Mass General Brigham
Health Plan

Short Acting Colony Stimulating Factor (CSF)
Effective 01/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	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, Releuko

- 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, Releuko)

- 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, Nivyestem, Reuleuko and/or Neupogen

1. Member meets ONE of the following:
    a. Authorization may be granted for Granix, Leukine, Nivestym, Releuko 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.
11/15/2023 – Reviewed and Updated; Added Releuko to criteria. Effective 1/1/2024