

RX.PA.013.MPC Granulocyte Colony-Stimulating Factors

The purpose of this policy is to define the prior authorization process for Granulocyte Colony-Stimulating Factors.

Leukine® (sargramostim) is indicated:

- For the use following induction chemotherapy in older adult patient with acute myelogenous leukemia (AML) to shorten time to neutrophil recovery and to reduce incidence of severe and life-threatening infections and infections resulting in death
- For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis
- For 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)
- For acceleration of myeloid recovery in patients undergoing allogeneic BMT from HLA-matched related donors
- In patients who have undergone allogeneic or autologous BMT in whom engraftment is delayed or has failed
- Increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])

DEFINITIONS

CYCLOPHOSPHAMIDE 100 MG (J9070)

CHOP – a chemotherapy regimen consisting of the following agents: cyclophosphamide, doxorubicin, vincristine, and prednisone.

Neutropenia – a reduction in the blood neutrophil count. Neutrophils represent 40-70% of the total white blood cell count and serve as the primary defense against infection.

The absolute neutrophil count is calculated via the following equation:

Absolute Neutrophil Count (ANC): Total white blood cell count (cells/ μ L) x % (neutrophils + bands). Bands represent immature neutrophils.

The severity of neutropenia relates to the relative risk of infection:

- Mild (ANC = 1000 – 1500/ μ L)
- Moderate (ANC = 500 – 1000/ μ L)
- Severe (ANC < 500/ μ L)

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. For Leukine® (sargramostim):

- For use in Acute Myeloid Leukemia (AML):
 - Must be age 55 or older
 - Must have a diagnosis of AML and receiving induction chemotherapy therapy
- For use in bone marrow transplant, must have ONE of the following:
 - Must require administration after autologous (not allogeneic) bone marrow transplant for non-Hodgkin’s lymphoma (NHL), acute lymphoblastic leukemia (ALL) or Hodgkin’s disease
 - Must require mobilization of progenitor cells into peripheral blood, often in conjunction with chemotherapy, for collection by leukapheresis
 - Must have undergone allogeneic bone marrow transplant from HLA
- For use in Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]:
 - Must have been exposed to myelosuppressive doses of radiation (suspected or confirmed)

Reauthorization Criteria:

All prior authorization renewals are reviewed 3-month basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 3-month intervals based upon chart documentation from the prescriber that the member’s condition has improved based upon the prescriber’s assessment while on therapy. For H-ARS: must provide documentation that the member’s CBC is being closely monitored to determine need for continued treatment.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes: J Code(s)

Code	Description
J2820	Injection, sargramostim (gm-csf), 50 mcg

Granulocyte Colony-Stimulating Factors

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REFERENCES

1. Zarxio [prescribing information]. Princeton, NJ: Sandoz, Inc.; March 2015.
2. Neupogen [prescribing information]. Thousand Oaks, CA: Amgen, Inc. September 2007
3. Neulasta [prescribing information]. Thousand Oaks, CA: Amgen, Inc. March 2018
4. Leukine [prescribing information]. Bridgewater, NJ; sanofi-aventis U.S. LLC; June 2012
5. Granix [prescribing information]. Sunnyvale, CA; Pharmacyclics, Inc.; November 2013
6. The Merck Manuals: Online Medical Library. Neutropenia.
<http://www.merck.com/mmpe/sec11/ch132/ch132b.html?qt=neutropenia&alt=sh>. (accessed January 7, 2014).
7. Smith TJ, Khatcheressian J, Lyman GH et al. 2006 update of recommendations for the use of white blood cell growth factors: an evidence-based clinical practice guideline. *J Clin Oncol* 2006;24:3187-3205
8. Blackwell k, Semiglazov V, Gasconp, et al. A Comparison of Proposed Biosimilar and Originator Filgrastim for the Prevention of Neutropenia in Patients with Breast Cancer Receiving Myelosuppressive Adjuvant or Neoadjuvant Chemotherapy: Phase III, Randomized, Double-Blind Trial (The PIONEER study). *Blood*: 124 (21)
9. The NCCN Clinical Practice Guidelines in Oncology: Myeloid Growth Factors (Version 2.2014). National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on: March, 8 2015.
10. Aapro MS, Bohlius J, Cameron DA, et al. 2010 update of EORTC guidelines for the use of granulocyte colony stimulating factor to reduce the incidence of chemotherapy-induced febrile neutropenia in adult patients with lymphoproliferative disorders and solid tumours. *Eur J Cancer* 2011;47(1):8-32.