# MEDICAL POLICY STATEMENT

| Original Effective Date | Next Annual Review Date | Last Review / Revision Date |
|---|---|---|
| 10/06/2015 | 10/06/2016 | 10/06/2015 |

| Policy Name | Policy Number |
|---|---|
| **Colony Stimulating Factors** | **SRx-0047** |

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

## A. SUBJECT

Colony Stimulating Factors

- Tbo-filgrastim (Granix)
- Pegfilgrastim (Neulasta)
- Filgrastim (Neupogen)
- Sargramostim (Leukine)
- Filgrastim-sndz (Zarxio)

## B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

Standard practice in protecting against chemotherapy-associated infection has been chemotherapy dose modification or dose delay, administration of progenitor-cell support, or selective use of prophylactic antibiotics. Chemotherapy associated neutropenic fever or infection has customarily involved treatment with intravenous antibiotics, usually accompanied by hospitalization. The hematopoietic colony-stimulating factors (CSFs) have been introduced into clinical practice as additional supportive measures that can reduce the likelihood of neutropenic complications due to chemotherapy.

The intent of the Colony Stimulating Factors (PA) Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents

## C. DEFINITIONS

- **Febrile neutropenia:** Febrile neutropenia can occur as a result of severe neutropenia; defined as the occurrence of fever (greater than or equal to 38.3˚C for more than 1 hour) in association with an ANC less than 0.5 x $10^9$/L or ANC less than 1.0 x $10^9$/L and a predicted decline to less than or equal to 0.5 x $10^9$/L over the subsequent 48 hours

## D. POLICY

I. **Filgrastim (Neupogen),Sargramostim (Leukine), Pegfilgrastim (Neulasta), Tbo-filgrastim (Granix) or Filgrastim-sndz (Zarxio)** is considered **medically appropriate** in **ANY 1 (one)** of the following:

**Primary Prophylaxis**

A. Acute myeloid leukemia (AML) for **ANY 1 (one)** of the following:
   1. Induction chemotherapy
   2. Consolidation chemotherapy

B. Solid tumor / non-myeloid malignancy with **ANY 1 (one)** of the following:
   1. Receiving myelosuppressive chemotherapeutic agents associated with a high risk of severe neutropenia (greater than 20% risk of febrile neutropenia) or intermediate-risk of severe neutropenia (10% to 20% risk of febrile neutropenia)
   2. Receiving myelosuppressive chemotherapeutic agents associated with low-risk (less than 10% risk) of febrile neutropenia if **ALL** the following:
      2.1 Chemotherapy is curative or adjuvant
      2.2 Individual is at significant risk for serious medical consequences of febrile neutropenia
   3. Undergoing myeloablative chemotherapy prior to allogeneic or autologous bone marrow transplantation

C. Myeloid engraftment for bone marrow transplant (BMT) with **ANY 1 (one)** of the following: (Neupogen & Leukine only)
   1. Failure or delay of myeloid engraftment
   2. Mobilization of peripheral blood progenitor cell prior to stem cell transplant
   3. Non-myeloid malignancy undergoing myeloablative chemotherapy followed by bone marrow or peripheral blood progenitor cell transplant

D. Myelodysplastic syndrome with **ALL** of the following: (Neupogen & Leukine only)
   1. Used in combination with epoetin alfa or darbepoetin alfa
   2. Anemia is symptomatic
   3. Severe neutropenia
   4. Individual is lower risk with no del(5q) cytogenetic abnormality
   5. History of infection
   6. Serum erythropoietin levels are less than or equal to 500 mU/mL
   7. Treatment is **ANY 1 (one)** of the following:
      6.1 Initial therapy in individual with ringed sideroblasts greater than or equal to 15%
      6.2 Following nonresponsive therapy with epoetin alfa or darbepoetin alfa in individual having ringed sideroblasts less than 15%

E. Severe chronic neutropenia with **ALL** of the following: (Neupogen & Leukine only)
   1. Disease type is **ANY 1 (one)** of the following:
      1.1 Symptomatic congenital neutropenia
      1.2 Symptomatic cyclic neutropenia
      1.3 Symptomatic idiopathic neutropenia
   2. Individual has/has history of **ALL** of the following:
      2.1 Absolute neutrophil count (ANC) of less than 500/$mm^3$
      2.2 Increased incidence and duration of clinical sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers)
      2.3 Acute exposure of myelosuppressive radiation doses

