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 Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (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.

RYBREVANT® is indicated[1]:

- **in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (*EGFR*) exon 20 insertion (ex20ins) mutations as detected by an FDA-approved test**
- **as a single agent for the treatment of adult patients with locally advanced or metastatic NSCLC with *EGFR* ex20ins mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy**

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[1] (5-3-2 Format)	11-Digit NDC (5-4-2 Format)	Description[1]
57894-501-01	57894-0501-01	350 mg/7 mL solution for intravenous infusion, in a single-use vial

Payers may require billing with NDCs. The NDC unit of measure for drugs supplied in vials in liquid form is "ML." The NDC quantity reported is based on the NDC quantity dispensed. Here are examples of weight-based doses of RYBREVANT®:

Dose to Be Billed	11-Digit NDC (5-4-2 Format)	Packaging	NDC Units of Measure	NDC Units
1,050 mg	57894-0501-01	350 mg/7 mL vial (liquid)	ML	21
1,400 mg	57894-0501-01	350 mg/7 mL vial (liquid)	ML	28
1,750 mg	57894-0501-01	350 mg/7 mL vial (liquid)	ML	35
2,100 mg	57894-0501-01	350 mg/7 mL vial (liquid)	ML	42

FDA, U.S. Food and Drug Administration.
CPT® is a registered trademark of the American Medical Association, 2023.

SELECTED IMPORTANT SAFETY INFORMATION

Warnings and Precautions for RYBREVANT® include Infusion-Related Reactions, Interstitial Lung Disease/Pneumonitis, Dermatologic Adverse Reactions, Ocular Toxicity, and Embryo-Fetal Toxicity.

Please see full Important Safety Information on pages 5-7 and full Prescribing Information for RYBREVANT®.

Current Procedural Terminology (CPT®)

Healthcare providers are responsible for selecting appropriate codes for each individual claim based on the patient's condition, the items and services that are furnished, and any specific payer requirements. Payer requirements for drug administration codes may vary. It is recommended to verify the correct administration codes with the payer. The codes below are provided for your consideration.*

Drug Administration

CPT® Code[2]	Description[2]
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Each additional hour (list separately in addition to code for primary procedure); use in conjunction with 96413; report for infusion intervals of greater than 30 minutes beyond 1-hour increments
96417	Each additional sequential infusion (different substance/drug), up to 1 hour (list separately in addition to code for primary procedure; use 96417 in conjunction with 96413; report only once per sequential infusion. Report 96415 for additional hour(s) of sequential infusion)
96409	Intravenous, push technique, single or initial substance/drug
96411	Intravenous, push technique, each additional substance/drug (list separately in addition to code for primary procedure); use 96411 in conjunction with 96409, 96413

Companion Diagnostic (CDx) for Treatment With RYBREVANT®

Select patients for treatment with RYBREVANT® based on the presence of *EGFR* ex20ins mutations in tumor or plasma specimens. If no mutation is detected in a plasma specimen, test tumor tissue.[1] Information on FDA-approved tests is available at: http://www.fda.gov/CompanionDiagnostics.†

CPT® Code[2]	Description[2]	Proprietary Name[3]	Clinical Lab and/or Manufacturer[3]
0022U	Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence or absence of variants and associated therapy(ies) to consider	Oncomine™ Dx Target Test	Thermo Fisher Scientific/Life Technologies Corp.
0242U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements	Guardant 360® CDx	Guardant Health Inc.

*These codes are not intended to be promotional or to encourage or suggest a use of a drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive and additional codes may apply. Please consult your CPT® codebook for more information.

†Janssen is not the manufacturer of companion diagnostic tests approved for RYBREVANT®.

DNA, deoxyribonucleic acid ; RNA, ribonucleic acid.

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Healthcare Common Procedure Coding System (HCPCS)

Drugs are typically reported with HCPCS codes assigned by the Centers for Medicare & Medicaid Services (CMS). The HCPCS code for RYBREVANT® is:

J9061 - Injection, amivantamab-vmjw, 2 mg[4]

Inaccurate reporting of drug HCPCS units is a common claims error and can result in denied or delayed payment.

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 HCPCS Units Based on J9061 (2 mg RYBREVANT® per Unit)
1	350 mg	175
3	1,050 mg	525
4	1,400 mg	700
5	1,750 mg	875
6	2,100 mg	1050

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

International Classification of Diseases, Tenth Revision, Clinical Modification (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 your consideration.*

Code[5]	Description[5]
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, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified 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

For RYBREVANT® as a single agent for *EGFR* ex20ins mutations post platinum-based chemotherapy, also consider:

Code[5]	Description[5]
Z92.21	Personal history of antineoplastic chemotherapy

*These codes are not intended to be promotional or to encourage or suggest a use of a drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive and additional codes may apply. Please consult your ICD-10-CM codebook for more information.

