Reference number(s)
3899-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-Long 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.

Plan Design Summary

This program applies to the colony stimulating factors-long 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 – Long Acting

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

	Product(s)
Preferred	• Fulphila (pegfilgrastim-jmdb) • Neulasta (including Onpro kit) (pegfilgrastim)

	Product(s)
Non-preferred	• Fylnetra (pegfilgrastim-pbbk) • Nyvepria (pegfilgrastim-apgf) • Rolvedon (eflapegrastim-xnst) • Stimufend (pegfilgrastim-fpgk) • Udenyca (pegfilgrastim-cbqv) • Ziextenzo (pegfilgrastim-bmez)

Step Therapy Criteria

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

- Member has had a documented intolerable adverse event to both of the preferred products, 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 products and biosimilar products).
- Member has received treatment with the requested non-preferred product in the past 365 days.

References

1. Neulasta [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2021.
2. Fulphila [package insert]. Cambridge, MA: Biocon Biologics Inc.; June 2023.
3. Fylnetra [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; May 2022.
4. Nyvepria [package insert]. Lake Forest, IL: Hospira, Inc.; March 2023.
5. Rolvedon [package insert]. Lake Forest, IL: Spectrum Pharmaceuticals, Inc.; November 2023.
6. Stimufend [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2023.
7. Udenyca [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; December 2023.
8. Ziextenzo [package insert]. Princeton, NJ: Sandoz Inc.; February 2024.