

# BILLING AND CODING GUIDE

## THE NEXT BRANCH IN G-CSF EVOLUTION



## THE FIRST AND ONLY PEG-FREE, LONG-ACTING G-CSF

Approved by the FDA

### **INDICATIONS**

Ryzneuta<sup>®</sup> 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.

### **Limitations of Use**

Ryzneuta<sup>®</sup> is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

### **SELECT IMPORTANT SAFETY INFORMATION**

### **CONTRAINDICATIONS**

Ryzneuta<sup>®</sup> is contraindicated in patients with a history of serious allergic reactions to granulocyte stimulating factors such as efbemalenograstim alfa-vuxw, pegfilgrastim, or filgrastim products.

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## **IMPORTANT SAFETY INFORMATION**

### **CONTRAINDICATIONS**

Ryzneuta® is contraindicated in patients with a history of serious allergic reactions to granulocyte stimulating factors such as efbemalenograstim alfa-vuxw, pegfilgrastim, or filgrastim products.

### **WARNINGS AND PRECAUTIONS**

#### **Splenic Rupture**

Splenic rupture, including fatal cases, can occur following the administration of recombinant human granulocyte colony stimulating factor (rhG-CSF) products. Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.

#### **Acute Respiratory Distress Syndrome (ARDS)**

ARDS can occur in patients receiving rhG-CSF products. Evaluate patients who develop fever and lung infiltrates or respiratory distress. Discontinue Ryzneuta® in patients with ARDS.

#### **Serious Allergic Reactions**

Serious allergic reactions, including anaphylaxis, can occur in patients receiving rhG-CSF products. Permanently discontinue Ryzneuta® in patients with serious allergic reactions. Ryzneuta® is contraindicated in patients with a history of serious allergic reactions to Ryzneuta® or other rhG-CSF products such as pegfilgrastim, eflapegrastim or filgrastim products.

#### **Sickle Cell Crisis in Patients with Sickle Cell Disorders**

Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving rhG-CSF products. Discontinue Ryzneuta® if sickle cell crisis occurs.

#### **Glomerulonephritis**

Glomerulonephritis has occurred in patients receiving rhG-CSF products. The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events of glomerulonephritis resolved after dose-reduction or discontinuation. Evaluate and consider dose-reduction or interruption of Ryzneuta® if causality is likely.

#### **Leukocytosis**

White blood cell (WBC) counts of  $100 \times 10^9/L$  or greater have been observed in patients receiving rhG-CSF products. Monitor complete blood count (CBC) during Ryzneuta® therapy. Discontinue Ryzneuta® treatment if WBC count of  $100 \times 10^9/L$  or greater occurs.

#### **Thrombocytopenia**

Thrombocytopenia has been reported in patients receiving rhG-CSF products. Thrombocytopenia occurred in 11% of Ryzneuta®-treated patients. One patient (0.4%) experienced severe thrombocytopenia. Monitor platelet counts.

### **Capillary Leak Syndrome**

Capillary leak syndrome has been reported after administration of rhG-CSF products and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency and severity, and may be life-threatening if treatment is delayed. If symptoms develop, closely monitor, and give standard symptomatic treatment, which may include a need for intensive care.

### **Potential for Tumor Growth Stimulatory Effects on Malignant Cells**

The granulocyte colony-stimulating factor (G-CSF) receptor through which Ryzneuta® acts has been found on tumor cell lines. The possibility that Ryzneuta® acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which Ryzneuta® is not approved, cannot be excluded.

### **Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer**

MDS and AML have been associated with the use of rhG-CSF products in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer. Monitor patients for signs and symptoms of MDS/AML in these settings.

### **Aortitis**

Aortitis has been reported in patients receiving rhG-CSF products. It may occur as early as the first week after start of therapy. Consider aortitis in patients who develop generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count) without known etiology. Discontinue Ryzneuta® if aortitis is suspected.

### **Nuclear Imaging**

Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone imaging results.

## **ADVERSE REACTIONS**

In study GC-627-04, the most common adverse reactions ( $\geq 10\%$ ) through cycle 1 were nausea (51%), anemia (15%), and thrombocytopenia (12%). Other adverse reactions reported by  $\geq 20\%$  of Ryzneuta®-treated patients with breast cancer receiving myelosuppressive chemotherapy in study GC-627-05 were fatigue and bone pain.