II. **Pegfilgrastim (Neulasta) or Tbo-filgrastim (Granix)** is considered **medically appropriate** with **ALL** of the following:
   A. Diagnosis of a solid tumor / non-myeloid malignancy
   B. Receiving myelosuppressive chemotherapeutic agents associated with a significant incidence of severe neutropenia (greater than 20% risk of febrile neutropenia) (e.g., doxorubicin, docetaxel)

**Note:** Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

**For Medicare Plan members, reference the Applicable National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). Compliance with NCDs and LCDs is required where applicable.**

**CONDITIONS OF COVERAGE**

**PLACE OF SERVICE**

Office, Outpatient, Home
**Preferred place of service is in the home*.
**Note:** CareSource supports administering inject able medications in various setting, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

**CONDITIONS OF COVERAGE**

**HCPCS**

J1440 filgrastim (g-csf), (Neupogen 300mcg)
J1441 filgrastim (g-csf), (Neupogen 480mcg)
J1442 filgrastim (g-csf), 1 microgram, (Neupogen)
J2505 Injection, pegfilgrastim, 6 mg (Neulasta)
J1446 Injection, tbo-filgrastim, 5 micrograms (Granix)
J2820 Injection, sargramostim (GM-CSF), 50 mcg (Leukine)
S9537 Home therapy; hematopoietic hormone injection therapy (e.g. erythropoietin, G-CSF, GM- CSF); per diem [when specified as G-CSF, GM-CSF]
Q5101,J3490 Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram (Zarxio)

**CPT**

**Step Therapy**
Under some plans, including plans that use an open or closed formulary, some of the medications in this policy may be subject to step-therapy. Refer to the CareSource formulary tool or PDL for further guidance.

**AUTHORIZATION PERIOD**
Authorization for therapy will be issued for **1 (one)** month or duration of chemotherapy regimen.

## E. RELATED POLICIES/RULES

## F. REVIEW/REVISION HISTORY

Date Issued: 10/06/2015
Date Reviewed: 10/06/2015
Date Revised:

## G. REFERENCES


1. Amgen, Inc. (2011, June). *Neulasta® (pegfilgrastim) injection for subcutaneous use*. Retrieved September 30, 2013 from http://pi.amgen.com/united_states/neulasta/neulasta_pi_hcp_english.pdf.
2. Lexi-Comp Online. (2013). AHFS DI. *Filgrastim*. Retrieved September 30, 2013 from Lexi-Comp Online with AHFS.
3. Lexi-Comp Online. (2013, November). AHFS DI. *Pegfilgrastim*. Retrieved September 30, 2013 from Lexi-Comp Online with AHFS.
4. MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2013, August). *Filgrastim*. Retrieved September 3, 2015 from MICROMEDEX Healthcare Series.
5. MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2013, August). *Pegfilgrastim*. Retrieved September 3, 2015 from MICROMEDEX Healthcare Series.
6. National Comprehensive Cancer Network. (2013). NCCN Drugs & Biologics Compendium™. *Filgrastim*. Retrieved September 30, 2013 from the National Comprehensive Cancer Network.
7. National Comprehensive Cancer Network. (2013). NCCN Drugs & Biologics Compendium™. *Pegfilgrastim*. Retrieved September 30, 2013 from the National Comprehensive Cancer Network.
8. U. S. Food and Drug Administration. (2013. September). Center for Drug Evaluation and Research. *Neupogen® (filgrastim).*
9. Retrieved September 30, 2013 from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/103353_5127lbl.pdf.
10. Sandoz, Inc. (2015, September). *Zarxio® (filgrastim-sndz) injection, solution.* Retrieved September 4, 2015 from http://www.zarxio.com/assets/pdf/zarxio-pi.pdf.
11. Amgen, Inc. (2015, July). *Neupogen® (filgrastim) injection for subcutaneous use.* Retrieved September 4, 2015 from http://pi.amgen.com/united_states/neupogen/neupogen_pi_hcp_english.pdf
12. MCG 19th edition; February 24, 2015


This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

**The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.**