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

+

LAZCLUZE™ (lazertinib)
Tablets | 240 mg/80 mg

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 Johnson & Johnson 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® Indication[1]

RYBREVANT® in combination with lazertinib is indicated 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 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.

Biomarker Testing

Select patients for treatment with RYBREVANT® based on the presence of a mutation as detected by an FDA-approved test. Testing may be performed using tumor or plasma specimens at any time from initial diagnosis; testing does not need to be repeated once *EGFR* mutation status has been established.[1]

The following codes are provided for your consideration:

Companion Diagnostics (CDx) for Treatment With RYBREVANT® + LAZCLUZE™

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.	Guardant360® CDx	Guardant Health Inc.

NOTE: Johnson & Johnson is not the manufacturer of companion diagnostic tests approved for RYBREVANT® + LAZCLUZE™.

Additional information on FDA-approved tests is available at: **http://www.fda.gov/CompanionDiagnostics**

DNA, deoxyribonucleic acid; Dx, diagnostic test; FDA, U.S. Food and Drug Administration; RNA, ribonucleic acid.
CPT® is a registered trademark of the American Medical Association, 2023.

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions for RYBREVANT® include Infusion-Related Reactions, Interstitial Lung Disease/Pneumonitis, Venous Thromboembolic Events with Concomitant Use of RYBREVANT® and LAZCLUZE™, Dermatologic Adverse Reactions, Ocular Toxicity, and Embryo-Fetal Toxicity.

Warnings and Precautions for LAZCLUZE™ include Venous Thromboembolic Events, Interstitial Lung Disease/Pneumonitis, Dermatologic Adverse Reactions, Ocular Toxicity, and Embryo-Fetal Toxicity.

Please see Important Safety Information on pages 6-8 and read full Prescribing Information for RYBREVANT® and full Prescribing Information for LAZCLUZE™.

RYBREVANT® Coding and Administration

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes[4]

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	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, 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

*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.

HCPCS Codes

Drugs are typically reported with HCPCS codes assigned by CMS. The HCPCS code for RYBREVANT® is[5]:

J9061 - Injection, amivantamab-vmjw, 2 mg

Inaccurate reporting of drug HCPCS units is a common claims error and may result in denied or delayed payment. Each 350 mg vial of RYBREVANT® represents 175 units of J9061. When coding with 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

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.

CPT® Codes

Drug administration services are reported on claim forms in both the physician office (CMS-1500) and hospital outpatient (CMS-1450) sites of care using the CPT® coding system. 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 following codes are provided for your consideration:

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

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.

CMS, Centers for Medicare & Medicaid Services.

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 RYBREVANT® NDC 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-dose vial

Billing With NDCs

Coding with the NDC on professional or institutional claims requires similar information and formats. 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. If the NDC unit of measure is ML, then the NDC quantity reported will equal the number of mL (milliliters) given to the patient. Here are examples for the 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

The drug is supplied as 350 mg/7 mL vial. Each vial equates to 7 NDC units. The 1,050 mg dose requires 3 vials (7 mL x 3 = 21 NDC units). The 1,400 mg dose requires 4 vials (7 mL x 4 = 28 NDC units). Accurate NDC coding typically requires reporting the following components in this order[6]:

- N4 qualifier
- 11-digit NDC
- 1 space
- 2-character NDC unit of measure (ML)
- Quantity dispensed

Using the RYBREVANT® examples illustrated above, here is how NDC coding would appear on professional claims:

- 1,050 mg dose - N457894050101 ML21
- 1,400 mg dose - N457894050101 ML28

Additional Information for Submitting Professional Claims for RYBREVANT®

For detailed guidance on completing Form CMS-1500 items, please see the Medicare Claims Processing Manual, Publication 100-04, Chapter 26, available at:
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf

Facility Claims: For detailed guidance on completing Form CMS-1450 items, please see the Medicare Claims Processing Manual, Publication 100-04, Chapter 25, available at:
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c25.pdf

For more information on submitting electronic claims, please see the CMS website at:
https://www.cms.gov/medicare/coding-billing/electronic-billing/electronic-healthcare-claims

LAZCLUZE™ Indication[7]

LAZCLUZE™ in combination with amivantamab is indicated 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 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.

LAZCLUZE™ Dosage Forms and Strengths[7]

LAZCLUZE™ (lazertinib) is available in 240 mg tablets and a lower-strength tablet if needed for dose reduction:

Strength	Package	NDC
240 mg	Bottle of 30 tablets	57894-240-30
80 mg	Bottle of 60 tablets	57894-080-60

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions for RYBREVANT® include Infusion-Related Reactions, Interstitial Lung Disease/Pneumonitis, Venous Thromboembolic Events with Concomitant Use of RYBREVANT® and LAZCLUZE™, Dermatologic Adverse Reactions, Ocular Toxicity, and Embryo-Fetal Toxicity.

