PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Colony Stimulating Factors – Pegfilgrastim Products, Rolvedon and Ryzneuta Preferred Specialty Management Policy for Flex, 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)
- Ryzneuta® (efbemalenograstim alfa-vuxw subcutaneous injection – Evive/Acrotech)
- Stimufend® (pegfilgrastim-fpgk subcutaneous injection – Fresenius)
- Udenyca® (pegfilgrastim-cbqv subcutaneous injection – Coherus)
- Ziextenzo™ (pegfilgrastim-bmez subcutaneous injection – Sandoz)

REVIEW DATE: 02/05/2025; selected revision 08/06/2025 and 09/10/2025

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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: [1-7]

- To **decrease the incidence of infection**, **as manifested by febrile neutropenia**, in patients (adults and pediatric) with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
- To increase survival in patients acutely exposed to myelosuppressive doses of radiation (**hematopoietic subsyndrome of acute radiation syndrome**) [Neulasta, Fylnetra, Stimufend, Udenyca, Ziextenzo only].

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.

Rolvedon and Ryzneuta, leukocyte growth factors, are 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.[8,9]

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. All documentation must include patient-specific identifying information.

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

Colony Stimulating Factors – Pegfilgrastim Products, Rolvedon and Ryzneuta Preferred Specialty Management Policy **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 respective 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 at least one of the following: Fulphila or Ziextenzo **[documentation required]**; AND **ii.** Patient cannot continue to use the Preferred medication(s) 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 product is not approved: Offer to review for the Preferred Product(s).
Rolvedon	**1.** Approve if the patient meets BOTH the following (A and B): **A)** Patient meets the standard *Colony Stimulating Factors – Rolvedon Prior Authorization Policy* criteria; AND **B)** Patient has tried at least one of the following: Fulphila or Ziextenzo **[documentation required]**. Note: A previous trial of any pegfilgrastim product (Neulasta, biosimilars) also satisfies this requirement **[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 and the requested product is not approved: Offer to review for the Preferred Product(s).
Ryzneuta	**1.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Colony Stimulating Factors – Ryzneuta Prior Authorization Policy* criteria; AND **B)** Patient has tried at least one of the following: Fulphila or Ziextenzo **[documentation required]**.

	Note: A previous trial of any pegfilgrastim product (Neulasta, biosimilars) also satisfies this requirement **[documentation required]**. **2.** If the patient has met criterion 1A (the standard *Colony Stimulating Factors – Ryzneuta Prior Authorization Policy* criteria) but criterion 1B is not met and the requested product is not approved: Offer to review for the Preferred Product(s).

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.
9. Ryzneuta® subcutaneous injection [prescribing information]. East Windsor, NJ: Evive/Acrotech; June 2025.

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.	02/07/2024
Annual Revision	No criteria changes.	02/05/2025
Selected Revision	**Title:** The title of the Policy was updated from "Colony Stimulating Factors – Pegfilgrastim Products and Rolvedon Preferred Specialty Management Policy for High Performance and National Preferred Formularies" to as written. **Ryzneuta**: Ryzneuta (efbemalenograstim alfa-vuxw subcutaneous injection) was added as Non-Preferred and exception criteria were added.	08/06/2025
Selected Revision	Added Flex Formulary to the Policy with the same criteria as High Performance and National Preferred Formularies.	09/10/2025