

## Aetna Medicare Part B Drug Step Criteria

### Short-acting Colony Stimulating Factors (CSF)

**Preferred product(s):  
Zarxio (filgrastim-sndz)**

This criteria document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization. Step criteria are applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Aetna Medicare Part B Drug Criteria. [Find Aetna Medicare Part B Drug Criteria documents.](#)

This program applies to CSF short-acting products as specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude use of the preferred product and may be based on previous use of a product. The coverage review process will determine situations where a clinical exception can be made. This program applies to all Medicare members who are new to treatment with a targeted product.

**For the indication(s) listed below (new starts only):**

1. 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
2. Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
3. 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 (BMT)
4. Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
5. Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
6. Stem cell transplantation-related indications
7. Agranulocytosis (non-chemotherapy drug induced)
8. Aplastic anemia
9. Neutropenia related to HIV/AIDS

**TABLE. CSF short-acting**

Status	Product(s)
<b>Preferred*</b>	Zarxio (filgrastim-sndz) – no prior authorization required
<b>Non-preferred (targeted)</b>	Granix (tbo-filgrastim) Leukine (sargramostim) Neupogen (filgrastim)



Reference number
1006-AMBST

	Nivestym (filgrastim-aafi) Nypozi (filgrastim-txid) Releuko (filgrastim-ayow)
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\*Preferred products do not require prior authorization

\*\*Non-preferred products may not be indicated for all indications listed above

**EXCEPTION CRITERIA**

Coverage for the targeted product(s) is provided when the member meets one or more of the following criteria:

1. Member has received an authorized dose of the requested product in the past 365 days (does not include samples or doses administered without prior authorization)
2. Documented inadequate response to a trial of the preferred product (documentation required upon request)
3. Documented intolerable adverse event to the preferred product (documentation required upon request)
4. The request is for a medically necessary indication not listed above

**REFERENCES**

1. Granix (tbo-filgrastim) injection [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2019.
2. Leukine (sargramostim) injection [package insert]. Lexington, MA: Partner Therapeutics, Inc.; August 2023.
3. Neupogen (filgrastim) injection [package insert]. Thousand Oaks, CA: Amgen, Inc; April 2023.
4. Nivestym (filgrastim-aafi) injection [package insert]. Lake Forest, IL: Hospira, Inc. a Pfizer Company; February 2024.
5. Nypozi (filgrastim-txis) injection [package insert]. San Diego, CA: Tanvex BioPharma USA, Inc; June 2024
6. Releuko (filgrastim-ayow) injection [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; February 2022.
7. Zarxio (filgrastim-sndz) injection [package insert]. Princeton, NJ: Sandoz, Inc.; January 2024.
8. Micromedex [database online]. New York, NY: Thomson Reuters, Inc.; 2019. Available at <http://www.micromedexsolutions.com/micromedex2/librarian>. Updated periodically. Accessed October 2019.
9. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; <http://online.lexi.com/lco/action/home> [available with subscription]. Accessed October 2019.

**DOCUMENT HISTORY**

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See Evidence of Coverage for a complete description of plan benefits, exclusions, limitations and conditions of coverage. Plan features and availability may vary by service area.

The formulary may change at any time. You will receive notice when necessary.