PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 10/09/2024

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.

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 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 year 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; human immunodeficiency virus (HIV) infection patients with 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.

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 3.2024 – January 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 2, 2024.