Warnings and Precautions for LAZCLUZE™ include Venous Thromboembolic Events, Interstitial Lung Disease/Pneumonitis, Dermatologic Adverse Reactions, Ocular Toxicity, and Embryo-Fetal Toxicity.

Please see Important Safety Information on pages 6-8 and read full Prescribing Information for RYBREVANT® and full Prescribing Information for LAZCLUZE™.

RYBREVANT® (amivantamab-vmjw) Injection for IV Use | 350 mg/7 mL (50 mg/mL) + LAZCLUZE™ (lazertinib) Tablets | 240 mg/80 mg

INDICATION

RYBREVANT® (amivantamab-vmjw) is indicated:

- in combination with LAZCLUZE™ (lazertinib) 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 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.

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. The median time to IRR onset is approximately 1 hour.

RYBREVANT® with LAZCLUZE™

RYBREVANT® in combination with LAZCLUZE™ can cause infusion-related reactions. In MARIPOSA (n=421), IRRs occurred in 63% of patients treated with RYBREVANT® in combination with LAZCLUZE™, including Grade 3 in 5% and Grade 4 in 1% of patients. The incidence of infusion modifications due to IRR was 54% of patients, and IRRs leading to dose reduction of RYBREVANT® occurred in 0.7% of patients. Infusion-related reactions leading to permanent discontinuation of RYBREVANT® occurred in 4.5% of patients receiving RYBREVANT® in combination with LAZCLUZE™.

Premedicate with antihistamines, antipyretics, and glucocorticoids and infuse RYBREVANT® as recommended. Administer RYBREVANT® via a peripheral line on Week 1 and Week 2 to reduce the risk of infusion-related reactions. Monitor patients for 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 severe and fatal interstitial lung disease (ILD)/pneumonitis.

RYBREVANT® with LAZCLUZE™

In MARIPOSA, ILD/pneumonitis occurred in 3.1% of patients treated with RYBREVANT® in combination with LAZCLUZE™, including Grade 3 in 1.0% and Grade 4 in 0.2% of patients. There was one fatal case (0.2%) of ILD/pneumonitis and 2.9% of patients permanently discontinued RYBREVANT® and LAZCLUZE™ due to ILD/pneumonitis.

Monitor patients for new or worsening symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). For patients receiving RYBREVANT® in combination with LAZCLUZE™, immediately withhold both drugs in patients with suspected ILD/pneumonitis and permanently discontinue if ILD/pneumonitis is confirmed.

Venous Thromboembolic (VTE) Events with Concomitant Use of RYBREVANT® and LAZCLUZE™

RYBREVANT® in combination with LAZCLUZE™ can cause serious and fatal venous thromboembolic (VTEs) events, including deep vein thrombosis and pulmonary embolism. The majority of these events occurred during the first four months of therapy.

In MARIPOSA, VTEs occurred in 36% of patients receiving RYBREVANT® in combination with LAZCLUZE™, including Grade 3 in 10% and Grade 4 in 0.5% of patients. On-study VTEs occurred in 1.2% of patients (n=5) while receiving anticoagulation therapy. There were two fatal cases of VTE (0.5%), 9% of patients had VTE leading to dose interruptions of RYBREVANT®, and 7% of patients had VTE leading to dose interruptions of LAZCLUZE™; 1% of patients had VTE leading to dose reductions of

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Venous Thromboembolic (VTE) Events with Concomitant Use of RYBREVANT® and LAZCLUZE™ (cont'd)

RYBREVANT®, and 0.5% of patients had VTE leading to dose reductions of LAZCLUZE™; 3.1% of patients had VTE leading to permanent discontinuation of RYBREVANT®, and 1.9% of patients had VTE leading to permanent discontinuation of LAZCLUZE™. The median time to onset of VTEs was 84 days (range: 6 to 777).

Administer prophylactic anticoagulation for the first four months of treatment. The use of Vitamin K antagonists is not recommended. Monitor for signs and symptoms of VTE events and treat as medically appropriate.

Withhold RYBREVANT® and LAZCLUZE™ based on severity. Once anticoagulant treatment has been initiated, resume RYBREVANT® and LAZCLUZE™ at the same dose level at the discretion of the healthcare provider. In the event of VTE recurrence despite therapeutic anticoagulation, permanently discontinue RYBREVANT® and continue treatment with LAZCLUZE™ at the same dose level at the discretion of the healthcare provider.

