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

+

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

Access and Reimbursement Guide

Includes relevant information for RYBREVANT® used in combination with LAZCLUZE™

Please see Important Safety Information on pages 32-37 and read full Prescribing Information for RYBREVANT® and full Prescribing Information for LAZCLUZE™.

Introduction

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 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.

Johnson & Johnson is pleased to provide you with this detailed information to assist you in obtaining reimbursement for RYBREVANT® + LAZCLUZE™ on behalf of your patients. We have developed this Access and Reimbursement Guide to provide coding information, access routes, and important product information that we hope will be helpful to you and your practice.

INDICATIONS[1]

- 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.
- in combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor.
- in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion 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 exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System.

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions for RYBREVANT® include Infusion-Related Reactions including anaphylaxis, 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 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.

Please see Important Safety Information on pages 32-37 and read full Prescribing Information for RYBREVANT® and full Prescribing Information for LAZCLUZE™.

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Biomarker Testing

Biomarker Testing

Biomarker tests have many uses in cancer care, including prognosis and risk assessment, screening, diagnosis, and selection of optimal treatment plans involving molecularly targeted therapies.[3] A biomarker test may be called a *companion diagnostic test* if it is paired with a specific treatment. CDx laboratory tests report results of genetic variations and are essential for the safe and effective use of a corresponding therapeutic product.[4]

Coverage

Biomarker testing is a covered benefit under Medicare[4] and may be covered by non-Medicare payers, but requirements and patient cost sharing can vary by payer and plan[5]:

Payer Type	Prior Authorization Requirement	Lab: In-network Requirement	Patient Cost Sharing	Verification of Benefits Recommended
Medicare ("Original")	No	Must participate in Medicare	No*	Yes
Medicare Advantage	Varies by plan	Yes	Yes†	Yes
Commercial	Varies by plan	Usually	Yes‡	Yes
Medicaid	Varies by plan	Must participate in Medicaid	Yes§	Yes

*No cost sharing after the annual Part B deductible is met.
†May vary by plan.
‡Varies by payer and plan.
§Often nominal; varies by state program and patient income level.

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

CDx, companion diagnostic test; FDA, U.S. Food and Drug Administration.

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Biomarker Testing (cont'd)

Patient Selection[1]

RYBREVANT® + LAZCLUZE™ for 1L treatment of NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations

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]

When verifying benefits, it may be helpful to identify the code for the requested test. The codes and descriptions in the table below are provided for your reference.

CDx Tests for Treatment With RYBREVANT® + LAZCLUZE™[6,7]

CPT® Code	Description	Proprietary Name	Clinical Lab and/or Manufacturer
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 CDx tests approved for RYBREVANT®.

Ordering

- Contact your reference laboratory to determine if the relevant test is available
- Verify the applicable CPT® code
- When verifying benefits, report the specific CPT® code to determine coverage and patient cost sharing

1L, first line; CDx, companion diagnostic test; CPT®, Current Procedural Terminology; DNA, deoxyribonucleic acid; Dx, diagnostic test; *EGFR*, epidermal growth factor receptor; FDA, U.S. Food and Drug Administration; NSCLC, non-small cell lung cancer; RNA, ribonucleic acid.

Please see Important Safety Information on pages 32-37 and read full Prescribing Information for RYBREVANT® and full Prescribing Information for LAZCLUZE™.

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RYBREVANT®

RYBREVANT® + LAZCLUZE™ for 1L treatment of NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations

1L, first line; CMS, Centers for Medicare & Medicaid Services; *EGFR*, epidermal growth factor receptor; NSCLC, non-small cell lung cancer.

Please see Important Safety Information on pages 32-37 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

RYBREVANT® Indication[1]

RYBREVANT® 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 Dosage Information[1]

- Administer premedications before each RYBREVANT® infusion as recommended
- Administer diluted RYBREVANT® intravenously according to the infusion rates in Table 9 of the Prescribing Information, with the initial dose as a split infusion on Week 1 on Day 1 and Day 2
- Administer RYBREVANT® via peripheral line for Week 1, Days 1 and 2 and Week 2 to reduce the risk of infusion-related reactions
- When administering RYBREVANT® in combination with LAZCLUZE™, administer LAZCLUZE™ orally any time before the RYBREVANT® infusion
- When administering RYBREVANT® in combination with LAZCLUZE™, administer anticoagulant prophylaxis to prevent venous thromboembolic (VTE) events for the first four months of treatment

Dosage and Administration[1]

Administer diluted RYBREVANT® intravenously. The recommended dosages of RYBREVANT®, in combination with LAZCLUZE™, based on baseline body weight, are detailed below:

Recommended Dosage of RYBREVANT® in Combination With LAZCLUZE™

Every 2 Weeks

Body Weight at Baseline*	Recommended Dose	Dosing Schedule	Number of 350 mg/7 mL RYBREVANT® Vials
Less than 80 kg	1,050 mg	Weekly (total of 5 doses) from Weeks 1 to 5 • Week 1—split infusion on Day 1 and Day 2 • Weeks 2 to 5—infusion on Day 1 • Week 6—no dose	3
		Every 2 weeks starting at Week 7 onward	
Greater than or equal to 80 kg	1,400 mg	Weekly (total of 5 doses) from Weeks 1 to 5 • Week 1—split infusion on Day 1 and Day 2 • Weeks 2 to 5—infusion on Day 1 • Week 6—no dose	4
		Every 2 weeks starting at Week 7 onward	

*Dose adjustments not required for subsequent body weight changes.

