Mass General Brigham
Health Plan

Short Acting Colony Stimulating Factors (CSFs):
Granix (tbo-filgrastim)
Leukine (sargramostim)
Neupogen (filgrastim)
Nivestym (filgrastim-aafi)
Nypozi (filgrastim-txid)
Releuko (filgrastim-ayow)
Zarxio (filgrastim-sndz)
Effective 01/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 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, Nypozi, Releuko, Zarxio:

- Acute myeloid leukemia (AML) following induction or consolidation chemotherapy: Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
- Peripheral blood progenitor cell (PBPC) cell collection and therapy: Mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

Neupogen, Nivestym, Nypozi, Releuko, Zarxio:

- Myelosuppressive chemotherapy recipients with non-myeloid malignancies: Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
- Bone marrow transplantation: Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation
- Severe chronic neutropenia: reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

Granix:

- 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

Leukine, Neupogen, Nypozi, Releuko, Zarxio:

- Hematopoietic Syndrome of Acute Radiation Syndrome: Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)

Leukine:

- Acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation in adult and pediatric patients 2 years of age and older.
- Acceleration of myeloid reconstitution following allogeneic bone marrow transplantation in adult and pediatric patients 2 years of age and older.
- Treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation in adult and pediatric patients 2 years of age and older.

Compendial Uses For (Neupogen, Granix, Zarxio, Nivestym, Nypozi, 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

Authorization may be reviewed for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when the following criteria are met:

Zarxio

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

Granix, Leukine, Nypozi, Nivestym, Reuleuko and/or Neupogen

1. Member meets ONE of the following:
    a. Documentation of previous treatment failure, intolerance or a contraindication with Zarxio
    b. Documentation of clinical rationale why Zarxio is not an appropriate therapy for the member

2. **Granix, Neupogen:** the requested doses are less than 180mcg.

Continuation Criteria
Requests for reauthorization will be approved when all of the following criteria are met:
1. **Granix, Leukine, Nivestym, Nypozi, Neupogen, Releuko:** Documentation of previous treatment failure, intolerance, or contraindication to Zarxio or clinical rationale why Zarxio is not an appropriate therapy for the member
2. Documentation of continuation of therapy and positive response to therapy.

Limitations
1. Initial approvals and reauthorizations will be granted for 6 months

References

1. Granix (tbo-filgrastim) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc; November 2023.
2. Leukine (sargramostim) [prescribing information]. Lexington, MA: Partner Therapeutics; August 2023.
3. Neupogen (filgrastim) [prescribing information]. Thousand Oaks, CA: Amgen; April 2023.
4. Nivestym (filgrastim-aafi) [prescribing information]. Lake Forest, IL: Hospira Inc; February 2024.
5. Nypozi (filgrastim-txid) [prescribing information]. San Diego, CA: Tanvex BioPharma USA, Inc.; June 2024.
6. Zarxio (filgrastim-sndz) [prescribing information]. Princeton, NJ: Sandoz Inc; October 2024.

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.
05/14/2025 – Reviewed and Updated at May P&T. Added Nypozi to the policy. Added language for members who are new to the plan. Updated background section to clarify the FDA-approved diagnoses for agents in policy. Effective 08/01/2025.
10/08/2025 – Reviewed and updated at October P&T. Updated policy to indicate it no longer applies to the medical benefit. Updated reauthorization criteria to require trial and failure with Zarxio. Effective 01/01/2026.