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/μL) x % (neutrophils + bands). Bands represent immature neutrophils.

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

- Mild (ANC = 1000 – 1500/μL)
- Moderate (ANC = 500 – 1000/uL)
- Severe (ANC < 500/μL)

PROCEDURE

A. 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)

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Granulocyte colony-stimulating factors will be considered investigational or experimental for any other use and will not be covered.

D. 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

REFERENCES

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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).
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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/2023*
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
New Policy	*11/2020*