	LYMPHOCYTOPENIA
288.59	OTHER DECREASED WHITE BLOOD CELL COUNT
363.20	CHORIORETINITIS UNSPECIFIED
V07.8	OTHER SPECIFIED PROPHYLACTIC OR TREATMENT MEASURE
V42.81	BONE MARROW REPLACED BY TRANSPLANT
V42.82	PERIPHERAL STEM CELLS REPLACED BY TRANSPLANT
V42.9	UNSPECIFIED ORGAN OR TISSUE REPLACED BY TRANSPLANT
V59.02	BLOOD DONORS STEM CELLS
V59.3	BONE MARROW DONORS
V66.2	CONVALESCENCE FOLLOWING CHEMOTHERAPY
V66.5	CONVALESCENCE FOLLOWING OTHER TREATMENT

ICD-9 Code(s) for Pegfilgrastim (J2505):

288.00- 288.04	NEUTROPENIA, UNSPECIFIED - NEUTROPENIA DUE TO INFECTION
288.09	OTHER NEUTROPENIA
288.50	LEUKOCYTOPENIA, UNSPECIFIED
288.51	LYMPHOCYTOPENIA
288.59	OTHER DECREASED WHITE BLOOD CELL COUNT
V07.8	OTHER SPECIFIED PROPHYLACTIC OR TREATMENT MEASURE
V66.2	CONVALESCENCE FOLLOWING CHEMOTHERAPY

ICD-9 Code(s) for Tbo-filgrastim (J1446):

288.00	NEUTROPENIA, UNSPECIFIED
288.03- 288.09	DRUG INDUCED NEUTROPENIA - OTHER NEUTROPENIA

Indications:

Sargramostim:

1. Acceleration of myeloid recovery in patients undergoing allogenic or autologous bone marrow transplantation following myeloablative chemotherapy for myeloid and non- myeloid malignancies.
2. Severe symptomatic chronic neutropenia, including congenital neutropenias, cyclic neutropenias and idiopathic neutropenias



3. Mobilization of peripheral stem cells when the transplant procedure itself is a covered benefit (See NCD 110.8.1).
4. HIV as follows:
 - A. AIDS leukopenia in children;
 - B. Amelioration of leukopenia in AIDS patients on AZT;
 - C. Amelioration of leukopenia in AIDS patients with CMV chorioretinitis on Ganciclovir;
 - D. Treatment of HIV infection-associated neutropenia.
5. Decreasing 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. Patients experiencing an episode of febrile neutropenia are most likely to have subsequent episodes and are eligible for such prophylaxis.
6. Enhancing neutrophil function in patients with myelodysplastic syndromes and a history of infection.
7. Drug induced neutropenia in patients with a history of infection.
8. Promoting myeloid engraftment following autologous or allogenic bone marrow transplantation or stem cell transplantation and in prolonging survival in patients who have undergone autologous or allogenic bone marrow transplants in whom engraftment is delayed or has failure in the presence or absence of infection.
9. Patients at higher risk for chemotherapy-induced infectious complications, even though the data supporting such use are not conclusive. Such risk factors might include the following: pre-existing neutropenia due to disease, extensive prior chemotherapy, or previous irradiation to the pelvis or other areas containing large amounts of bone marrow; a history of recurrent febrile neutropenia while receiving earlier chemotherapy of similar or lesser dose-intensity; or conditions potentially enhancing the risk of serious infection, e.g., advanced physiologic age or frailty, poor performance status and more advanced cancer, decreased immune function, open wounds, or already-active tissue infections. (The possible risk factors in this paragraph are not meant to be all-inclusive.)
10. **Filgrastim**: decreasing the duration of neutropenia after the completion of acute myelocytic leukemia (AML) induction or consolidation chemotherapy in adult patients.
11. **Sargramostim**: decreasing the duration of neutropenia after the completion of acute myelocytic leukemia (AML) induction chemotherapy in older patients (55 years of age and older).

**Pegfilgrastim:**

- Decreasing the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.
- Patients at higher risk for chemotherapy-induced infectious complications, even though the data supporting such use are not conclusive. Such risk factors might include the following: pre-existing neutropenia due to disease, extensive prior chemotherapy, or previous irradiation to the pelvis or other areas containing large amounts of bone marrow; a history of recurrent febrile neutropenia while receiving earlier chemotherapy of similar or lesser dose-intensity; or conditions potentially enhancing the risk of serious infection, e.g., advanced physiologic age or frailty, poor performance status and more advanced cancer, decreased immune function, open wounds, or already-active tissue infections. (The possible risk factors in this paragraph are not meant to be all-inclusive.)

Tbo-filgrastim:

For reduction in 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.

Limitations:**Colony stimulating factors are not covered when:**

1. Self-administered
2. Administered by a caregiver
3. Administered in association with radiation therapy
4. Routinely used for afebrile neutropenia

Background:

Colony-stimulating factors are glycoproteins which act on hematopoietic cells by binding to specific cell surface receptors and stimulating proliferation, differentiation commitment, and some end-cell functional activation.

Definitions:



HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

References:

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