Effective Date **1/1/2024**
Next Review Date… **1/1/2025**
Coverage Policy Number **IP0526**

Eflapegrastim

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Related Coverage Resources

Pegfilgrastim (IP0070)

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.

Overview

This policy supports medical necessity review for eflapegrastim-xnst (**Rolvedon**™).

Additional criteria that support the review for medical necessity exceptions of non-covered products are located in the Non-Covered Product Table by the respective plan type and drug list where applicable.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Eflapegrastim-xnst (Rolvedon) is considered medically necessary when the following are met:

Non-myeloid malignancy receiving myelosuppressive chemotherapy associated with an increased risk of febrile neutropenia. Individual meets **ALL** of the following criteria:

A. 18 years of age or older

B. Prescribed by or in consultation with an oncologist or hematologist
C. Non-Covered Product Criteria is met, refer to below table(s)

Dosing. The recommended dose of Rolvedon is 13.2 mg by subcutaneous injection no more frequently than once every 2 weeks.

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Rolvedon (Eflapegrastim-xnst subcutaneous injection)	**Standard/Performance/Value/Advantage/Legacy Drug List Plans:** Documented trial AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to **ONE** of the following: 1. Neulasta [may require prior authorization] 2. Nyvepria [may require prior authorization] 3. Udenyca [may require prior authorization] **Cigna Total Savings Drug List Plans:** Documented trial AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to **ONE** of the following: 1. Neulasta [may require prior authorization] 2. Nyvepria [may require prior authorization] 3. Udenyca [may require prior authorization] 4. Ziextenzo [may require prior authorization]

Individual and Family Plan Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Rolvedon (Eflapegrastim-xnst subcutaneous injection)	Documented trial AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to **ONE** of the following: 1. Neulasta [may require prior authorization] 2. Nyvepria [may require prior authorization] 3. Udenyca [may require prior authorization]

Reauthorization Criteria

Continuation of eflapegrastim-xnst (Rolvedon) is considered medically necessary for individuals with non-myeloid malignancy receiving myelosuppressive chemotherapy associated with an increased risk of febrile neutropenia when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Approval duration up to 6 months.
Reauthorization approval duration up to 6 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

> **Peripheral Blood Progenitor Cell Collection and Therapy.** As a limitation of use in the Rolvedon prescribing information, it is noted that Rolvedon is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J1449	Injection, eflapegrastim-xnst, 0.1 mg (Code effective 04/01/2023)

Background

OVERVIEW
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.[1]

Limitation of use: Rolvedon is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.[1]

Safety and effectiveness in pediatric patients have not been established.[1]

Guidelines
According to the National Comprehensive Cancer Network (NCCN) guidelines for hematopoietic growth factors (version 1.2022 – December 22, 2021), evaluation of risk for febrile neutropenia following chemotherapy in adults with solid tumors and non-myeloid malignancies should occur prior to the first chemotherapy cycle. For a patient at high risk (> 20% risk), granulocyte colony-stimulating factor (G-CSF) is recommended (category 1). For a patient at intermediate risk (10% to 20% risk), consider G-CSF if the patient has at least one of the following risk factors: including prior chemotherapy or radiation therapy; persistent neutropenia; bone marrow involvement by tumor; recent surgery and/or open wounds; liver dysfunction; renal dysfunction; and age > 65 years receiving full chemotherapy dose intensity (category 2A). Recommended G-CSFs include filgrastim (category 1), Granix® (tbo-filgrastim subcutaneous injection) [category 1], pegfilgrastim (category 1), or Rolvedon (category 2A).

Additional Clinical Information

Dosing and Availability
The recommended dosage of Rolvedon is a single subcutaneous injection of 13.2 mg administered once per chemotherapy cycle. Administer approximately 24 hours after cytotoxic chemotherapy. Do not administer within the period from 14 days before to 24 hours after administration of cytotoxic chemotherapy.[1]

Rolvedon is available in 13.2 mg/0.6 mL as a clear, colorless, preservative-free solution in a single-dose prefilled syringe.[1]

References

1. Rolvedon™ subcutaneous injection [prescribing information]. Irvine, CA: Spectrum; September 2022.
2. The NCCN Hematopoietic Growth Factors Clinical Practice Guidelines in Oncology (version 1.2022 – December 22, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 6, 2022.