PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Colony Stimulating Factors – Pegfilgrastim Products and Rolvedon Preferred Specialty Management Policy

- 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)
- Udenyca™ (pegfilgrastim-cbqv subcutaneous injection – Coherus)
- Ziextenzo™ (pegfilgrastim-bmez subcutaneous injection – Sandoz)

REVIEW DATE: 09/21/2022; selected revision 11/09/2022, 01/18/2023

OVERVIEW

Pegfilgrastim products are indicated for the treatment of a variety of **neutropenia-related conditions**.[1-6]

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.[2-6] However, minor differences in clinically inactive components are allowed. At this time, Fulphila, Fylnetra, Nyvepria, Udenyca, 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.[7]

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). If the patient meets the respective standard *Colony Stimulating Factors Prior Authorization Policy* criteria but has not tried at least one Preferred Product or meet exception criteria, a review will be offered for the Preferred Products using the respective standard *Colony Stimulating Factors Prior Authorization Policy* criteria. Approval durations are as noted in the corresponding *Prior Authorization Policy*.

Documentation: Documentation is required for the use of Non-Preferred Products 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.

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

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Neulasta, Fylnetra, Nyvepria, Udenyca	**1.** Patient meets the following criteria (A and B): **A)** Patient meets the standard *Colony Stimulating Factors – Pegfilgrastim Products Prior Authorization Policy* criteria; AND **B)** Patient meets BOTH of the following (i and ii): **i.** Patient has tried one of Fulphila or Ziextenzo **[documentation required]**; AND **ii.** Patient cannot continue to use the Preferred medication 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. **2.** If the patient has met criterion 1A (the standard *Colony Stimulating Factors – Pegfilgrastim Products Prior Authorization Policy* criteria) but criterion 1B is not met, the requested agent is not approved: offer to review for a Preferred Product.
Rolvedon	**1.** Patient meets the following criteria (A and B): **A)** Patient meets the standard *Colony Stimulating Factors – Rolvedon Prior Authorization Policy* criteria; AND **B)** Patient has tried one of Fulphila or Ziextenzo **[documentation required]**. Note: A trial of any pegfilgrastim product (Neulasta, biosimilars) also counts **[documentation required]**. **2.** If the patient has met criterion 1A (the standard *Colony Stimulating Factors – Rolvedon Prior Authorization Policy* criteria) but criterion 1B is not met, the requested agent is not approved: offer to review for a Preferred Product.

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. Rolvedon™ subcutaneous injection [prescribing information]. Irvine, CA: Spectrum; September 2022.