

**Short Acting Colony Stimulating Factor (CSF)  
Effective 01/01/2022**

<b>Plan</b>	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	These medications have been designated specialty and must be filled at a contracted specialty pharmacy when filled via that pharmacy benefit.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

**Overview**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

**Leukine, Neupogen, Nivestym, Zarxio**

- Myelosuppressive chemotherapy recipients with non-myeloid malignancies: To decrease the incidence of infection (neutropenic fever) in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy associated with a significant incidence of severe neutropenia with fever
- Acute myeloid leukemia (AML) following induction or consolidation chemotherapy: To reduce the time to neutrophil recovery and the duration of fever following induction or consolidation chemotherapy in adults with AML
- Bone marrow transplantation: To reduce the duration of neutropenia and neutropenia-related events (e.g., neutropenic fever) in patients with non-myeloid malignancies receiving myeloablative chemotherapy followed by marrow transplantation
- Peripheral blood progenitor (PBPC) cell collection and therapy: Mobilization of autologous hematopoietic progenitor cells into the peripheral blood for apheresis collection
- Severe chronic neutropenia: Long-term administration to reduce the incidence and duration of neutropenic complications (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital, cyclic, or idiopathic neutropenia

**Granix**

- Myelosuppressive chemotherapy recipients with non-myeloid malignancies: To decrease the duration of severe neutropenia in adult and pediatric patients ≥1 month of age with non-myeloid



malignancies receiving myelosuppressive chemotherapy associated with a clinically significant incidence of neutropenic fever

#### **Neupogen only**

- Hematopoietic radiation injury syndrome, acute: To increase survival in patients acutely exposed to myelosuppressive doses of radiation

#### **Compendial Uses For (Neupogen, Granix, Zarxio, Nivestym)**

- Treatment of chemotherapy-induced febrile neutropenia in patients with non-myeloid malignancies
- Treatment of anemia in patients with myelodysplastic syndromes (MDS)
- Treatment of neutropenia in patients with MDS
- Following chemotherapy for acute lymphocytic leukemia (ALL)
- Stem cell transplantation-related indications
- Agranulocytosis
- Aplastic anemia
- Neutropenia related to HIV/AIDS

#### **Compendial Uses for Leukine**

- Neuroblastoma in high-risk pediatric patients
- Primary prophylaxis of neutropenia in patients receiving chemotherapy (outside of transplant and AML) or who are at high risk for neutropenic fever.

#### **Coverage Guidelines**

##### **Zarxio**

1. Authorization may be granted for Zarxio for members being treated for any of the FDA indications or compendial uses.

##### **Granix, Leukine, Nivestem and/or Neupogen**

1. Member meets ONE of the following:
  - a. Authorization may be granted for Granix, Leukine, Nivestem or Neupogen, when prescriber has submitted documentation of previous treatment failure, intolerance or a contraindication with Zarxio
  - b. The prescriber has submitted clinical rationale why Zarxio is not an appropriate therapy.
2. For Granix, Neupogen: the requested doses are less than 180mcg.

##### **Continuation Criteria**

Reauthorization requires physician documentation of continuation of therapy and positive response to therapy.

##### **Limitations**

Initial authorizations and reauthorizations will be granted for 6 months

##### **References**

1. Granix (tbo-filgrastim) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc; March 2019.
2. Leukine (sargramostim) [prescribing information]. Lexington, MA: Partner Therapeutics; May 2018.



3. Neupogen (filgrastim) [prescribing information]. Thousand Oaks, CA: Amgen; June 2018
4. Nivestym (filgrastim-aafi) [prescribing information]. Lake Forest, IL: Hospira Inc; July 2018
5. Zarxio (filgrastim-sndz) [prescribing information]. Princeton, NJ: Sandoz Inc; August 2019

### **Review History**

06/19/19 – Updated (Added Zarxio as preferred agent, Neulasta is on separate criteria, added Nivestym as new biosimilar to CSF criteria)

11/18/2020- Updated (Added Nivestym to preferred agent with Zarxio, combined non-preferred agents Leukine, Neupogen and Granix under same heading)

11/17/2021 – Updated and Reviewed at Nov P&T; Zarxio remains preferred product. Moved Nivestym to non-preferred agent along with Leukine, Neupogen, Granix. Effective 01/01/2022

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