Administer RYBREVANT® until disease progression or unacceptable toxicity.[1]
Refer to the LAZCLUZE™ Prescribing Information for recommended LAZCLUZE™ dosing information.[1]

Please see Important Safety Information on pages 32-37 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

Coding for Diagnosis

ICD-10-CM Diagnosis Coding

ICD-10-CM diagnosis codes use 3 to 7 alpha and numeric characters to achieve the greatest level of specificity. Codes with 3 characters are included in ICD-10-CM as the heading of a category of codes that may be further subdivided by use of additional characters to provide greater detail. A 3-character code is to be used only if it is not further subdivided. A code is invalid if it has not been coded to the full number of characters required for that code, including the seventh character, if applicable.[8]

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.*

ICD-10-CM Diagnosis Code[9]	Description[9]
C34.10	Malignant neoplasm of upper lobe, unspecified 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
C34.20	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.

FDA, U.S. Food and Drug Administration; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Coding for RYBREVANT®

HCPCS Codes

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

J9061 - Injection, amivantamab-vmjw, 2 mg[10]

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 for J9061, report the total number of 2 mg increments administered. The table below 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. MACs and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

CMS, Centers for Medicare & Medicaid Services; HCPCS, Healthcare Common Procedure Coding System; MAC, Medicare Administrative Contractors.

Coding for RYBREVANT® (cont'd)

NDC

The NDC is a unique number that identifies a drug's labeler, product, and trade package size. The NDC is most often used on pharmacy claims, including drugs provided for home infusion. However, the NDC is also required on Medicare claims for dual-eligible beneficiaries (Medicaid cross-over claims)[11] and claims for many private payers.[12] 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:

RYBREVANT® NDC

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

Payer requirements for NDC use and format can vary widely. Please contact your payers for specific coding policies and more information on correct billing and claims submission.

FDA, U.S. Food and Drug Administration; NDC, National Drug Code.

Coding for RYBREVANT® (cont'd)

Billing With NDC Units

Coding with the NDC on professional or institutional claims requires similar information and formats. The NDC unit of measure is determined by how the drug is supplied. 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®[1]:

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

In these examples, the drug is supplied as a 350 mg/7 mL vial. Each vial equates to 7 NDC units, and the NDC unit of measure is ML. 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[11]:

- N4 qualifier
- 11-digit NDC
- 1 space
- 2-character NDC unit of measure (eg, ML, GR, UN)
- 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**

GR, gram; NDC, National Drug Code; UN, unit.

Please see Important Safety Information on pages 32-37 and read full Prescribing Information for RYBREVANT® and full Prescribing Information for LAZCLUZE™.

Coding for Administration

CPT® Codes

CPT® codes are the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. 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.

Chemotherapy administration CPT® codes (96401-96549), often referred to as "complex" codes, apply to the parenteral administration of chemotherapy, to anti-neoplastic agents provided for treatment of noncancer diagnoses, or to substances such as certain monoclonal antibodies and other biologic response modifiers. Complex drug administration services require special considerations to prepare, dose, or dispose, and typically these services entail professional skill and patient monitoring significantly beyond that required for therapeutic infusions.[6]

Payer requirements for drug administration codes may vary. It is recommended to verify the correct administration coding with the payer. The codes below are provided for your consideration.*

CPT® Code[6]	Description[6]
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; CPT®, Current Procedural Terminology; FDA, U.S. Food and Drug Administration.

Other Coding Considerations

When coding and billing for RYBREVANT® and drug administration services, you may also need to provide additional coding detail, describe concomitant services or supplies, or account for modification to a service. This section reviews some of those additional considerations.

POS Codes

The POS code set provides setting information necessary to appropriately pay professional service claims. The POS is the location of the provider's face-to-face encounter with the patient. POS codes are required on all claims for professional services (billed on CMS-1500, Item 24B). The physician practice setting is indicated with POS code 11. To differentiate between on-campus and off-campus PBDs, CMS created POS code 19 and revised the description for outpatient hospitals POS code 22. Professional services delivered in outpatient hospital settings must specifically include the off-campus or on-campus POS codes on the claim form.

POS Codes and Descriptions[13]

Code	Name	Description
11	Office	Location, other than a hospital, skilled nursing facility, military treatment facility, community health center, state or local public health clinic, or intermediate care facility, where the healthcare professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis
19	Off-Campus – Outpatient Hospital	A portion of an off-campus hospital provider-based department that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization
22	On-Campus – Outpatient Hospital	A portion of a hospital's main campus that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization

CMS, Centers for Medicare & Medicaid Services; PBD, provider-based department; POS, place of service.

