PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Colony Stimulating Factors – Pegfilgrastim Products and Rolvedon Preferred Specialty Management Policy for High Performance and National Preferred Formularies

- Fulphila® (pegfilgrastim-jmdb subcutaneous injection – Mylan)
- Fylnetra® (pegfilgrastim-pbbk subcutaneous injection – Amneal)
- Neulasta® (pegfilgrastim subcutaneous injection – Amgen)
- Nyvepria™ (pegfilgrastim-apgf subcutaneous injection – Pfizer)
- Rolvedon® (eflapegrastim-xnst subcutaneous injection – Spectrum)
- Stimufend® (pegfilgrastim-fpgk subcutaneous injection – Fresenius)
- Udenyca® (pegfilgrastim-cbqv subcutaneous injection – Coherus)
- Ziextenzo™ (pegfilgrastim-bmez subcutaneous injection – Sandoz)

REVIEW DATE: 02/05/2025

OVERVIEW

Pegfilgrastim products are indicated for the treatment of a variety of **neutropenia-related conditions**.[1-7] Fulphila, Fylnetra, Nyvepria, Udenyca, Stimufend, 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. However, minor differences in clinically inactive components are allowed. At this time, Fulphila, Fylnetra, Nyvepria, Udenyca, Stimufend, and Ziextenzo have only demonstrated biosimilarity, not interchangeability.

Rolvedon, a leukocyte growth factor, is indicated to **decrease the incidence of infection, as manifested by febrile neutropenia**, in adults with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.[8]

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Colony Stimulating Factors Prior Authorization Policy* criteria. The program also directs the patient to try at least one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). Approval durations are as noted in the respective standard *Colony Stimulating Factors Prior Authorization Policy*. If the patient meets the respective standard *Colony Stimulating Factors Prior Authorization Policy* criteria but has not tried a Preferred Product, a review will be offered for the Preferred Product(s) using the respective standard *Colony Stimulating Factors Prior Authorization Policy* criteria.

Documentation: Documentation is required for the use of the pegfilgrastim products or Rolvedon, as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Automation: None.

Non-Preferred Products: Neulasta, Fylnetra, Nyvepria, Rolvedon, Stimufend, Udenyca

RECOMMENDED EXCEPTION CRITERIA

REFERENCES

1. Neulasta® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; October 2024.
2. Fulphila® subcutaneous injection [prescribing information]. Rockford, IL: Mylan; October 2021.
3. Udenyca® subcutaneous injection [prescribing information]. Redwood City, CA: Coherus; August 2024.
4. Ziextenzo™ subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; March 2021.
5. Nyvepria™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; June 2023.
6. Fylnetra® subcutaneous injection [prescribing information]. Bridgewater, NJ: Amneal; May 2022.
7. Stimufend® subcutaneous injection [prescribing information]. Fresenius; Lake Zurich, IL; October 2023.
8. Rolvedon™ subcutaneous injection [prescribing information]. Irvine, CA: Spectrum; November 2023.