Reference number(s)
4282-D

This document applies to the following:

Product	Applies
Medicare Part B	☑
Medicare Part B: Advanced Biosimilars First	☑

Medicare Part B Step Therapy Colony Stimulating Factors – Short Acting

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary

This program applies to the colony stimulating factors – short acting products specified in this document. Coverage for the non-preferred product is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with the non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Colony Stimulating Factors – Short Acting

Medications considered preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Zarxio (filgrastim-sndz)
Non-preferred	• Granix (TBO-filgrastim) • Leukine (sargramostim) • Neupogen (filgrastim) • Nivestym (filgrastim-aafi) • Releuko (filgrastim-ayow)

Step Therapy Criteria

Coverage for the non-preferred products, Granix, Neupogen, Nivestym or Releuko, is provided when the member meets one of the following criteria:

- Member has had a documented intolerable adverse event to the preferred product, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
- Member is requesting Granix, Neupogen vials or Nivestym and has a documented latex allergy that the prescriber states the member must use latex-free products. Neupogen pre-filled syringes contain latex and are not covered under this criterion.
- Neupogen, Nivestym, or Granix are requested for doses less than 180 mcg.
- Member has received treatment with the requested non-preferred product in the past 365 days.

Coverage for the non-preferred product, Leukine, is provided when the member meets one of the following criteria:

- Member has had a documented inadequate response or an intolerable adverse event to the preferred product.
- Leukine is being requested for an indication that is not FDA-approved for the preferred product.
- Member has received treatment with the requested non-preferred product in the past 365 days.

References

1. Granix [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2023.
2. Leukine [package insert]. Lexington, MA: Partner Therapeutics, Inc.; August 2023.
3. Neupogen [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2023.
4. Nivestym [package insert]. Lake Forest, IL: Hospira, Inc., a Pfizer Company: February 2024.
5. Releuko [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; September 2023.
6. Zarxio [package insert]. Princeton, NJ: Sandoz, Inc.; October 2024.