Other Coding Considerations (cont'd)

Revenue Codes

Many payers require use of American Hospital Association revenue codes to bill for services provided in hospital outpatient departments. Revenue codes consist of a leading zero followed by 3 other digits and are used on CMS-1450 claim forms to assign costs to broad categories of hospital revenue centers. Codes used for Medicare claims are available from Medicare contractors. Generally, CMS does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under the OPPS, since hospitals' assignment of cost vary. Where explicit instructions are not provided, providers should report their charges in Locator Box 42 under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.[14] The following revenue codes may be applicable to CMS-1450 claims for RYBREVANT® and its administration:

Revenue Codes and Descriptions[15]

Code	Description
0335	Chemotherapy administration – IV
0510	Clinic, general
0636	Pharmacy, drugs requiring detailed coding

CMS, Centers for Medicare & Medicaid Services; HCPCS, Healthcare Common Procedure Coding System; IV, intravenous; OPPS, Outpatient Prospective Patient System.

Other Coding Considerations (cont'd)

CPT® and HCPCS Modifiers

Modifiers are used to indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition or code. They add more information, and help to eliminate the appearance of duplicate billing and unbundling. Appropriately used, modifiers increase coding and reimbursement accuracy. The following tables summarize modifiers that may be applicable to RYBREVANT® coding and billing in physician offices and hospital outpatient departments.

Summary of CPT® and HCPCS Modifiers

Modifier	Description	Indication and Placement	Physician Claims (CMS-1500)	CMS-1450 Locator Box 44
25	Significant, separately identifiable E/M service by the same physician or other qualified HCP on the same day of the procedure or other service[6]	• Patient requires distinct E/M service in addition to drug administration procedure[6] • Must be substantiated with documentation[6] • Append the modifier to the relevant E/M code[6]	✓ Required by Medicare	✓ Required by Medicare
PO*	Excepted service provided at an off-campus, outpatient, PBD of a hospital[14]	• Report with every HCPCS code for all outpatient hospital items and services furnished in an excepted off-campus PBD of a hospital[14]	N/A	✓ Required by Medicare
PN*	Nonexcepted service provided at an off-campus, outpatient, PBD of a hospital[14]	• Report on each claim line for nonexcepted items and services including those for which payment will not be adjusted, such as separately payable drugs[14] • Modifier PN will trigger a payment rate under the Medicare PFS[14]	N/A	✓ Required by Medicare
JW	Drug amount discarded/ not administered to any patient[16]	• Unused drug remains after applicable dose is administered from single-use vial[16] • CMS issued a discarded drug policy and requires use of the JW modifier; other payer policies may vary[16] • Append the modifier to the HCPCS drug code on a line separate from that reporting the administered dose, and document the administered and discarded amounts in the medical record[16]	✓ Required by Medicare	✓ Required by Medicare
JZ	No discarded drug amounts[16]	• Applies to single-dose containers of drugs for which the JW modifier would be required if there were discarded amounts[16] • Append the modifier to the HCPCS drug code on the claim line with the administered amount[16]	✓ Required by Medicare	✓ Required by Medicare

*Neither the PO nor the PN modifier is to be reported by the following hospital departments: a dedicated emergency department or a PBD that is "on the campus" or within 250 yards of the hospital or in a remote location of the hospital.[14]

CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; E/M, evaluation and management; HCP, healthcare professional; HCPCS, Healthcare Common Procedure Coding System; PBD, provider-based department; PFS, Physician Fee Schedule.

Other Coding Considerations (cont'd)

340B Modifiers

When RYBREVANT® has been acquired with the 340B Drug Pricing Program Discount, Medicare requires reporting an HCPCS modifier on claims billed by outpatient hospital facilities. Both the JG and TB modifiers are for informational purposes only and do not affect payment. Correct modifier selection is based on the type of entity reporting and the pass-through status of the drug.

Reporting Requirements for 340B Modifiers[14]

Modifier	Description	Indication and Placement
JG	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes	• Must be reported by hospitals (except for rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities	• Must be reported by hospitals designated as "select entities" (rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs • Must be reported by all OPPS providers for pass-through drugs (status indicator "G") purchased through the 340B drug discount program • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs

HCPCS, Healthcare Common Procedure Coding System; OPPS, Outpatient Prospective Patient System; PPS, Prospective Payment System.

Other Coding Considerations (cont'd)

Same-Day E/M Services

It may be necessary to provide E/M services on the same day as a drug administration procedure. Depending on the payer, E/M services that are medically necessary, separate and distinct from the drug administration procedure, and documented appropriately are generally covered. Please note that Medicare has a specific policy regarding the use of CPT® code 99211 in the physician office:

CPT® code 99211 cannot be paid if it is billed, with or without modifier 25, with a chemotherapy or nonchemotherapy drug administration code.[17]

Thus CPT® 99211 cannot be paid on the same day as an office-based infusion of RYBREVANT®. If a chemotherapy service and a significantly identifiable E/M service are provided on the same day, a different diagnosis is not required.[17]

