VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 09/20/2023

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 2.2023 – March 6, 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. 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). Recommended G-CSFs include filgrastim (category 1), Granix® (tbo-filgrastim subcutaneous injection) [category 1], pegfilgrastim (category 1), or Rolvedon (category 2A).

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 the following:

FDA-Approved Indication

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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, iii, or iv):
     - **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 sargramostim products (e.g., Leukine).
       - **b)** A reduced dose or frequency of chemotherapy may compromise treatment outcome; OR
     - **iv.** 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; AND
       Note: Examples of risk factors include sepsis syndrome; age > 65 years; severe neutropenia (absolute neutrophil count [ANC] < 100 cells/mm^3); neutropenia expected to be > 10 days in duration; invasive fungal infection; or other clinically documented infections.
   - **C)** The medication is prescribed by or in consultation with an oncologist or hematologist.

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

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 2.2023 – March 6, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 7, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	10/12/2022
Update	**12/06/2022:** No criteria changes. The Overview section was updated to reflect National Comprehensive Cancer Network guidelines with the placement of Rolvedon.	--
Early Annual Revision	No criteria changes.	09/06/2023