



MED RX POLICY

- POLICY:** Colony Stimulating Factors – Pegfilgrastim Products Med Rx Policy
- Fulphila™ (pegfilgrastim-jmdb subcutaneous injection – Mylan)
 - Fylnetra® (pegfilgrastim-pbbk subcutaneous injection – Amneal)
 - Neulasta® (pegfilgrastim subcutaneous injection – Amgen)
 - Nyvepria™ (pegfilgrastim-apgf subcutaneous injection – Hospira)
 - Stimufend® (pegfilgrastim-fpgk subcutaneous injection – Fresenius Kabi)
 - Udenyca™ (pegfilgrastim-cbqv subcutaneous injection – Coherus)
 - Ziextenzo™ (pegfilgrastim-bmez subcutaneous injection – Sandoz)

REVIEW DATE: 09/21/2022; selected revision 11/09/2022, 01/04/2023

OVERVIEW

Pegfilgrastim products are indicated for the treatment of a variety of **neutropenia-related conditions**.¹⁻⁷

Fulphila, Fylnetra, Nyvepria, Udenyca, and Ziextenzo were approved as biosimilars to Neulasta, indicating no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, dosage form, and strength as Neulasta.²⁻⁷ However, minor differences in clinically inactive components are allowed. At this time, Fulphila, Fylnetra, Nyvepria, Stimufend, Udenyca, and Ziextenzo have only demonstrated biosimilarity, not interchangeability.

POLICY STATEMENT

This Med Rx program has been developed to encourage the use of Preferred Products. For all products (Preferred and Non-Preferred), the patient is required to meet the standard *Colony Stimulating Factors – Pegfilgrastim Products Utilization Management Medical Policy* criteria. This program also directs the patient to try at least two Preferred Products prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for the duration noted in the *Colony Stimulating Factors – Pegfilgrastim Products Utilization Management Medical Policy*.

Automation: None.

Preferred Products: Neulasta, Udenyca, Ziextenzo
Non-Preferred Products: Fulphila, Fylnetra, Nyvepria, Stimufend

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Fulphila, Fylnetra, Nyvepria, Stimufend	<ol style="list-style-type: none"> 1. Approve if the patient meets the following criteria (A <u>and</u> B): <ol style="list-style-type: none"> A) Patient meets the standard <i>Colony Stimulating Factors – Pegfilgrastim Products Utilization Management Medical Policy</i> criteria; AND B) Patient meets BOTH of the following (i <u>and</u> ii): <ol style="list-style-type: none"> i. Patient has tried two of Neulasta, Udenyca, and Ziextenzo; AND ii. Patient cannot continue to use the Preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction.

REFERENCES

1. Neulasta® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; March 2021.
2. Fulphila® subcutaneous injection [prescribing information]. Rockford, IL: Mylan; October 2021.
3. Udenyca™ subcutaneous injection [prescribing information]. Redwood City, CA: Coherus; June 2021.
4. Ziextenzo™ subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; March 2021.
5. Nyvepria™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; June 2022.
6. Fylnetra® subcutaneous injection [prescribing information]. Bridgewater, NJ: Amneal; May 2022.
7. Stimufend® subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; May 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Nyvepria: This product was moved to the Non-Preferred Product list and removed from exception criteria that list the Preferred Products. Ziextenzo: This product was moved to the Preferred Product list and added to exception criteria that list the Preferred Products.	09/15/2021
Annual Revision	No criteria changes.	09/21/2022
Selected Revision	Fylnetra: This product was added to the policy as a Non-Preferred Product. Non-Preferred Products: The exception for a patient to receive a Non-Preferred Product for further medication to complete the current cycle of chemotherapy was removed from criteria.	11/09/2022
Selected Revision	Stimufend: This product was added to the policy as a Non-Preferred Product.	01/04/2023