Partial Additional Hours of Infusion Time

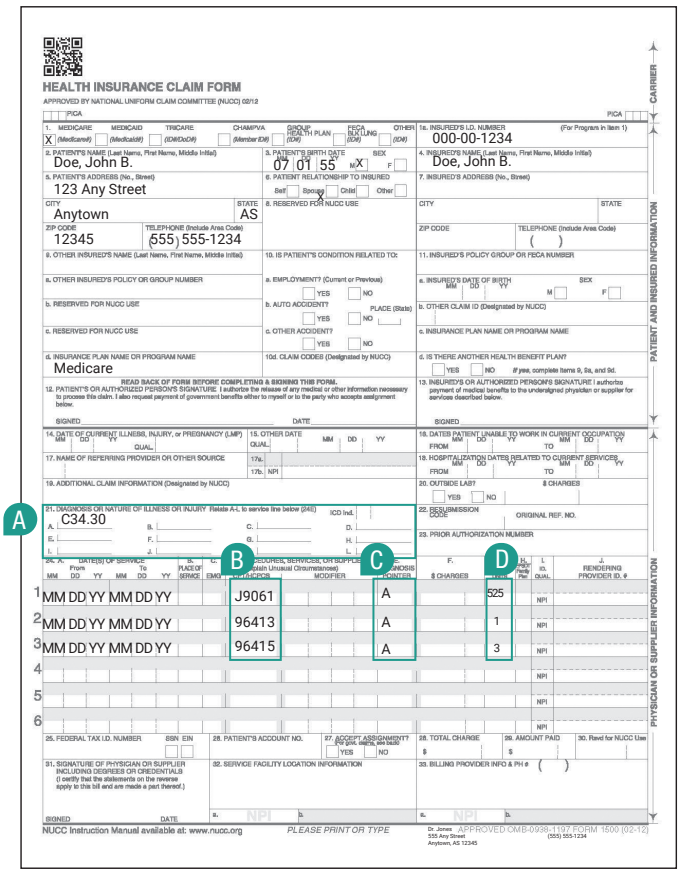
CMS has a policy for reporting add-on infusion codes when less than a full hour of service is provided. CPT® code 96415 (for "each additional hour") is to be used for infusion intervals greater than 30 minutes beyond 1-hour increments.[17] If the incremental infusion time is 30 minutes or less, the time is not to be billed separately.[16] Document infusion start and stop times in the medical record. Some payers may require reporting the actual number of minutes on claims. Time associated with interruptions in the infusion process (eg, when drug is not flowing or when IV saline is used to keep a line patent while no drug is infusing) does not count toward billable infusion time.

Drugs Supplied at No Cost to Patient

Under certain circumstances, qualified patients may acquire donated or no-cost drugs, or drugs may be covered under a pharmacy benefit and delivered to the administering provider. When the drug was supplied by a third party at no cost to the provider, it should not be billed by the provider to Medicare or any other payer. However, the administration of the drug, regardless of the source, is a service that represents an expense to the provider. Therefore, administration of the drug is payable if the drug would have been covered if the provider purchased it. When reporting drug administration services with no drug charge, it is common to require the drug HCPCS code on the same claim. To accommodate claim-processing edits, it may also be necessary to include a nominal charge of $0.01 (one cent).[18] Payer policies may vary.

CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; E/M, evaluation and management; HCPCS, Healthcare Common Procedure Coding System; IV, intravenous.

Physician Office Sample Claim Form (CMS-1500) for RYBREVANT® 1,050 mg



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE (Medicare#) X — 1a. INSURED'S I.D. NUMBER: 000-00-1234 — (For Program in Item 1)

2. PATIENT'S NAME: Doe, John B.

3. PATIENT'S BIRTH DATE: 07 01 55 — SEX: M X

4. INSURED'S NAME: Doe, John B.

5. PATIENT'S ADDRESS: 123 Any Street

6. PATIENT RELATIONSHIP TO INSURED: Self X

7. INSURED'S ADDRESS (No., Street)

CITY: Anytown — STATE: AS — ZIP CODE: 12345 — TELEPHONE: (555) 555-1234

9. OTHER INSURED'S NAME

11. INSURED'S POLICY GROUP OR FECA NUMBER

d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY: A. C34.30

	24A. DATE(S) OF SERVICE	B. PLACE OF SERVICE	C. PROCEDURES, SERVICES, OR SUPPLIES	D. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	J. RENDERING PROVIDER ID. #
1	MM DD YY MM DD YY		J9061	A		525	NPI
2	MM DD YY MM DD YY		96413	A		1	NPI
3	MM DD YY MM DD YY		96415	A		3	NPI
4							NPI
5							NPI
6							NPI

25. FEDERAL TAX I.D. NUMBER — 26. PATIENT'S ACCOUNT NO. — 27. ACCEPT ASSIGNMENT? YES NO — 28. TOTAL CHARGE $ — 29. AMOUNT PAID $ — 30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS — 32. SERVICE FACILITY LOCATION INFORMATION — 33. BILLING PROVIDER INFO & PH #

NUCC Instruction Manual available at: www.nucc.org — PLEASE PRINT OR TYPE — APPROVED OMB-0938-1197 FORM 1500 (02-12)

A **Item 21** – Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order

B **Item 24D** – Indicate appropriate CPT®, HCPCS codes, and modifiers (if applicable)

RYBREVANT®
J9061 – Injection, amivantamab-vmjw, 2 mg

Infusion Services
96413 – Chemotherapy administration, intravenous infusion technique; up to 1 hour
96415 – Each additional hour

C **Item 24E** – Refer to the diagnosis for this service (see Item 21). Enter only 1 diagnosis pointer per line

