



PHARMACY POLICY STATEMENT

Original Effective Date		Next Annual Review		Last Revision	
10/06/2015		10/06/2017		11/29/2016	
Policy Name				Policy Number	
Colony Stimulating Factors				SRx-0047	
Policy Type					
Medical	Administrative	PHARMACY		Reimbursement	

Pharmacy 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, Pharmacy Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Pharmacy 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 Pharmacy Policy Statement. If there is a conflict between the Pharmacy 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.

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A. INTRODUCTION

Cancer treatments (e.g., chemotherapy) and procedures like bone marrow transplants can affect white blood cell counts by decreasing them to levels that will increase the patient’s risk of infection. Colony-stimulating factors may be introduced to help support white blood cell levels and therefore strengthen the immune system.

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of patients for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of preferred agents. The CareSource Pharmacy Policy Statement is a guideline for determining health care coverage for our patients with benefit plans covering prescription drugs. Pharmacy Policy Statements are written on selected prescription drugs requiring prior authorization or step therapy. The Pharmacy Policy Statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

NOTE: The Introduction section is for your general knowledge and is not to be construed as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals and is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider can also be a place where medical care is given, like a hospital, clinic or lab. This policy informs providers about when a service may be covered.

B. 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 10⁹/L or ANC less than 1.0 x 10⁹/L and a predicted decline to less than or equal to 0.5 x 10⁹/L over the subsequent 48 hours

C. POLICY COVERAGE CRITERIA

1. Site of Service

Site of Service Administration	Coverage Criteria
Office, Outpatient, Home	<p>Preferred place of service is in the home.</p> <p>CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective settings that are supportive of the patient’s medical condition(s) and unique needs and condition(s). The decision on the most appropriate setting for administration is based on the member’s current medical condition(s) and any required monitoring or additional services that may coincide with the delivery of the specific medication.</p>



2. Coverage Criteria

CareSource will approve the use of Filgrastim (Neupogen), Sargramostim (Leukine), or Filgrastim-sndz (Zarxio), or Pegfilgrastim (Neulasta, tbo-filgrastim (Granix) and consider use medically necessary when the criteria have been met for each condition listed below. Prior authorization request should be submitted with chart notes and documentation supporting medical necessity.

Drug	Coverage criteria for acute myeloid leukemia (AML):
Zarxio	<ol style="list-style-type: none"> 1) <i>Patient is receiving Induction chemotherapy</i> 2) <i>Patient is receiving Consolidation chemotherapy</i>
Luekine, Neupogen	<ol style="list-style-type: none"> 1) <i>Patient is receiving Induction chemotherapy</i> 2) <i>Patient is receiving Consolidation chemotherapy</i> 3) <i>A minimum of a 14 day trial of Zarxio, and documented clinical reason Zarxio cannot be used.</i>

Drug	Coverage criteria for solid tumor/non-myeloid malignancy:
Granix, Leukine, Neulasta, or Neupogen	<ol style="list-style-type: none"> 1) <i>Patient is 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)</i> 2) <i>Patient is receiving myelosuppressive chemotherapeutic agents associated with low-risk (less than 10% risk) of febrile neutropenia if ALL the following:</i> <ol style="list-style-type: none"> a) <i>Chemotherapy is curative or adjuvant</i> b) <i>Individual is at significant risk for serious medical consequences of febrile neutropenia</i> 3) <i>Patient is undergoing myeloablative chemotherapy prior to allogeneic or autologous bone marrow transplantation</i> 4) <i>Leukine may not be used in patients younger than 55 years old.</i> 5) <i>A minimum of a 14 day trial of Zarxio, and documented clinical reason Zarxio cannot be used.</i>



Drug	Coverage criteria for myeloid engraftment for bone marrow transplant (BMT):
Zarxio	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
Luekine, Neupogen	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 4) Luekine may not be used in patients younger than 55 years old. 5) A minimum of a 14 day trial of Zarxio, and documented clinical reason Zarxio cannot be used.

Drug	Coverage criteria for severe chronic neutropenia:
Zarxio	1) Disease type is one of the following: a) Symptomatic congenital neutropenia b) Symptomatic cyclic neutropenia c) Symptomatic idiopathic neutropenia 2) Patient has/has history of ALL of the following: a) Absolute neutrophil count (ANC) of less than 500/mm ³ b) Increased incidence and duration of clinical sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) c) Acute exposure of myelosuppressive radiation doses
Neupogen	1) Disease type is one of the following: a) Symptomatic congenital neutropenia b) Symptomatic cyclic neutropenia c) Symptomatic idiopathic neutropenia 2) Patient has/has history of ALL of the following: a) Absolute neutrophil count (ANC) of less than 500/mm ³ b) Increased incidence and duration of clinical sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) c) Acute exposure of myelosuppressive radiation doses 3) A minimum of a 14 day trial of Zarxio, and documented clinical reason Zarxio cannot be used.



