Mass General Brigham
Health Plan

Granulocyte Stimulating Agents
Granix (TBO-filgrastim)
Nivestym (filgrastim-aafi)
Releuko (filgrastim-ayow)
Zarxio (filgrastim-sndz)
Effective 06/05/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
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.

No PA	PA Required
Fulphila® (pegfilgrastim-jmdb)	Granix® (TBO-filgrastim)
Fylnetra® (pegfilgrastim-pbbk)	Nivestym® (filgrastim-aafi)
Leukine® (sargramostim)	Releuko®(filgrastim-ayow)
Neulasta® (pegfilgrastim)	Zarxio® (filgrastim-sndz)
Neupogen® (filgrastim)	
Nyvepria® (pegfilgrastim-apgf)	
Rolvedon® (eflapegrastim-xnst) MB	
Stimufend® (pegfilgrastim-fpgk)	
Udenyca® (pegfilgrastim-cbqv)	
Ziextenzo® (pegfilgrastim-bmez)	

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan 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, and documentation is provided:

Granix® (TBO-filgrastim)
Prescriber provides documentation of the following:
1. Indication of reduction in the incidence of infection, as manifested by febrile neutropenia, in members with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever

Nivestym® (filgrastim-aafi)
Zarxio® (filgrastim-sndz)
Prescriber provides documentation of the following:
1. Indication of **ONE** of the following:
    a. Reduction in the incidence of infection, as manifested by febrile neutropenia, in members with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
    b. Reduction in the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of members with acute myeloid leukemia
    c. Reduction in the duration of neutropenia and neutropenia-related clinical sequelae, in members with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation
    d. Mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
    e. Reduction in the incidence and duration of sequelae of severe neutropenia in symptomatic members with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

Releuko® (filgrastim- ayow)
Prescriber provides documentation of the following:
1. Indication of **ONE** of the following:
    a. Reduction in the incidence of infection, as manifested by febrile neutropenia, in members with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
    b. Reduction in the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of members with acute myeloid leukemia
    c. Reduction in the duration of neutropenia and neutropenia-related clinical sequelae, in members with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation
    d. Reduction in the incidence and duration of sequelae of severe neutropenia in symptomatic members with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

Continuation of Therapy
Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

Limitations
1. Initial authorizations and reauthorizations will be granted for 12 months

References
1. Neupogen® [package insert]. Thousand Oaks (CA): Amgen Pharmaceuticals; Feb 2021.

2. Granix® [package insert]. North Wales (PA): Teva Pharmaceuticals; Nov 2019.
3. Teva Announces FDA Grants Approval for Tbo-filgrastim for the Treatment of Chemotherapy-Induced Neutropenia [press release on the Internet]. North Wales (PA): Teva Pharmaceuticals. 2012 Aug 30 [cited 2018 October 31]. Available from: https://www.tevapharm.com/news/teva_announces_fda_grants_approval_for_tbo_filgrastim_for_the_treatment_of_chemotherapy_induced_neutropenia_08_12.aspx.
4. Zarxio® [package insert]. Princeton (NJ): Sandoz; Mar 2021.
5. Nivestym® [package insert]. Lake Forest (IL): Pfizer; Apr 2021.
6. Relueko® [package insert]. Bridgewater (NJ): Amneal Pharmaceuticals; Feb 2022.

Review History

10/20/2020- Switched from SGM to Custom; Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021

02/08/2023 - Reviewed and updated for Feb P&T. Matched MH UPPL criteria. Added Releuko® (filgrastim- ayow) to criteria. Diagnoses are now embedded within the criteria. Effective 4/1/23.

05/10/23 – Reviewed and updated for P&T. Biosimilars to Neulasta®, including Fylnetra® (pegfilgrastim-pbbk), Rolvedon (eflapegrastim-xnst), and Stimufend® (pegfilgrastim-fpgk) have been added to policy without PA. Separated Rx vs MB policies and removed preferred product requirement for requests through MB. Effective 6/5/23.