Please see accompanying full Prescribing Information (PI) or visit [ryzneuta.com/PI](http://ryzneuta.com/PI) for full PI.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call **1-800-FDA-1088**.

## Ryzneuta® Billing and Coding Guide

Coverage, coding, and payment for Ryzneuta® (efbemalenograstim alfa-vuxw) varies by payer, plan, setting of care, and patient. The information below provides a general coverage, coding, and payment framework for Ryzneuta® across major payer segments. Healthcare professionals should always verify coverage, coding, and payment guidelines on a patient-specific basis.

### Commonly Used Billing Codes for Ryzneuta® (efbemalenograstim alfa-vuxw)

#### Healthcare Common Procedure Coding System (HCPCS)<sup>2</sup>

**J9361** Injection, efbemalenograstim alfa-vuxw, 0.5 mg

#### HCPCS modifier<sup>3</sup>

<b>JB</b>	Subcutaneous administration
<b>JW</b>	Drug amount discarded/not administered to any patient
<b>JZ</b>	Zero drug amount discarded/not administered to any patient

#### National Drug Code (11-digit format)<sup>1</sup>

Ryzneuta® 20 mg/mL prefilled syringe – 72893-0016-02

#### Current Procedural Terminology Codes for Drug Administration (CPT)<sup>4</sup>

**96372** – Therapeutic, prophylactic, or diagnostic injection (subcutaneous or intramuscular)

#### ICD-10-CM Diagnosis Codes<sup>5</sup>

Note:\* Codes listed below are examples; allowable diagnosis codes may vary by payer.

<b>D61.810</b>	Antineoplastic chemotherapy-induced pancytopenia
<b>D70.1</b>	Agranulocytosis secondary to cancer chemotherapy
<b>T45.1X5A</b>	Adverse effect of antineoplastic and immunosuppressive drugs initial encounter
<b>T45.1X5D</b>	Adverse effect of antineoplastic and immunosuppressive drugs subsequent encounter
<b>T45.1X5S</b>	Adverse effect of antineoplastic and immunosuppressive drugs sequela
<b>Z51.11</b>	Encounter for antineoplastic chemotherapy

\*This is not an exhaustive list of ICD-10-CM codes that may apply to Ryzneuta®. Some payers may require other ICD-10-CM diagnostic codes. Acrotech Biopharma Inc. and its subsidiaries do not guarantee coverage and/or reimbursement. Coverage, coding, and reimbursement policies vary significantly by payer, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following receipt of claims. Healthcare professionals should always verify coverage, coding, and reimbursement guidelines on a payer- and patient-specific basis.

#### SELECT IMPORTANT SAFETY INFORMATION

##### CONTRAINDICATIONS

Ryzneuta® is contraindicated in patients with a history of serious allergic reactions to granulocyte stimulating factors such as efbemalenograstim alfa-vuxw, pegfilgrastim, or filgrastim products.

##### WARNINGS AND PRECAUTIONS

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**Please see full Important Safety Information on pages 2 and 3.**

**Please see accompanying full Prescribing Information (PI) or visit [ryzneuta.com/PI](https://ryzneuta.com/PI) for full PI.**

1. Ryzneuta® [Prescribing Information], Acrotech Biopharma Inc.
2. Centers for Medicare & Medicaid Services (CMS). Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations: First Quarter, 2024 HCPCS Coding Cycle. Accessed June 10, 2025. <https://www.cms.gov/files/document/2024-hcpcs-application-summary-quarter-1-2024-drugs-and-biologicals.pdf>.
3. Centers for Medicare & Medicaid Services (CMS). Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy: Frequently Asked Questions. Accessed June 10, 2025. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf>.
4. American Medical Association. CPT® Code 96372: Injection of Drug/Substance Under Skin or Into Muscle. Accessed June 30, 2025. <https://www.ama-assn.org/practice-management/cpt/cpt-code-96372-injection-drugsubstance-under-skin-or-muscle>.
5. Centers for Medicare & Medicaid Services (CMS). ICD-10. Accessed June 10, 2025. <https://www.cms.gov/medicare/coding-billing/icd-10-codes>.

