



Preferred Specialty Management Colony Stimulating Factors – Pegfilgrastim Products

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

NPF Medical Necessity

Drugs Affected

- Fulphila™ (pegfilgrastim-jmdb injection for subcutaneous use)
- Neulasta® (pegfilgrastim injection for subcutaneous use)
- Nyvepria™ (pegfilgrastim-apgf injection for subcutaneous use)
- Udenyca™ (pegfilgrastim-cbqv injection for subcutaneous use)
- Ziextenzo™ (pegfilgrastim-bmez injection for subcutaneous use)

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. For all medications (Preferred and Non-Preferred), the individual is required to meet the standard *Colony Stimulating Factors – Pegfilgrastim Products Prior Authorization Policy* criteria. The program also directs the individual 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 individual 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.

Preferred Product(s): Fulphila, Nyvepria, Ziextenzo
Non-Preferred Product(s): Neulasta, Udenyca

Cigna covers Non-Preferred Products as medically necessary when the following criteria are met:

Non-Preferred Products	Exception Criteria
Neulasta	<p>1. Individual must meet the following criteria (A <u>and</u> B):</p> <p>A) Individual meets the standard <i>Colony Stimulating Factors – Pegfilgrastim Products Prior Authorization Policy</i> criteria; AND</p> <p>B) Individual meets one of the following (i <u>or</u> ii):</p> <p>i. Individual meets both of the following (a <u>and</u> b):</p> <p>a) Individual has tried one of Fulphila, Nyvepria, or Ziextenzo [documentation required]; AND</p> <p>b) Individual 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</p> <p>ii. Individual has initiated therapy with Neulasta and requires further medication to complete the current cycle of chemotherapy. If the individual has met criterion 1A (the standard <i>Colony Stimulating Factors – Pegfilgrastim Prior Authorization Policy</i> criteria), but criterion 1B is not met, the requested agent is not approved: offer to review for a Preferred Product.</p>
Udenyca	<p>1. Individual must meet the following criteria (A <u>and</u> B):</p> <p>A) Individual meets the standard <i>Colony Stimulating Factors – Pegfilgrastim Products Prior Authorization Policy</i> criteria; AND</p> <p>B) Individual meets one of the following (i <u>or</u> ii):</p> <p>i. Individual meets both of the following (a <u>and</u> b):</p> <p>a) Individual has tried one of Fulphila, Nyvepria, or Ziextenzo [documentation required]; AND</p> <p>b) Individual 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</p> <p>ii. Individual has initiated therapy with Udenyca and requires further medication to complete the current cycle of chemotherapy. If the individual has met criterion 1A (the standard <i>Colony Stimulating Factors – Pegfilgrastim Prior Authorization Policy</i> criteria), but criterion 1B is not met, the requested agent is not approved: offer to review for a Preferred Product.</p>

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

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.

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.

Revision History

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/23/2020
Selected Revision	Added Nyvepria to the policy as a Preferred Product.	03/31/2021

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