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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	January 13, 2023
Subject:	Rolvedon	**Page:**	1 of 4

Last Review Date: March 7, 2025

Rolvedon

Description

Rolvedon (eflapegrastim-xnst)

Background
Rolvedon (eflapegrastim-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

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

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 2025. National Comprehensive Cancer Network, Inc. Accessed on January 13, 2025.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.