Drug Coverage Policy

Effective Date 1/15/2026
Coverage Policy Number.....IP0526
Policy Title.....Rolvedon

Colony Stimulating Factors – Rolvedon

- Rolvedon® (eflapegrastim-xnst subcutaneous injection – Spectrum)

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

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 1.2025 – October 11, 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. Treatment for patients with radiation -induced myelosuppression following a radiologic/nuclear incident (hematopoietic acute radiation syndrome [H-ARS]) is also recommended. Of note, pegfilgrastim products, Rolvedon, and Ryzneuta® (efbemalenograstim alfa-vuxw subcutaneous injection) have only been studied for prophylactic use, not for treatment of febrile neutropenia.

Dosing Information
Definitive dosing has not been established for the use of Rolvedon in the treatment of adults with H-ARS. Neulasta® (pegfilgrastim subcutaneous injection) is indicated for this use and per the labeling, the recommended dose is two doses administered subcutaneously via single-dose prefilled syringe one week apart.[3] Rolvedon is available as a 13.2 mg/0.6 mL single-dose prefilled syringe.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for medical benefit coverage of Rolvedon. Approval is required for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Rolvedon as well as the monitoring required for adverse events and long-term efficacy, approval requires Rolvedon to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Rolvedon is considered medically necessary when ONE of the following are met:

FDA-Approved Indication

1. **Cancer in a Patient Receiving Myelosuppressive Chemotherapy**. Approve for 6 months if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen); OR
     - **ii.** Patient meets BOTH of the following (a and b):

a) Patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia, but the risk is less than 20% based on the chemotherapy regimen; AND

b) Patient has at least one risk factor for febrile neutropenia according to the prescriber; OR

Note: Examples of risk factors include age > 65 years receiving full chemotherapy dose intensity; prior chemotherapy or radiation therapy; persistent neutropenia; bone marrow involvement by tumor; recent surgery and/or open wounds; liver dysfunction (bilirubin > 2.0 mg/dL); renal dysfunction (creatine clearance < 50 mL/min); poor performance status; patient with human immunodeficiency virus (HIV) infection and low CD4 counts.

iii. Patient meets BOTH of the following (a and b):

a) Patient has had a neutropenic complication from a prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor; AND

Note: Examples of colony stimulating factors include filgrastim products, pegfilgrastim products, Ryzneuta (efbemalenograstim alfa-vuxw subcutaneous injection).

b) A reduced dose or frequency of chemotherapy may compromise treatment outcome; AND

C) The medication is prescribed by or in consultation with an oncologist or hematologist.

Dosing. Approve up to 13.2 mg by subcutaneous injection no more frequently than once every 2 weeks.

Other Use with Supportive Evidence

2. **Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).** Approve for 1 month if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) The medication is prescribed by or in consultation with a physician who has expertise in treating acute radiation syndrome.

   Dosing. Approve two doses of up to 13.2 mg by subcutaneous injection no more frequently than 1 week apart.

Conditions Not Covered

Rolvedon for any other use is considered not medically necessary, 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. [1]

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)

References

1. Rolvedon® subcutaneous injection [prescribing information]. Irvine, CA: Spectrum; June 2023.
2. The NCCN Hematopoietic Growth Factors Clinical Practice Guidelines in Oncology (version 1.2025 – October 11, 2024). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 7, 2025.
3. Neulasta® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; March 2021.

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
Selected Revision	**Updated** policy template.	12/1/2025
Annual Revision	**Policy Title.** **Updated from** "Eflapegrastim" **to** "Colony Stimulating Factors – Rolvedon" **Cancer in a Patient Receiving Myelosuppressive Chemotherapy**. **Updated from** "Non-myeloid malignancy receiving myelosuppressive chemotherapy associated with an increased risk of febrile neutropenia" **to** "Cancer in a Patient Receiving Myelosuppressive Chemotherapy." **Added** "Patient meets ONE of the following: Patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen); OR Patient meets BOTH of the following (a and b): Patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia, but the risk is less than 20% based on the chemotherapy regimen; AND Patient has at least one risk factor for febrile neutropenia according to the prescriber; OR	1/15/2026

	Note: Examples of risk factors include age > 65 years receiving full chemotherapy dose intensity; prior chemotherapy or radiation therapy; persistent neutropenia; bone marrow involvement by tumor; recent surgery and/or open wounds; liver dysfunction (bilirubin > 2.0 mg/dL); renal dysfunction (creatine clearance < 50 mL/min); poor performance status; patient with human immunodeficiency virus (HIV) infection and low CD4 counts. Patient meets BOTH of the following (a and b): Patient has had a neutropenic complication from a prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor; AND Note: Examples of colony stimulating factors include filgrastim products, pegfilgrastim products, Ryzneuta (efbemalenograstim alfa-vuxw subcutaneous injection). A reduced dose or frequency of chemotherapy may compromise treatment outcome; AND The medication is prescribed by or in consultation with an oncologist or hematologist. **Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome):** This Other Use with Supportive Evidence was added as a new condition of approval. A new dosing limitation was added.	

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