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

Access and Reimbursement Guide

Includes relevant information for RYBREVANT® used in combination with chemotherapy (carboplatin + pemetrexed) or as a single agent

Please see Important Safety Information on pages 36–41 and read full Prescribing Information for RYBREVANT®.

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 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.

Indications[1]

RYBREVANT® is indicated:

- 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.

J&J is pleased to provide you with this detailed information to assist you in obtaining reimbursement for RYBREVANT® on behalf of your patients. We have developed this Access and Reimbursement Guide to provide coding information, a list of specialty distributors, and important product information that we hope will be helpful to you and your practice.

SELECT 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 Important Safety Information on pages 36–41 and read full Prescribing Information for RYBREVANT®.

NOTE: All content in the Biomarker Testing section applies to both RYBREVANT® + chemotherapy and RYBREVANT® as a single agent unless otherwise specified.

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.[2] A biomarker test may be called a *companion diagnostic (CDx) 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.[3]

Coverage

Biomarker testing is a covered benefit under Medicare[3] and may be covered by non-Medicare payers, but requirements and patient cost sharing can vary by payer and plan[4]:

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

FDA, U.S. Food and Drug Administration.

Biomarker Testing (cont'd)

Patient Selection[1]

RYBREVANT® + chemotherapy for 2L NSCLC with *EGFR*+ mutations* after progression on an *EGFR* TKI or 1L NSCLC with *EGFR* exon 20 insertion mutations

RYBREVANT® is indicated 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.
- 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.

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]

RYBREVANT® as a single agent for NSCLC with *EGFR* exon 20 insertion mutations post platinum-based chemotherapy

RYBREVANT® 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.

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 for Treatment With RYBREVANT® as a Single Agent or With Chemotherapy[5]

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 Current Procedural Terminology (CPT®) code
- When verifying benefits, report the specific CPT® code to determine coverage and patient cost sharing

**EGFR*+* includes exon 19 deletions and exon 21 L858R substitution mutations.*
1L, first line; 2L, second line; DNA, deoxyribonucleic acid; *EGFR*, epidermal growth factor receptor; NSCLC, non-small cell lung cancer; RNA, ribonucleic acid; TKI, tyrosine kinase inhibitor.

Please see Important Safety Information on pages 36–41 and read full Prescribing Information for RYBREVANT®.

Dosage and Administration

RYBREVANT® + chemotherapy for 2L NSCLC with *EGFR*+ mutations* after progression on an *EGFR* TKI or 1L NSCLC with *EGFR* exon 20 insertion mutations

RYBREVANT® as a single agent for NSCLC with *EGFR* exon 20 insertion mutations post platinum-based chemotherapy

**EGFR*+* includes exon 19 deletions and exon 21 L858R substitution mutations.

1L, first line; 2L, second line; *EGFR*, epidermal growth factor receptor; NSCLC, non-small cell lung cancer; TKI, tyrosine kinase inhibitor.

Please see Important Safety Information on pages 36–41 and read full Prescribing Information for RYBREVANT®.

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

Indications[1]

RYBREVANT® is indicated 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.
- 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.

Important Dosage Information[1]

- Administer premedications before each RYBREVANT® infusion as recommended
- Administer diluted RYBREVANT® intravenously according to the infusion rates on page 9, 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 carboplatin and pemetrexed, infuse pemetrexed first, carboplatin second, and RYBREVANT® last

Dosage and Administration[1]

The recommended dosages of RYBREVANT®, used in combination with carboplatin and pemetrexed, based on baseline body weight, are detailed below:

Recommended Dosage for RYBREVANT® in Combination With Carboplatin and Pemetrexed for Treatment of NSCLC—Every 3-Week Dosing

Body Weight at Baseline*	Recommended Dose	Dosing Schedule
Less than 80 kg	1,400 mg	Weekly (total of 4 doses) from Weeks 1 to 4 • Week 1—split infusion on Day 1 and Day 2 • Weeks 2 to 4—infusion on Day 1 • Weeks 5 and 6—no dose
	1,750 mg	Every 3 weeks starting at Week 7 onward
Greater than or equal to 80 kg	1,750 mg	Weekly (total of 4 doses) from Weeks 1 to 4 • Week 1—split infusion on Day 1 and Day 2 • Weeks 2 to 4—infusion on Day 1 • Weeks 5 and 6—no dose
	2,100 mg	Every 3 weeks starting at Week 7 onward

*Dose adjustment is not required for subsequent body weight changes.

