RYBREVANT®
(amivantamab-vmjw)
Injection for IV Use | 350 mg/7 mL (50 mg/mL)

Coding Reference

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all CPT® and HCPCS codes are supplied for informational purposes only and represent no statement, promise or guarantee by Janssen Biotech, Inc., that these codes will be appropriate or that reimbursement will be made. It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. We strongly recommend you consult the payer organization for its reimbursement policies.

National Drug Code (NDC)

Although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. It is important to confirm with your payer if an NDC is needed and the format the payer requires. To convert the 10-digit format to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below:

FDA Specified 10-Digit NDC (5-3-2 format)	11-Digit NDC (5-4-2 format)	Description
57894-501-01	57894-0501-01	350 mg/7 mL solution for intravenous infusion, in a single-use vial

Here are examples for the weight-based doses of RYBREVANT®:

RYBREVANT® NDC Units				
Dose to be Billed	**11-Digit NDC (5-4-2 format)**	**Packaging**	**NDC Units of Measure**	**NDC Quantity**
1050 mg	57894-0501-01	350 mg/7 mL vial (liquid)	ML	21
1400 mg	57894-0501-01	350 mg/7 mL vial (liquid)	ML	28

Current Procedural Terminology (CPT®)

Healthcare providers are responsible for selecting appropriate codes for any particular claim based on the patient's condition, the items and services that are furnished, and any specific payer requirements. The CPT® codes most commonly associated with RYBREVANT® therapy are:

Drug Administration

CPT® Code	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour single or initial substance or drug
96415	Each additional hour (list separately in addition to code for the primary service)

Companion Diagnostic Tests

Select patients for treatment with RYBREVANT® based on the presence of *EGFR* exon 20 insertion mutations. Information on FDA-approved tests is available at: http://www.fda.gov/CompanionDiagnostics. Janssen is not the manufacturer of FDA-approved CDx tests for RYBREVANT®.

CPT® Code	Proprietary Name	Clinical Lab and/or Manufacturer
81445	N/A	N/A
81455	N/A	N/A
0242U	Guardant 360® CDx	Guardant Health Inc.
0022U	Oncomine™ Dx Target Test	Thermo Fisher Scientific/Life Technologies Corp.

Healthcare Common Procedure Coding System (HCPCS)

Healthcare provider administered drugs are typically reported with product specific HCPCS codes. Effective January 1, 2022, the HCPCS code for RYBREVANT® is:

J9061 - Injection, amivantamab-vmjw, 2 mg.

This code applies in all sites of care and replaces all miscellaneous or temporary codes previously in use.

Each 350 mg vial of RYBREVANT® represents 175 units of J9061. When coding for J9061, report the total number of 2-mg increments administered. The following table illustrates the correlation between RYBREVANT® vials, milligrams, and HCPCS units used for billing:

Number of 350-mg vials of RYBREVANT®	Total milligrams (mg)	Number of billing units based on J9061 (2-mg RYBREVANT® per unit)
1	350 mg	175
3	1050 mg	525
4	1400 mg	700

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage for any specific service by the Medicare and/or Medicaid program. HCPCS codes are used to describe a product, procedure, or service on an insurance claim. Payers such as Medicare Administrative Contractors (MACs) and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and what payment rules are to be applied to such claims.

ICD-10-CM Diagnosis Codes

Payer requirements for ICD-10-CM codes will vary. It is essential to verify the correct diagnosis coding with each payer. The codes below are provided for consideration and are not intended to be promotional or to encourage or suggest a use of drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive; additional codes may apply.

Code	Description
C34.10	Malignant neoplasm of upper lobe, unspecific bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecific bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung

Code	Description
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping, sites of unspecific bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus or lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus or lung
C34.90	Malignant neoplasm of unspecified part of unspecific bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

References:

1. American Medical Association. Current Procedural Terminology: CPT® 2021: Professional Edition. AMA Press; 2020.
2. Centers for Medicare and Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions Third Quarter 2021 Coding Cycle for Drug and Biological Products. Accessed November 12, 2021. https://www.cms.gov/files/document/2021-hcpcs-application-summary-quarter-3-2021-drugs-and-biologics-updated-10012021.pdf
3. Centers for Medicare and Medicaid Services. January 2022 Alpha-numeric HCPCS file. Accessed November 12, 2021. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update
4. Centers for Medicare and Medicaid Services. ICD-10-CM Codes File FY 2022. Accessed November 23, 2021. https://www.cms.gov/medicare/icd-10/2022-icd-10-cm

HCP Indication & Important Safety Information

INDICATION

RYBREVANT® (amivantamab-vmjw) is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

RYBREVANT® can cause infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting.

