UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Colony Stimulating Factors – Rolvedon Utilization Management Medical Policy
- Rolvedon® (eflapegrastim-xnst subcutaneous injection – Spectrum)

REVIEW DATE: 10/29/2025

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.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Rolvedon. Approval is recommended 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rolvedon is recommended in those who meet one of the following criteria:

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 RECOMMENDED FOR APPROVAL

Coverage of Rolvedon is not recommended in the following situations:

1. **Peripheral Blood Progenitor Cell (PBPC) 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]

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	No criteria changes.	09/20/2023
Selected Revision	**Cancer in a Patient Receiving Myelosuppressive Chemotherapy**: The criterion for "Patient who has received chemotherapy has febrile neutropenia and has at least one risk factor for poor clinical outcomes or for developing infection-associated complications according to the prescriber" was removed. The note providing examples of colony-stimulating factors was updated to add Ryzneuta and remove sargramostim products (e.g. Leukine).	12/20/2023
Annual Revision	**Cancer in a Patient Receiving Myelosuppressive Chemotherapy**: The Note providing examples of risk factors for febrile neutropenia was updated from "≥ 65 years" to "> 65 years of age receiving full chemotherapy dose intensity", liver dysfunction was defined as "bilirubin > 2.0 mg/dL", renal dysfunction was defined as "creatine clearance < 50 mL/min", and human immunodeficiency infection patients was clarified to add "with low CD4 counts." The requirement for a patient to have had a neutropenic complication from "prior chemotherapy" was updated to add "cycle."	10/09/2024
Annual Revision	**Cancer in a Patient Receiving Myelosuppressive Chemotherapy**: The Note was updated from "human immunodeficiency virus (HIV) infection patients with low CD4 counts" to "a patient with HIV infection and low CD4 counts." In addition, dosing was clarified to be up to 13.2 mg (previously was 13.2 mg). **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.	10/29/2025