Drug	Coverage criteria for hematopoietic radiation injury syndrome:
Neulasta, Neupogen	1) Prescribed by physician with expertise in treating acute radiation syndrome 2) Member whose age is between 13 and 59 years old meets one or more of the following criteria; a) Member is diagnosed with whole body or significant partial body exposure greater than 3 Grays. b) Member experiences clinical signs and symptoms of level 3 or 4 degree hematotoxicity. 3) Member whose age is less than 12 years old or greater than 60 years old who's exposure radiation dose is greater than or equal to 2 Grays

All other uses of Filgrastim (Neupogen), Sargramostim (Leukine), or Filgrastim-sndz (Zarxio), or Pegfilgrastim (Neulasta, tbo-filgrastim (Granix) are considered experimental/investigational; and therefore, will follow CareSource's off-label policy.

Please note that this policy is reviewed on an annual basis. New drugs and indications receiving FDA approval may not be reflected in this policy immediately.

Notes:

- Documented diagnosis must be confirmed by portions of the individual's medical record which need to be supplied with prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider's office, or hospital admission notes.
- Patient is required to have completed the trial(s) listed in the above criteria unless the patient is unable to tolerate or has a contraindication to trial medications. Documentation such as chart notes or pharmacy claims may be requested to verify trial(s), intolerance, or contraindication(s).
- Refer to the product package insert for dosing, administration and safety guidelines.

3. Dosage and Quantity Limits (listed if applicable)

Information for patients with renal or hepatic impairment is not included. See package insert for individual agents.

Condition	Dosage and Quantity Limit
All Conditions	Not Applicable



4. Authorization Period

Condition	Approval Period
All Conditions	<p>The initial authorization for therapy will be issued for 14 days or duration of chemotherapy regimen.</p> <p>Continued treatment may be considered when Biological response is shown by an increase in absolute neutrophil count. A reauthorization after successful initiation period will be placed for 1 month.</p> <p>ALL authorizations are subject to continued eligibility.</p>

5. Coding

CPT	
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	Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram (Zarxio)

D. RELATED POLICIES

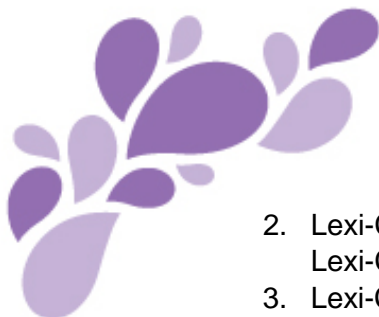
AD-0004: Medical Necessity - Off-Label, Approved Orphan and Compassionate Use Drugs

E. REVIEW/REVISION HISTORY

DATE	ACTION/DESCRIPTION
10/6/2015	Date issued.
11/29/2016	Removed myelodysplastic syndrome (off label), added in 14 day trial of Zarxio, added age minimum for Leukine, updated policy format and separated by line of business.

F. REFERENCES

- Amgen, Inc. (2011, June). Neulasta® (pegfilgrastim) injection for subcutaneous use. Retrieved November 22nd 2016 from http://pi.amgen.com/united_states/neulasta/neulasta_pi_hcp_english.pdf.



2. Lexi-Comp Online. (2016). AHFS DI. Filgrastim. Retrieved September 30, 2013 from Lexi-Comp Online with AHFS.
3. Lexi-Comp Online. (2016, 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 November 22, 2016 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 November 22, 2016 from the National Comprehensive Cancer Network.
7. National Comprehensive Cancer Network. (2016). NCCN Drugs & Biologics Compendium™. Pegfilgrastim. Retrieved November 22, 2016 from the National Comprehensive Cancer Network.
8. U. S. Food and Drug Administration. (2016. November). Center for Drug Evaluation and Research. Neupogen® (filgrastim).
9. Retrieved November 22, 2016 from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/103353_5127lbl.pdf.
10. Sandoz, Inc. (2016, September). Zarxio® (filgrastim-sndz) injection, solution. Retrieved November 22, 2016 from <http://www.zarxio.com/assets/pdf/zarxio-pi.pdf>.
11. Amgen, Inc. (2015, July). Neupogen® (filgrastim) injection for subcutaneous use. Retrieved November 22nd, 2016 from http://pi.amgen.com/united_states/neupogen/neupogen_pi_hcp_english.pdf
12. Prescribing information. Leukine (Sargramostim). Genzyme Corporation. August 2013.
13. MCG 20th edition, 2016

The Pharmacy Policy detailed above has received due consideration and is approved.