D **Item 24G** – Enter the units for items/services provided

RYBREVANT®
J9061 – Enter the amount of drug in HCPCS units according to the drug-specific descriptor and dose:
- 2 mg = 1 unit
- 1,050 mg dose = 525 units

Infusion Services
96413 – Enter 1 unit for the first hour
96415 – Enter 1 unit for each additional hour

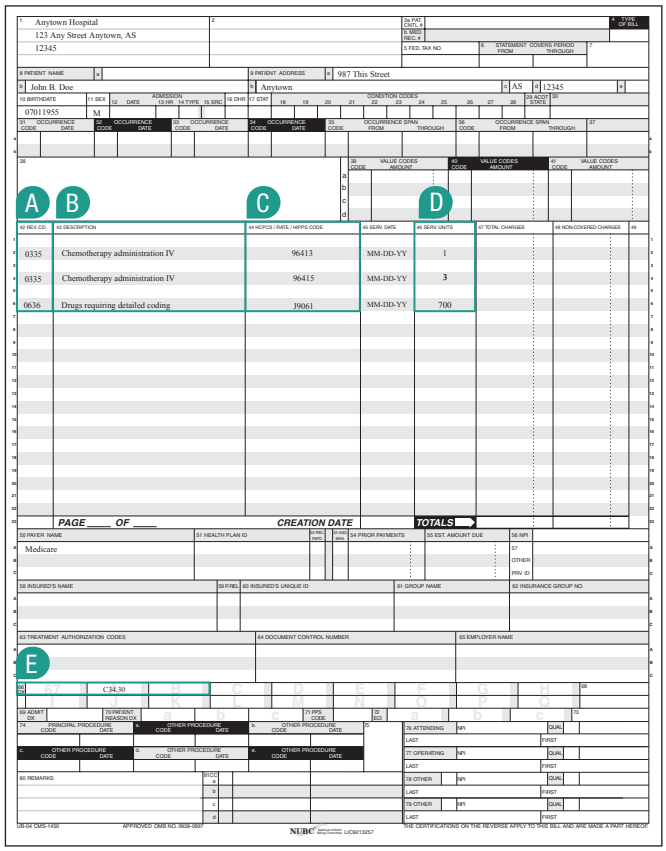
The fact that a drug, device, procedure, or service is assigned both an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program but indicates only how the product, procedure, or service may be paid if covered by the program. FIs/MACs and/or the state Medicaid program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

1L, first line; CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; *EGFR*, epidermal growth factor receptor; FI, Fiscal Intermediary; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; MAC, Medicare Administrative Contractor; NSCLC, non-small cell lung cancer.

Please see Important Safety Information on pages 32-37 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

Hospital Outpatient Department Sample Claim Form (CMS-1450) for RYBREVANT® 1,400 mg



A **Locator Box 42** – List revenue codes in ascending order

B **Locator Box 43** – Enter narrative description for corresponding revenue codes

C **Locator Box 44** – Indicate appropriate CPT®, HCPCS codes, and modifiers (if applicable)

RYBREVANT®
J9061 – Injection, amivantamab-vmjw, 2 mg

D **Locator Box 46** – Enter the units for items/services provided

RYBREVANT®
J9061 – Enter the amount of drug in HCPCS units according to the drug-specific descriptor and dose:
- 2 mg = 1 unit
- 1,400 mg dose = 700 units

Infusion Services
96413 – Enter 1 unit for the first hour
96415 – Enter 1 unit for each additional hour

E **Locator Box 67** – Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service, and enter the diagnoses in priority order

The fact that a drug, device, procedure, or service is assigned both 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. FIs/MACs and/or the state Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

1L, first line; CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; *EGFR*, epidermal growth factor receptor; FI, Fiscal Intermediary; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; MAC, Medicare Administrative Contractor; NSCLC, non-small cell lung cancer.

Please see Important Safety Information on pages 32-37 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

LAZCLUZE™

RYBREVANT® + LAZCLUZE™ for 1L treatment of NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations

1L, first line; *EGFR*, epidermal growth factor receptor; NSCLC, non-small cell lung cancer.

Please see Important Safety Information on pages 32-37 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

LAZCLUZE™ Indication[2]

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.

Dosage

The recommended dosage of LAZCLUZE™ is:

240 mg LAZCLUZE™

Orally once daily

- LAZCLUZE™ is indicated in combination with RYBREVANT®
- Continue treatment until disease progression or unacceptable toxicity

Administer LAZCLUZE™ at any time prior to RYBREVANT® when given on the same day. Refer to the RYBREVANT® Prescribing Information for recommended RYBREVANT® dosing information.[2]

Please see Important Safety Information on pages 32-37 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

Important Administration Instructions[2]

Tablets must be **swallowed whole**.
Do not crush, split, or chew.

May be taken
with or without food.

Must be taken **before scheduled** RYBREVANT® infusion when given on the same day.

If a patient misses a dose of LAZCLUZE™ within 12 hours, instruct them to take the missed dose. If more than 12 hours have passed since the dose was to be given, instruct the patient to take the next dose at its scheduled time. If vomiting occurs any time after taking LAZCLUZE™, instruct the patient to take the next dose at its scheduled time.