Dermatologic Adverse Reactions

RYBREVANT® can cause severe rash including toxic epidermal necrolysis (TEN), dermatitis acneiform, pruritus, and dry skin.

RYBREVANT® with LAZCLUZE™

In MARIPOSA, rash occurred in 86% of patients treated with RYBREVANT® in combination with LAZCLUZE™, including Grade 3 in 26% of patients. The median time to onset of rash was 14 days (range: 1 to 556 days). Rash leading to dose interruptions occurred in 37% of patients for RYBREVANT® and 30% for LAZCLUZE™, rash leading to dose reductions occurred in 23% of patients for RYBREVANT® and 19% for LAZCLUZE™, and rash leading to permanent discontinuation occurred in 5% of patients for RYBREVANT® and 1.7% for LAZCLUZE™.

Instruct patients to limit sun exposure during and for 2 months after treatment with RYBREVANT® or LAZCLUZE™ in combination with RYBREVANT®. Advise patients to wear protective clothing and use broad-spectrum UVA/UVB sunscreen. Alcohol-free (e.g., isopropanol-free, ethanol-free) emollient cream is recommended for dry skin.

When initiating RYBREVANT® treatment with or without LAZCLUZE™, administer alcohol-free emollient cream to reduce the risk of dermatologic adverse reactions. Consider prophylactic measures (e.g. use of oral antibiotics) to reduce the risk of dermatologic reactions. 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. For patients receiving RYBREVANT® in combination with LAZCLUZE™, withhold, dose reduce or permanently discontinue both drugs based on severity.

Ocular Toxicity

RYBREVANT® can cause ocular toxicity including keratitis, blepharitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, eye pruritus, and uveitis.

RYBREVANT® with LAZCLUZE™

In MARIPOSA, ocular toxicity occurred in 16% of patients treated with RYBREVANT® in combination with LAZCLUZE™, including Grade 3 or 4 ocular toxicity in 0.7% of patients. Withhold, reduce the dose, or permanently discontinue RYBREVANT® and continue LAZCLUZE™ based on severity.

Promptly refer patients with new or worsening eye symptoms to an ophthalmologist. Withhold, dose reduce or permanently discontinue RYBREVANT® based on severity.

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® and LAZCLUZE™ 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®.

Advise females of reproductive potential to use effective contraception during treatment with LAZCLUZE™ and for 3 weeks after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with LAZCLUZE™ and for 3 weeks after the last dose.

Adverse Reactions

RYBREVANT® with LAZCLUZE™

For the 421 patients in the MARIPOSA clinical trial who received RYBREVANT® in combination with LAZCLUZE™, the most common adverse reactions (≥20%) were rash (86%), nail toxicity (71%), infusion- related reactions (RYBREVANT®, 63%), musculoskeletal pain (47%), stomatitis (43%), edema (43%), VTE (36%), paresthesia (35%), fatigue (32%), diarrhea (31%), constipation (29%), COVID-19 (26%), hemorrhage (25%), dry skin (25%), decreased appetite (24%), pruritus (24%), nausea (21%), and ocular toxicity (16%). The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased albumin (8%), decreased sodium (7%), increased ALT (7%), decreased potassium (5%), decreased hemoglobin (3.8%), increased AST (3.8%), increased GGT (2.6%), and increased magnesium (2.6%).

Serious adverse reactions occurred in 49% of patients who received RYBREVANT® in combination with LAZCLUZE™. Serious adverse reactions occurring in ≥2% of patients included VTE (11%), pneumonia (4%), ILD/pneumonitis and rash (2.9% each), COVID-19 (2.4%) and pleural effusion and infusion-related reaction (RYBREVANT®) (2.1% each). Fatal adverse reactions occurred in 7% of patients who received RYBREVANT® in combination with LAZCLUZE™ due to death not otherwise specified (1.2%); sepsis and respiratory failure (1% each); pneumonia, myocardial infarction, and sudden death (0.7% each); cerebral infarction, pulmonary embolism (PE), and COVID-19 infection (0.5% each); and ILD/pneumonitis, acute respiratory distress syndrome (ARDS), and cardiopulmonary arrest (0.2% each).

LAZCLUZE™ Drug Interactions

Avoid concomitant use of LAZCLUZE™ with strong and moderate CYP3A4 inducers. Consider an alternate concomitant medication with no potential to induce CYP3A4.

Monitor for adverse reactions associated with a CYP3A4 or BCRP substrate where minimal concentration changes may lead to serious adverse reactions, as recommended in the approved product labeling for the CYP3A4 or BCRP substrate.

cp-464671v1

References

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