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Section:	Prescription Drugs	Effective Date:	July 1, 2026
Subsection:	Hematological Agents	Original Policy Date:	January 13, 2023
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Last Review Date: June 11, 2026

Rolvedon

Description

Rolvedon (eflapeg rastim-xnst)

Background

Rolvedon (eflapeg rastim-xnst) is a recombinant human granulocyte growth factor that binds to granulocyte colony-stimulating factor (G-CSF) receptors on myeloid progenitor cells and neutrophils, triggering signaling pathways that control cell differentiation, proliferation, migration, and survival (1).

Regulatory Status

FDA-approved indication: Rolvedon is a leukocyte growth factor 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 (1).

Limitations of Use: Rolvedon is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation (1).

Rolvedon contains warnings for the following: splenic rupture, acute respiratory distress syndrome, serious allergic reactions, sickle cell crisis in patients with sickle cell disorders, glomerulonephritis, leukocytosis, thrombocytopenia, capillary leak syndrome, potential for tumor growth stimulatory effects on malignant cells, myelodysplastic syndrome (MDS) and acute

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myeloid leukemia (AML) in patients with breast and lung cancer, aortitis, and nuclear imaging (1).

The safety and effectiveness of Rolvedon in pediatric patients less than 18 years of age have not been established (1).

Related policies

Leukine, Neulasta, Neupogen

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Rolvedon may be considered **medically necessary** if the conditions indicated below are met.

Rolvedon may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Prophylaxis for chemotherapy induced febrile neutropenia
2. Treatment of chemotherapy induced febrile neutropenia

AND the following for **ALL** diagnoses:

- a. **NOT** used in combination with another granulocyte colony-stimulating factor (G-CSF)

Prior – Approval Renewal Requirements

Same as above

Policy Guidelines**Pre - PA Allowance**

None

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Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Rolvedon is a recombinant human granulocyte growth factor that binds to granulocyte colony-stimulating factor (G-CSF) receptors and 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. The safety and effectiveness of Rolvedon in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Rolvedon while maintaining optimal therapeutic outcomes.

References

- 1. Rolvedon [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; November 2023.
- 2. NCCN Clinical Practice Guidelines in Oncology® Hematopoietic Growth Factors 2026. National Comprehensive Cancer Network, Inc. Accessed on May 1, 2026.

Policy History

Date	Reason
October 2022	Addition to PA
March 2023	Annual review and reference update
June 2023	Annual review and reference update
June 2024	Annual review and reference update
March 2025	Annual review and reference update
June 2025	Annual review and reference update
June 2026	Annual review and reference update

Keywords

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