Dosage Forms and Strengths[2]

LAZCLUZE™ (lazertinib) is available in 240 mg tablets and a lower-strength tablet if needed for dose reduction[2]:

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

NDC, National Drug Code.

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions for RYBREVANT® include Infusion-Related Reactions including anaphylaxis, 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 32-37 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

Coding for Diagnosis

ICD-10-CM Diagnosis Coding

Payer requirements for ICD-10-CM diagnosis codes will vary. Please verify the correct diagnosis coding with each payer. The codes* below are provided for your consideration when prescribing LAZCLUZE™ in combination with RYBREVANT®:

ICD-10-CM Diagnosis Code[9]	Description
C34.10	Malignant neoplasm of upper lobe, unspecified 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
C34.20	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 coding resource for more information.

FDA, U.S. Food and Drug Administration; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Please see Important Safety Information on pages 32-37 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

Where to Order

Please see Important Safety Information on pages 32-37 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

Accessing RYBREVANT® and LAZCLUZE™

Specialty Distributors

- You may order RYBREVANT® from authorized specialty distributors (please see list below)
- If you are a hospital or in-office dispensing pharmacy, you may order LAZCLUZE™ from authorized specialty distributors. All other providers and practices, please contact the authorized specialty pharmacy provider (please see page 26)

Authorized Specialty Distributor Network

Name	Phone Number	Fax	Website	Drug Fulfillment
CuraScript SD (Priority Healthcare)	877-599-7748	800-862-6208	curascriptsd.com	RYBREVANT® only
Cencora (AmerisourceBergen)	800-746-6273	800-547-9413	asdhealthcare.com	RYBREVANT® and LAZCLUZE™
Cencora Oncology Supply (AmerisourceBergen Oncology Supply)	800-633-7555	800-248-8205	oncologysupply.com	RYBREVANT® and LAZCLUZE™
Cardinal Health Specialty Pharmaceutical Distribution	**Physician offices:** 877-453-3972 **Hospitals/All others:** 855-855-0708	614-652-7043	specialtyonline.cardinalhealth.com orderexpress.cardinalhealth.com	RYBREVANT® and LAZCLUZE™
Cardinal P.R. 120 (Puerto Rico)	787-625-4200	787-625-4398	cardinalhealth.pr	RYBREVANT® and LAZCLUZE™
McKesson Plasma and Biologics	877-625-2566	888-752-7626	connect.mckesson.com	RYBREVANT® and LAZCLUZE™
McKesson Specialty Health	**Oncology:** 800-482-6700 **Multispecialty:** 855-477-9800	**Oncology:** 855-824-9489 **Multispecialty:** 800-800-5673	mckessonspecialtyhealth.com	RYBREVANT® and LAZCLUZE™

NOTE: Johnson & Johnson does not endorse the use of any of the listed specialty distributors in particular.

Accessing RYBREVANT® and LAZCLUZE™ (cont'd)

Specialty Pharmacy Provider for LAZCLUZE™

Specialty Pharmacy	Phone	Fax	Website	ePrescribe
Onco360	(877) 662-6633	(877) 662-6355	https://onco360.com	OncoMed dba Onco360 or NPI# 1679618151

The specialty pharmacy process is designed to facilitate smooth patient onboarding for timely initiation of therapy. When making a referral, please be prepared with:

- A copy of the front and back of your patient's medical and prescription insurance cards
- Patient demographics and clinical notes

In addition to dispensing, Onco360 provides ongoing care from their pharmacy team:

- **Onco Care Coordinators:** A patient can expect a welcome call within the first 3 days of receiving their LAZCLUZE™ prescription. They will validate the patient's insurance information and provide any support to ensure medication access: benefits investigation, insurance verification, prior authorization support, exception requests/appeal support, and patient financial assistance
  - Once insurance is confirmed, LAZCLUZE™ will be shipped to the patient's preferred location at the beginning of every treatment cycle. Patients can expect a refill reminder before medication is shipped

- **Onco360 Pharmacist:** Patients will receive an initial consultation call from an oncology pharmacist to review the medication, provide dosing instructions, and identify potential side effects to ensure they stay on treatment

- **Onco360 Nurse:** Each patient will receive a call from an oncology nurse at the beginning of treatment and get in-depth education on adverse event management, advice on how to stay on treatment, and when to contact their doctor. The nurse will also check in at the end of each treatment cycle to ensure there were no barriers to adherence
  - Patients can contact a nurse Monday to Friday, 8 AM to 8 PM Eastern time to discuss any concerns they have about LAZCLUZE™

dba, doing business as; NPI, National Provider Identifier.

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Patient Support

Coverage Decisions

Third-party payers may require more than a prescription to cover RYBREVANT® in combination with LAZCLUZE™. A summary of the medical necessity of treatment and specific responses to PA requirements are often necessary. If the payer determines the initial information inadequate to grant coverage, it may also be necessary to request an exception or support an appeal.

Medical Necessity

Medical necessity refers to healthcare services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms, and that meet accepted standards of medicine. Generally, payers provide coverage only for health-related services they determine to be medically necessary. Payer policies define medical necessity criteria, including indications, required diagnostic test results, and any limitations of coverage that may apply.