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INDICATIONS

RYBREVANT® (amivantamab-vmjw) is indicated in combination with carboplatin and pemetrexed for the first-line 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.

RYBREVANT® (amivantamab-vmjw) is indicated as a single agent for the treatment of adult patients with locally advanced or metastatic NSCLC with *EGFR* exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

The safety population of RYBREVANT® with carboplatin and pemetrexed described in Warnings and Precautions was based on 151 patients in the PAPILLON study.

The safety population of RYBREVANT® as a single agent described in Warnings and Precautions was based on 129 patients in the CHRYSALIS study.

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.

RYBREVANT® with Carboplatin and Pemetrexed

RYBREVANT® in combination with carboplatin and pemetrexed can cause infusion-related reactions. Based on the safety population, infusion-related reactions occurred in 42% of patients treated with RYBREVANT® in combination with carboplatin and pemetrexed, including Grade 3 (1.3%) adverse reactions. The incidence of infusion modifications due to IRR was 40%, and 0.7% of patients permanently discontinued RYBREVANT®.

RYBREVANT® as a Single Agent

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.

RYBREVANT® with Carboplatin and Pemetrexed

Based on the safety population, Grade 3 ILD/pneumonitis occurred in 2.6% of patients treated with RYBREVANT® in combination with carboplatin and pemetrexed. All patients required permanent discontinuation.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

RYBREVANT® as a Single Agent

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.

RYBREVANT® with Carboplatin and Pemetrexed

RYBREVANT® in combination with carboplatin and pemetrexed can cause dermatologic adverse reactions. Based on the safety population, rash occurred in 89% of patients treated with RYBREVANT® in combination with carboplatin and pemetrexed, including Grade 3 (19%) adverse reactions. Rash leading to dose reductions occurred in 19% of patients; 2% permanently discontinued RYBREVANT®, and 1.3% discontinued pemetrexed.

RYBREVANT® as a Single Agent

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® as a single agent.

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.

RYBREVANT® with Carboplatin and Pemetrexed

Based on the safety population, RYBREVANT® in combination with carboplatin and pemetrexed can cause ocular toxicity including blepharitis, dry eye, conjunctival redness, blurred vision, and eye pruritus. All events were Grade 1-2.

RYBREVANT® as a Single Agent

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.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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 last dose of RYBREVANT®.

Adverse Reactions

RYBREVANT® with Carboplatin and Pemetrexed

For the 151 patients in the PAPILLON clinical trial who received RYBREVANT® in combination with carboplatin and pemetrexed, the most common adverse reactions (≥20%) were rash (90%), nail toxicity (62%), stomatitis (43%), infusion-related reaction (42%), fatigue (42%), edema (40%), constipation (40%), decreased appetite (36%), nausea (36%), COVID-19 (24%), diarrhea (21%), and vomiting (21%). The most common Grade 3 to 4 laboratory abnormalities (≥2%) were decreased albumin (7%), increased alanine aminotransferase (4%), increased gamma-glutamyl transferase (4%), decreased sodium (7%), decreased potassium (11%), decreased magnesium (2%), and decreases in white blood cells (17%), hemoglobin (11%), neutrophils (36%), platelets (10%), and lymphocytes (11%).

Serious adverse reactions occurred in 37% of patients who received RYBREVANT® in combination with carboplatin and pemetrexed. Serious adverse reactions in ≥2% of patients included rash, pneumonia, ILD, pulmonary embolism, vomiting, and COVID-19. Fatal adverse reactions occurred in 7 patients (4.6%) due to pneumonia, cerebrovascular accident, cardio-respiratory arrest, COVID-19, sepsis, and death not otherwise specified.

RYBREVANT® as a Single Agent

For the 129 patients in the CHRYSALIS clinical trial who received RYBREVANT® as a single agent, 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%).

Serious adverse reactions occurred in 30% of patients who received RYBREVANT®. Serious adverse reactions in ≥2% of patients included pulmonary embolism, pneumonitis/ILD, dyspnea, musculoskeletal pain, pneumonia, and muscular weakness. Fatal adverse reactions occurred in 2 patients (1.5%) due to pneumonia and 1 patient (0.8%) due to sudden death.

Please read full Prescribing Information for RYBREVANT®.

cp-213274v4

References: 1. RYBREVANT® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Current Procedural Terminology: CPT® 2024: Professional Edition. American Medical Association. AMA Press; 2023. **3.** List of cleared or approved companion diagnostic devices (in vitro and imaging tools). Food and Drug Administration. December 21, 2023. Accessed February 28, 2024. https://www.fda.gov/media/119249/download?attachment **4.** January 2024 Alpha-numeric HCPCS file. Updated December 7, 2023. Accessed February 29, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **5.** 2024 ICD-10-CM Tabular List of Diseases and Injuries. Centers for Medicare & Medicaid Services. Accessed February 28, 2024. https://www.cms.gov/medicare/icd-10/2024-icd-10-cm

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