Based on the safety population, IRR occurred in 66% of patients treated with RYBREVANT®. Among patients receiving treatment on Week 1 Day 1, 65% experienced an IRR, while the incidence of IRR was 3.4% with the Day 2 infusion, 0.4% with the Week 2 infusion, and cumulatively 1.1% with subsequent infusions. Of the reported IRRs, 97% were Grade 1-2, 2.2% were Grade 3, and 0.4% were Grade 4. The median time to onset was 1 hour (range 0.1 to 18 hours) after start of infusion. The incidence of infusion modifications due to IRR was 62% and 1.3% of patients permanently discontinued RYBREVANT® due to IRR.

Premedicate with antihistamines, antipyretics, and glucocorticoids and infuse RYBREVANT® as recommended. Administer RYBREVANT® via a peripheral line on Week 1 and Week 2. Monitor patients for any signs and symptoms of infusion reactions during RYBREVANT® infusion in a setting where cardiopulmonary resuscitation medication and equipment are available. Interrupt infusion if IRR is suspected. Reduce the infusion rate or permanently discontinue RYBREVANT® based on severity.

Interstitial Lung Disease/Pneumonitis

RYBREVANT® can cause interstitial lung disease (ILD)/pneumonitis. Based on the safety population, ILD/pneumonitis occurred in 3.3% of patients treated with RYBREVANT®, with 0.7% of patients experiencing Grade 3 ILD/pneumonitis. Three patients (1%) discontinued RYBREVANT® due to ILD/pneumonitis.

Monitor patients for new or worsening symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold RYBREVANT® in patients with suspected ILD/pneumonitis and permanently discontinue if ILD/pneumonitis is confirmed.

Dermatologic Adverse Reactions

RYBREVANT® can cause rash (including dermatitis acneiform), pruritus and dry skin. Based on the safety population, rash occurred in 74% of patients treated with RYBREVANT®, including Grade 3 rash in 3.3% of patients. The median time to onset of rash was 14 days (range: 1 to 276 days). Rash leading to dose reduction occurred in 5% of patients, and RYBREVANT® was permanently discontinued due to rash in 0.7% of patients.

Toxic epidermal necrolysis occurred in one patient (0.3%) treated with RYBREVANT®.

Instruct patients to limit sun exposure during and for 2 months after treatment with RYBREVANT®. Advise patients to wear protective clothing and use broad-spectrum UVA/UVB sunscreen. Alcohol-free emollient cream is recommended for dry skin.

If skin reactions develop, start topical corticosteroids and topical and/or oral antibiotics. For Grade 3 reactions, add oral steroids and consider dermatologic consultation. Promptly refer patients presenting with severe rash, atypical appearance or distribution, or lack of improvement within 2 weeks to a dermatologist. Withhold, dose reduce or permanently discontinue RYBREVANT® based on severity.

Ocular Toxicity

RYBREVANT® can cause ocular toxicity including keratitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, and uveitis. Based on the safety population, keratitis occurred in 0.7% and uveitis occurred in 0.3% of patients treated with RYBREVANT®. All events were Grade 1-2. Promptly refer patients presenting with eye symptoms to an ophthalmologist. Withhold, dose reduce or permanently discontinue RYBREVANT® based on severity.

Embryo-Fetal Toxicity

Based on its mechanism of action and findings from animal models, RYBREVANT® can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment and for 3 months after the final dose of RYBREVANT®.

Adverse Reactions

The most common adverse reactions (≥20%) were rash (84%), IRR (64%), paronychia (50%), musculoskeletal pain (47%), dyspnea (37%), nausea (36%), fatigue (33%), edema (27%), stomatitis (26%), cough (25%), constipation (23%), and vomiting (22%). The most common Grade 3 to 4 laboratory abnormalities (≥2%) were decreased lymphocytes (8%), decreased albumin (8%), decreased phosphate (8%), decreased potassium (6%), increased alkaline phosphatase (4.8%), increased glucose (4%), increased gamma-glutamyl transferase (4%), and decreased sodium (4%).

Please read full Prescribing Information for RYBREVANT®

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Janssen Oncology

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