When third-party payers consider coverage requests for RYBREVANT® in combination with LAZCLUZE™, they will first determine if the therapy is covered under their policies. Next, they will look for evidence supporting medical necessity, which may include, but not be limited to:

- Patient diagnosis and alignment with indications for requested therapy
- Biomarker test results: positive for *EGFR* exon 19 deletions or exon 21 L858R substitution mutations, detected by an FDA-approved test
- Summary of patient's current medical condition and history
- Rationale for requested therapy and expected outcome(s)

View a sample letter of medical necessity for RYBREVANT® + LAZCLUZE™.

EGFR, epidermal growth factor receptor; FDA, U.S. Food and Drug Administration; PA, prior authorization.

Please see Important Safety Information on pages 32-37 and read full Prescribing Information for RYBREVANT® and full Prescribing Information for LAZCLUZE™.

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Coverage Decisions (cont'd)

Prior Authorization

Prior authorization (also referred to as pre-authorization or "pre-auth") is a common payer process that requires establishing medical necessity within the framework of specific payer coverage criteria. Cancer therapies are often subject to PA, but the requirements and processes can vary by payer. There may be different paths for the authorization of a drug that is HCP-administered (typically covered under the medical benefit) and oral drugs that are self-administered by the patient (typically a pharmacy benefit). When requesting coverage for RYBREVANT® in combination with LAZCLUZE™, it is important to include both drugs in the discussion to ensure the therapy is approved as prescribed.

Items you may want to prepare for a PA request:

- Letter of medical necessity
- Prescribing information for the requested drugs
- Lab results (positive for *EGFR* exon 19 deletions or exon 21 L858R substitution mutations)
- Patient history and physical findings, including:
  - Diagnosis (ICD-10-CM)
  - Previous therapies/procedures and response to the interventions
  - Current symptoms/condition

Exception Request

An exception is a type of coverage determination that may apply when a product has been recently approved and a plan has not yet made a coverage decision (eg, is not on formulary or subject to a "new-to-market" NDC block) or if a payer's coverage requirements cannot be met (eg, step therapy, quantity limits). A request for exception asks that the restrictions placed on a specific drug be released as the therapy is medically appropriate and necessary for a patient's treatment. Providers must typically submit a supporting statement with details about the rationale for the request. Payer policies and processes, including the time in which a decision is to be expected, can vary.

View a sample exception request letter for RYBREVANT® + LAZCLUZE™.

EGFR, epidermal growth factor receptor; HCP, healthcare professional; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code; PA, prior authorization.

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Coverage Decisions (cont'd)

Appeals

Appeals are the procedures used to challenge a payer's denial of benefits that a beneficiary believes they are entitled to receive. If a payer denies an initial request for coverage or an exception request, the decision may be appealed. The payer's notice of denial should include the reason for that decision, as well as instructions for filing an appeal. Most plans have multiple, progressive levels of appeal, allowing beneficiaries to continue advancing their request if initial efforts are not successful. Appeals may be initiated by the patient or their healthcare provider. No matter the origin, it is generally necessary for prescribers to submit a supporting statement providing details of why the patient is clinically appropriate for the prescribed medication. To resolve some requests, it may be helpful to schedule a peer-to-peer review between the treating physician and the medical director at the health plan.

Tips for filing an appeal:

- Review the denial notice to determine the reason for denial and to identify the appeal process requirements (documentation, time frame, etc)
- Review the accuracy and completeness of the original PA request (patient information, supporting documentation, etc)
- Develop a comprehensive response, making sure to address the payer's stated reason for denial
- Include any supporting documentation required by the payer (copy of the denial letter, letter of medical necessity, patient records, etc)

PA, prior authorization.

Once you have made the clinical decision to prescribe RYBREVANT® + LAZCLUZE™, Johnson & Johnson has resources to help you support your patients.

J&J

withMe

Access and Affordability Resources Plus Personalized Support for Your Patients

At Johnson & Johnson, we are committed to helping people in their fight against cancer

J&J withMe is your single source for access, affordability, and treatment support programs from Johnson & Johnson. Your patients will be connected to RYBREVANT withMe.

- **Access support to help navigate payer processes:** J&J withMe helps verify insurance coverage for your patients taking RYBREVANT® + LAZCLUZE™, providing benefits investigation support, prior authorization support, information on the exceptions and appeals process, and reimbursement information
- **Affordability resources for your patients:** Help patients discover ways to afford their RYBREVANT® + LAZCLUZE™—regardless of their insurance type or even if they have no insurance at all
- **Dedicated, free 1-on-1 support for your patients throughout their treatment journey:** Each patient's RYBREVANT® + LAZCLUZE™ treatment journey is unique. We're here to help by providing personalized 1-on-1 support from oncology-trained nurses*

Get started with J&J withMe

- Visit **Portal.JNJwithMe.com** to investigate insurance coverage for your patients, enroll your patients in savings, or sign them up for Care Navigator support*
- Visit **JNJwithMe.com/hcp/** for access and affordability information for the J&J medicine you prescribed
- Bookmark these links for quick and easy access!
- Questions? Call **833-JNJ-wMe1 (833-565-9631),** Monday through Friday, 8:00 AM to 8:00 PM ET

The patient support and resources provided by RYBREVANT withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe RYBREVANT®.

