Effective Date 08/01/2025
Coverage Policy Number IP0526

Eflapegrastim

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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. 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.

Overview

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

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. The patient meets the following criteria:
A. 18 years of age or older

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

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

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

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 12 months.
Reauthorization approval duration up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **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 granulocyte colony stimulating factor (G-CSF), 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 (PBPCs) for hematopoietic stem cell transplantation.[1]

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

Guidelines
The National Comprehensive Cancer Network (NCCN) guidelines for **hematopoietic growth factors** (version 3.2024 – January 30, 2024) recommend Rolvedon, along with other CSFs, for prophylactic use if the patient is receiving anti-cancer medications that are associated with a high (> 20%) incidence of severe neutropenia with fever.[2] Consider CSF therapy for patients with an intermediate (10% to 20%) probability of developing febrile neutropenia based on risk factors. The NCCN guidelines also recommend therapy with CSFs in other scenarios in those given myelosuppressive chemotherapy. Of note, pegfilgrastim, Rolvedon, and Ryzneuta® (efbemalenograstim alfa-vuxw subcutaneous injection) have only been studied for prophylactic use, not for treatment of febrile neutropenia.

References

1. Rolvedon® subcutaneous injection [prescribing information]. Irvine, CA: Spectrum; June 2023.
2. The NCCN Hematopoietic Growth Factors Clinical Practice Guidelines in Oncology (version 3.2024 – January 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 2, 2024

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	Employer Group Non-Covered Products and Criteria table for Cigna Total Savings Drug List Plan: Removed Neulasta, added Fulphila	11/15/2024
Selected Revision	**Removed** preferred product requirements Employer Group and Individual and Family Plans.	02/01/2025
Selected Revision	**Removed** the specialist prescribing requirement. **Updated** the authorization and reauthorization durations from 6 months to 12 months.	08/01/2025

The policy effective date is in force until updated or retired.