## Medicare Fee-for-Service\*

Ryzneuta® is eligible for Medicare Part B fee-for-service coverage for the treatment of its FDA-approved indications when administered “incident to” a physician’s service and when reasonable and necessary for the individual patient.<sup>6</sup> Medicare contractors have the discretion to issue Local Coverage Determinations or other written coverage and coding guidance for Ryzneuta®.

In the physician office setting and the hospital outpatient setting, Part B Ryzneuta® claims are submitted to the local A/B Medicare Administrative Contractor (MAC) using HCPCS code J9361. Payment for most covered Part B drugs is currently based on the average sales price (ASP) + 6%. Until Ryzneuta® establishes an ASP, payment is based on WAC + 3%.<sup>2,7</sup>

## Medicaid\*

Medicaid coverage, coding, and payment for Ryzneuta® varies significantly by state program and should be verified for each particular state.

In general, Ryzneuta® is eligible for coverage for the treatment of its FDA-approved indications when administered in the physician setting. Most state Medicaid programs require that physicians submit Ryzneuta® claims using the HCPCS code J9361. Additionally, federal law requires providers to include a National Drug Code on Medicaid claims for physician-administered drugs to help the government capture drug rebates under the Medicaid Drug Rebate Program. Please refer to your state Medicaid program for specific guidance on billing HCPCS codes and NDCs.<sup>8</sup>

### **SELECT IMPORTANT SAFETY INFORMATION**

#### **WARNINGS AND PRECAUTIONS**

##### **Glomerulonephritis**

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6. Centers for Medicare & Medicaid Services (CMS). Medicare Benefit Policy Manual: Chapter 15 – Covered Medical and Other Health Services. Definition of drug or biological, §50.1; Approved Use of Drug, §50.4.1. January 16, 2025. Accessed June 12, 2025. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>.

7. Centers for Medicare & Medicaid Services (CMS). ASP Regulations & Policy: Payment policy for drugs and biologicals under Medicare Part B. Section 303(c) of the Medicare Modernization Act of 2003 (Pub L No. 112-34108-173). Accessed June 10, 2025. <https://www.cms.gov/medicare/payment/part-b-drugs/asp-regulations-policy>.

8. Deficit Reduction Act of 2005 (Pub L No. 109-171), §6002. February 8, 2006. Accessed June 10, 2025. <https://www.govinfo.gov/content/pkg/PLAW-109publ171/pdf/PLAW-109publ171.pdf>.

## Private/Commercial Payers\*

Coverage, coding, and payment guidelines vary significantly by private/commercial payer, plan, setting of care, and patient. Patients and providers should verify patient-specific benefits to determine if Ryzneuta® is covered under each specific commercial insurance plan and/or if prior authorization is required.

Most private payers require that physicians submit Ryzneuta® claims using the HCPCS code J9361. Additionally, some private payers request the addition of an 11-digit NDC on claim forms.

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#### **WARNINGS AND PRECAUTIONS**

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## How to Complete the CMS-1500 Form for Physician Office<sup>9\*</sup>

### Box 21. DIAGNOSIS CODES

Enter the appropriate ICD-10-CM code(s).

### Box 24. A. DATE(S) OF SERVICE

Enter the date of service (i.e., the date when Ryzneuta<sup>®</sup> prefilled syringe for injection was administered).

### Box 24. G. SERVICE UNITS

Enter units of service for Ryzneuta<sup>®</sup> (i.e., 40 service units = 20 mg). Ryzneuta<sup>®</sup> dose is 20 mg/mL in a prefilled syringe.  
Enter 1 unit for the procedure code.

### Box 24. D. J-CODE

Enter the J-code (J9361: Injection, efbemalenograstim alfa-vuxw, 0.5 mg).

### Box 24. D. PROCEDURE CODE

Enter the CPT code (96372: Therapeutic, prophylactic, or diagnostic injection [subcutaneous or intramuscular]) with the appropriate modifier (JB, subcutaneous injection; JW, drug amount discarded/not administered to any patient; JZ, zero drug amount discarded/not administered to any patient).

