PRIOR AUTHORIZATION POLICY

POLICY: Colony Stimulating Factors – Rolvedon Prior Authorization Policy
- Rolvedon™ (eflapegrastim-xnst subcutaneous injection − Spectrum)

REVIEW DATE: 09/20/2023; selected revision 12/20/2023

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 2.2024 – December 12, 2023), 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.[2] 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). Evaluation prior to second and subsequent chemotherapy cycles should also be completed and patients who experienced febrile neutropenia or a dose-limiting neutropenic event without prior use of G-CSFs in which a reduction in dose or frequency is not appropriate, the use of G-CSFs should be considered (category 2A). Recommended G-CSFs include filgrastim (category 1), Granix® (tbo-filgrastim subcutaneous injection) [category 1], pegfilgrastim (category 1), Rolvedon (category 2A), and Ryzneuta® (efbemalenograstim alfa-vuxw subcutaneous injection) [category 2A]. It is noted that the long-acting CSFs, pegfilgrastim, Rolvedon, and Ryzneuta® (efbemalenograstim alfa-vuxw subcutaneous injection), have only been studied for prophylactic use, not for treatment of febrile neutropenia. For treatment of a patient with radiation-induced myelosuppression following a radiologic/nuclear incident, therapeutic use of filgrastim, pegfilgrastim, Granix® (tbo-filgrastim subcutaneous injection), Leukine® (sargramostim subcutaneous injection), Rolvedon, or Ryzneuta® (efbemalenograstim alfa-vuxw subcutaneous injection) may be used (category 2A). Of note, throughout the recommendations, it is acknowledged that an FDA-approved biosimilar is an appropriate substitute for filgrastim or pegfilgrastim.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Rolvedon. 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 the following criteria:

FDA-Approved Indication

1. **Cancer in a Patient Receiving Myelosuppressive Chemotherapy**. Approve for 6 months if the patient meets 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; prior chemotherapy or radiation therapy; persistent neutropenia; bone marrow involvement by tumor; recent surgery and/or open wounds; liver and/or renal dysfunction; poor performance status; or human immunodeficiency virus (HIV) infection.
     - **iii.** Patient meets both of the following (a and b):
       - **a)** Patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor; AND
         Note: Examples of colony stimulating factors include filgrastim products, pegfilgrastim products, and Ryzneuta.
       - **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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Rolvedon is not recommended in the following situations:

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]

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 2.2024 – December 12, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 12, 2023.