Reference number(s)
5630-A

STANDARD MEDICARE PART B MANAGEMENT

ROLVEDON (eflapegrastim-xnst)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Rolvedon is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.

B. Compendial Uses
1. Stem cell transplantation-related indications
2. Prophylaxis for chemotherapy-induced febrile neutropenia in patients with solid tumors
3. Hematopoietic acute radiation syndrome
4. Hairy cell leukemia, neutropenic fever

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
Primary Prophylaxis of Febrile Neutropenia
Documentation of the member's diagnosis and chemotherapeutic regimen.

III. CRITERIA FOR INITIAL APPROVAL

A. Prevention of neutropenia in cancer patients receiving myelosuppressive chemotherapy
Authorization of 6 months may be granted for prevention of febrile neutropenia for members with solid tumors or non-myeloid malignancies when the requested medication will not be administered with weekly chemotherapy regimens and the member will not be receiving chemotherapy and radiation therapy at the same time.

B. **Other indications**
Authorization of 6 months may be granted for members with any of the following indications:
1. Stem cell transplantation-related indications

2. Hematopoietic subsyndrome of acute radiation syndrome
3. Hairy cell leukemia with neutropenic fever following chemotherapy

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Rolvedon.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Hairy cell leukemia
4. NCCN Guideline: Hematopoietic growth factors
5. NCCN Guideline: Hematopoietic cell transplantation

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Rolvedon are covered in addition to the following:

1. Stem cell transplantation-related indications
2. Prophylaxis for chemotherapy-induced febrile neutropenia in patients with solid tumors
3. Hematopoietic acute radiation syndrome
4. Hairy cell leukemia, neutropenic fever

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Rolvedon for stem cell transplantation-related indications can be found in the National Comprehensive Cancer Network's guideline for hematopoietic cell transplantation. The NCCN Guideline for hematopoietic cell transplantation supports the use of G-CSF as treatment for hematopoietic cell mobilization for autologous donors in combination with plerixafor.

Support for using Rolvedon as prophylaxis for chemotherapy-induced febrile neutropenia in patients with solid tumors can be found in the National Comprehensive Cancer Network's guideline for hematopoietic growth factors. The NCCN Guideline supports the use of Rolvedon for prophylaxis of chemotherapy-induced febrile neutropenia or other dose limiting neutropenic events in high-risk, intermediate-risk and low-risk patients with solid tumors.

Support for using Rolvedon to treat hematopoietic acute radiation syndrome can be found in the National Comprehensive Cancer Network's guideline for hematopoietic growth factors. The NCCN Guideline for

hematopoietic growth factors supports the use of G-CSF in patients with radiation-induced myelosuppression following a radiologic/nuclear incident.

Support for using Rolvedon in hairy cell leukemia for neutropenic fever in a patient being treated for hairy cell leukemia can be found in the National Comprehensive Cancer Network's guideline for hairy cell leukemia. The NCCN Guideline for hairy cell leukemia supports using neutrophil growth factors for patients with neutropenic fever following systemic therapy.

VII. REFERENCES

1. Rolvedon [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; September 2022.
2. Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the use of white blood cell growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol*. 2015;33(28):3199-3212.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation. Version 2.2022. https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf Accessed September 22, 2022.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors. Version 1.2022. https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf Accessed September 22, 2022.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia. Version 1.2023. https://www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf Accessed September 22, 2022.