*Care Navigators do not provide medical advice.

Please see Important Safety Information on pages 32-37 and read full Prescribing Information for RYBREVANT® and full Prescribing Information for LAZCLUZE™.

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INDICATIONS

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.
- in combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor.
- in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion 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 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

Infusion-Related Reactions

RYBREVANT® can cause infusion-related reactions (IRR) including anaphylaxis; 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™.

RYBREVANT® with Carboplatin and Pemetrexed

Based on the pooled safety population (n=281), IRR occurred in 50% of patients treated with RYBREVANT® in combination with carboplatin and pemetrexed, including Grade 3 (3.2%) adverse reactions. The incidence of infusion modifications due to IRR was 46%, and 2.8% of patients permanently discontinued RYBREVANT® due to IRR.

RYBREVANT® as a Single Agent

In CHRYSALIS (n=302), 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.

Please see Important Safety Information on pages 32-37 and read full Prescribing Information for RYBREVANT® and full Prescribing Information for LAZCLUZE™.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infusion-Related Reactions (cont'd)

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. If an anaphylactic reaction occurs, permanently discontinue RYBREVANT®.

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.

RYBREVANT® with Carboplatin and Pemetrexed

Based on the pooled safety population, ILD/pneumonitis occurred in 2.1% treated with RYBREVANT® in combination with carboplatin and pemetrexed with 1.8% of patients experiencing Grade 3 ILD/pneumonitis. 2.1% discontinued RYBREVANT® due to ILD/pneumonitis.

RYBREVANT® as a Single Agent

In CHRYSALIS, ILD/pneumonitis occurred in 3.3% of patients treated with RYBREVANT®, with 0.7% of patients experiencing Grade 3 ILD/pneumonitis. Three patients (1%) permanently discontinued RYBREVANT® 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. For patients receiving RYBREVANT® as a single agent or in combination with carboplatin and pemetrexed, immediately withhold RYBREVANT® 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 (VTE) 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 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

Please see Important Safety Information on pages 32-37 and read full Prescribing Information for RYBREVANT® and full Prescribing Information for LAZCLUZE™.

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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 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™.

RYBREVANT® with Carboplatin and Pemetrexed

Based on the pooled safety population, rash occurred in 82% of patients treated with RYBREVANT® in combination with carboplatin and pemetrexed, including Grade 3 (15%) adverse reactions. Rash leading to dose reductions occurred in 14% of patients, and 2.5% permanently discontinued RYBREVANT® and 3.1% discontinued pemetrexed.

RYBREVANT® as a Single Agent

In CHRYSALIS, rash occurred in 74% of patients treated with RYBREVANT® as a single agent, 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® 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.

Please see Important Safety Information on pages 32-37 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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Dermatologic Adverse Reactions (cont'd)

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, reduce the dose, or permanently discontinue both drugs based on severity. For patients receiving RYBREVANT® as a single agent or in combination with carboplatin and pemetrexed, withhold, dose reduce or permanently discontinue RYBREVANT® 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.

RYBREVANT® with Carboplatin and Pemetrexed

Based on the pooled safety population, ocular toxicity occurred in 16% of patients treated with RYBREVANT® in combination with carboplatin and pemetrexed. All events were Grade 1 or 2.

RYBREVANT® as a Single Agent

In CHRYSALIS, 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 with new or worsening eye symptoms to an ophthalmologist. Withhold, reduce the dose, or permanently discontinue RYBREVANT® based on severity.

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

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Adverse Reactions (cont'd)

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).

RYBREVANT® with Carboplatin and Pemetrexed

For the 130 patients in the MARIPOSA-2 clinical trial who received RYBREVANT® in combination with carboplatin and pemetrexed, the most common adverse reactions (≥20%) were rash (72%), infusion-related reactions (59%), fatigue (51%), nail toxicity (45%), nausea (45%), constipation (39%), edema (36%), stomatitis (35%), decreased appetite (31%), musculoskeletal pain (30%), vomiting (25%), and COVID-19 (21%). The most common Grade 3 to 4 laboratory abnormalities (≥2%) were decreased neutrophils (49%), decreased white blood cells (42%), decreased lymphocytes (28%), decreased platelets (17%), decreased hemoglobin (12%), decreased potassium (11%), decreased sodium (11%), increased alanine aminotransferase (3.9%), decreased albumin (3.8%), and increased gamma-glutamyl transferase (3.1%).

In MARIPOSA-2, serious adverse reactions occurred in 32% of patients who received RYBREVANT® in combination with carboplatin and pemetrexed. Serious adverse reactions in >2% of patients included dyspnea (3.1%), thrombocytopenia (3.1%), sepsis (2.3%), and pulmonary embolism (2.3%). Fatal adverse reactions occurred in 2.3% of patients who received RYBREVANT® in combination with carboplatin and pemetrexed; these included respiratory failure, sepsis, and ventricular fibrillation (0.8% each).

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%).

In PAPILLON, 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.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Adverse Reactions (cont'd)

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.

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.

Please read full Prescribing Information for RYBREVANT®.
Please read full Prescribing Information for LAZCLUZE™.

cp-213274v7

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