## How to Complete the CMS-1450 Form for Outpatient Hospital<sup>10\*</sup>

### Boxes 42 and 43. REVENUE CODE and DESCRIPTION

Enter revenue code (0636: Drugs requiring detailed coding) and description (Ryzneuta<sup>®</sup> injection).  
Enter revenue code and description for cost center where services were performed (e.g., 0510, clinic).

### Box 44. PRODUCT CODE

Enter J-code (J9361: Injection, efbemalenograstim alfa-vuxw, 0.5 mg).

### Box 44. PROCEDURE CODE

Enter the CPT code (96372: Therapeutic, prophylactic, or diagnostic injection [subcutaneous or intramuscular]) with the appropriate modifier (JB, subcutaneous injection; JW, drug amount discarded/not administered to any patient; JZ, zero drug amount discarded/not administered to any patient).

### Box 46. SERVICE UNITS

Enter units of service for Ryzneuta<sup>®</sup> (i.e., 40 service units = 20 mg). Ryzneuta<sup>®</sup> dose is 20 mg/mL in a prefilled syringe.  
Enter 1 unit for the procedure code.

### Box 67. DIAGNOSIS CODES

Enter the appropriate ICD-10-CM code(s).

9. Centers for Medicare & Medicaid Services (CMS). CMS Forms List. CMS-1500 Health Insurance Claim Form. January 2, 2012. Accessed September 15, 2025. <https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms1500.pdf>.  
10. Centers for Medicare & Medicaid Services (CMS). PRA Listing. CMS-1450 Medicare Uniform Institutional Provider Bill. June 6, 2023. Accessed September 15, 2025. <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1450>.

\*This sample form is provided as a reference to assist with coding and billing for Ryzneuta<sup>®</sup> and associated services. Healthcare providers should choose coding options that most accurately align with their internal protocols, payer policies, practice procedures, and specific services delivered. It is the provider's responsibility to verify the accuracy and validity of all billing and claims to ensure proper reimbursement.



**Acrotech Access Support™**

**ACROTECH ACCESS SUPPORT™**  
is designed to help patients and healthcare professionals gain appropriate access to Ryzneuta®

**Visit the Reimbursement & Patient Assistance Website**



1-888-537-8277



**FAX**  
1-866-930-1562



AcrotechPatientAccess.com

The Acrotech Access Support™ program includes a patient assistance program (PAP) that provides Ryzneuta® free of charge to enrolled patients who meet the income, insurance, and citizenship/residency eligibility criteria.

- If approved, the Acrotech Access Support™ distributor will ship the patient-labeled product to the prescribing physician for future outpatient therapy.
- The Acrotech Access Support™ PAP does not replace the product administered prior to the patient's PAP approval date.

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Distributor	Phone	Website
McKesson Specialty Practice Solutions	(800) 482-6700	<a href="https://www.mckesson.com/specialty/">https://www.mckesson.com/specialty/</a>
McKesson Plasma and Biologics	(877) 625-2566	<a href="https://www.mckesson.com/business-solutions/our-businesses/mckesson-plasma-biologics/">https://www.mckesson.com/business-solutions/our-businesses/mckesson-plasma-biologics/</a>
Cardinal Health Specialty Pharmacy	(866) 677-4844	<a href="https://www.cardinalhealth.com/en/cmp/ext/phr/pd/specialty-pharmacy.html">https://www.cardinalhealth.com/en/cmp/ext/phr/pd/specialty-pharmacy.html</a>
Cencora Oncology Supply	(800) 633-7555	<a href="https://www.oncologysupply.com/">https://www.oncologysupply.com/</a>
Cencora ASD Healthcare	(800) 746-6273	<a href="https://www.asdhealthcare.com/">https://www.asdhealthcare.com/</a>
Morris & Dickson	(800) 388-3833	<a href="https://www.morrisdickson.com/">https://www.morrisdickson.com/</a>

This is not an inclusive list. Availability is subject to change. Please check with Acrotech Biopharma Inc. to obtain a full list of distributors.



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This guide may contain references or links to other websites maintained by third parties not under Acrotech's control. Such references or links are provided merely for convenience, and Acrotech Biopharma Inc. makes no representations or warranties of any kind with respect to any third-party site. The inclusion of the reference or link does not imply endorsement of the site, and Acrotech Biopharma Inc. is not liable for any damages or injuries of any kind arising from such content or information or your use thereof.