PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Colony Stimulating Factors – Pegfilgrastim Products Preferred Specialty Management Policy for 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)
- Stimufend® (pegfilgrastim-fpgk subcutaneous injection – Fresenius)
- Udenyca™ (pegfilgrastim-cbqv subcutaneous injection – Coherus)
- Ziextenzo™ (pegfilgrastim-bmez subcutaneous injection – Sandoz)

REVIEW DATE: 02/07/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

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

Colony Stimulating Factors – Pegfilgrastim Products non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Neulasta, Fylnetra, Nyvepria, Stimufend, Udenyca	**1.** Approve if the patient meets both of the following (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 and

	the requested agent is not approved: Offer to review for the Preferred Product(s).

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]. Fresenius; Lake Zurich, IL; September 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/04/2023
Early Annual Revision	**Title:** The title of the Policy was changed to add "for High Performance and National Preferred Formularies". Previously, there was not a separate Policy for any formulary. No criteria changes.	02/07/2024