PREFERRED SPECIALTY MANAGEMENT POLICY

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

- Fulphila™ (pegfilgrastim-jmdb injection for subcutaneous use – Mylan)
- Neulasta® (pegfilgrastim injection for subcutaneous use – Amgen)
- Nyvepria™ (pegfilgrastim-apgf injection for subcutaneous use – Pfizer)
- Udenyca™ (pegfilgrastim-cbqv injection for subcutaneous use – Coherus Biosciences)
- Ziextenzo™ (pegfilgrastim-bmez injection for subcutaneous use – Sandoz)

REVIEW DATE: 09/23/2020; selected revision 03/31/2021

OVERVIEW

Pegfilgrastim products are indicated for the treatment of a variety of neutropenia-related conditions.[1-5] Pegfilgrastim products are colony-stimulating factors that act on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation. Fulphila, Nyvepria, Udenyca and Ziextenzo were approved as a biosimilar 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, Nyvepria, Udenyca and Ziextenzo have only demonstrated biosimilarity, not interchangeability.

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 standard *Colony Stimulating Factors – Pegfilgrastim Products 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 standard *Colony Stimulating Factors – Pegfilgrastim Products 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 standard *Colony Stimulating Factors – Pegfilgrastim Products Utilization Review Medical 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, Nyvepria, Ziextenzo
Non-Preferred Products: Neulasta, Udenyca

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Neulasta	**1.** Patient must meet the following criteria (A and B): **A)** Patient meets the standard *Colony Stimulating Factors – Pegfilgrastim Products Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i or ii): **i.** Patient meets both of the following (a and b): **a)** Patient has tried one of Fulphila, Nyvepria, or Ziextenzo **[documentation required]**; AND **b)** 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; OR **ii.** Patient has initiated therapy with Neulasta and requires further medication to complete the current cycle of chemotherapy. **2.** If the patient has met criterion 1A (the standard *Colony Stimulating Factors – Pegfilgrastim Prior Authorization Policy* criteria), but criterion 1B is not met, the requested agent is not approved: offer to review for a Preferred Product.
Udenyca	**1.** Patient must meet the following criteria (A and B): **A)** Patient meets the standard *Colony Stimulating Factors – Pegfilgrastim Products Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i or ii): **i.** Patient meets both of the following (a and b): **a)** Patient has tried one of Fulphila, Nyvepria, or Ziextenzo **[documentation required]**; AND **b)** 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; OR **ii.** Patient has initiated therapy with Udenyca and requires further medication to complete the current cycle of chemotherapy. **2.** If the patient has met criterion 1A (the standard *Colony Stimulating Factors – Pegfilgrastim 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. Fulphila® injection for subcutaneous use [prescribing information]. Rockford, IL: Mylan; May 2019.
2. Neulasta® injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen; April 2019.
3. Udenyca™ injection for subcutaneous use [prescribing information]. Redwood City, CA: Coherus Biosciences; February 2019.
4. Ziextenzo™ injection for subcutaneous use [prescribing information]. Princeton, NJ: Sandoz; November 2019.
5. Nyvepria™ injection for subcutaneous use [prescribing information]. New York, NY: Pfizer; December 2020.