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Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	December 8, 2023
Subject:	Ryzneuta	**Page:**	1 of 3

Last Review Date: September 19, 2025

Ryzneuta

Description

Ryzneuta (efbemalenograstim alfa-vuxw)

Background
Ryzneuta (efbemalenograstim alfa-vuxw) is a colony-stimulating factor that acts on hematopoietic cells by binding to specific surface receptors, thereby signaling proliferation, differentiation, commitment, and end cell functional activation (1).

Regulatory Status
FDA-approved indication: Ryzneuta 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 a clinically significant incidence of febrile neutropenia (1).

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

Ryzneuta contains warnings for the following: splenic rupture, acute respiratory distress syndrome, serious allergic reactions, sickle cell crisis in patients with sickle cell disorders, glomerulonephritis, thrombocytopenia, capillary leak syndrome, myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) in patients with breast and lung cancer (1).

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

Related policies
Leukine, Neulasta, Neupogen, Rolvedon

Policy

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

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

Ryzneuta 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

Ryzneuta is a colony-stimulating factor 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 Ryzneuta 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 Ryzneuta while maintaining optimal therapeutic outcomes.

References

1. Ryzneuta [package insert]. Singapore: Evive Biotechnology Singapore PTE. LTD.; November 2023.
2. NCCN Clinical Practice Guidelines in Oncology® Hematopoietic Growth Factors 2025. National Comprehensive Cancer Network, Inc. Accessed on August 8, 2025.

Policy History

Date	Reason
December 2023	Addition to PA
September 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.