Administer RYBREVANT® until disease progression or unacceptable toxicity.[1]

When administering RYBREVANT® in combination with carboplatin and pemetrexed, infuse pemetrexed first, carboplatin second, and RYBREVANT® last. Follow the manufacturers' Prescribing Information for complete information for the other drugs.[1]

Dosage and Administration[1] (cont'd)

Recommended Premedications[1]

Prior to initial infusion of RYBREVANT® (Week 1, Days 1 and 2), administer premedications to reduce the risk of infusion-related reactions (IRRs), as detailed in the table below:

Medication	Dose	Route of Administration	Dosing Window Prior to RYBREVANT® Administration
Antihistamine*	Diphenhydramine (25 to 50 mg) or equivalent	Intravenous	15 to 30 minutes
		Oral	30 to 60 minutes
Antipyretic*	Acetaminophen (650 to 1,000 mg)	Intravenous	15 to 30 minutes
		Oral	30 to 60 minutes
Glucocorticoid†	Dexamethasone (20 mg) or equivalent	Intravenous	45 to 60 minutes
Glucocorticoid‡	Dexamethasone (10 mg) or equivalent	Intravenous	45 to 60 minutes

*Required at all doses.
†Required at initial dose (Week 1, Day 1).
‡Required at second dose (Week 1, Day 2); optional for subsequent doses.

Glucocorticoid administration is required for Week 1, Days 1 and 2 doses only and upon re-initiation after prolonged dose interruptions, then as necessary for subsequent infusions. Administer both antihistamine and antipyretic prior to all infusions.

Administration[1]

Administer the diluted RYBREVANT® solution by intravenous infusion using an infusion set fitted with a flow regulator and with an in-line, sterile, nonpyrogenic, low protein-binding polyethersulfone (PES) filter (pore size 0.2 micrometer).

Administration sets must be made of either polyurethane (PU), polybutadiene (PBD), polyvinylchloride (PVC), polypropylene (PP), or polyethylene (PE).

The administration set with filter **must** be primed with either 5% dextrose injection or 0.9% sodium chloride injection prior to the initiation of each RYBREVANT® infusion.

Do not infuse RYBREVANT® concomitantly in the same intravenous line with other agents.

Administer RYBREVANT® in combination with carboplatin and pemetrexed infusions every 3 weeks intravenously until disease progression or unacceptable toxicity.

Administer RYBREVANT® via a peripheral line on Week 1 and Week 2 to reduce the risk of IRRs during initial treatment.

RYBREVANT® may be administered via central line for subsequent weeks.

For the initial infusion, prepare RYBREVANT® as close to administration time as possible to allow for the possibility of extended infusion time in the event of an IRR.

Administer the pemetrexed infusion first, carboplatin infusion second, and the RYBREVANT® infusion last.

Dosage and Administration[1] (cont'd)

Infusion Rates of RYBREVANT® in Combination With Carboplatin and Pemetrexed for Treatment of NSCLC

Body Weight Less Than 80 kg

Week	Dose (per 250 mL bag)	Initial Infusion Rate	Subsequent Infusion Rate*
Week 1 (split-dose infusion)			
Week 1, Day 1	350 mg	50 mL/hr	75 mL/hr
Week 1, Day 2	1,050 mg	33 mL/hr	50 mL/hr
Week 2	1,400 mg	65 mL/hr	
Week 3	1,400 mg	85 mL/hr	
Week 4	1,400 mg	125 mL/hr	
Weeks 5 and 6	No dose		
Week 7 and every 3 weeks thereafter	1,750 mg	125 mL/hr	

Body Weight Greater Than or Equal to 80 kg

Week	Dose (per 250 mL bag)	Initial Infusion Rate	Subsequent Infusion Rate*
Week 1 (split-dose infusion)			
Week 1, Day 1	350 mg	50 mL/hr	75 mL/hr
Week 1, Day 2	1,400 mg	25 mL/hr	50 mL/hr
Week 2	1,750 mg	65 mL/hr	
Week 3	1,750 mg	85 mL/hr	
Week 4	1,750 mg	125 mL/hr	
Weeks 5 and 6	No dose		
Week 7 and every 3 weeks thereafter	2,100 mg	125 mL/hr	

*In the absence of IRRs, increase the initial infusion rate to the subsequent infusion rate after 2 hours based on patient tolerance. Total infusion time is approximately 4 to 6 hours for Day 1 and 6 to 8 hours for Day 2. Subsequent infusion time is approximately 2 hours.

Indication[1]

RYBREVANT® 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.

Dosage and Administration[1]

The recommended dosages of RYBREVANT® as a single agent, based on baseline body weight, are detailed below. Administer RYBREVANT® until disease progression or unacceptable toxicity.

Recommended Dosage Schedule for RYBREVANT® as a Single Agent—Every 2-Week Dosing

Body Weight at Baseline*	Recommended Dose	Dosing Schedule
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
		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
		Every 2 weeks starting at Week 7 onward

*Dose adjustment is not required for subsequent body weight changes. Please refer to the full Prescribing Information for RYBREVANT® for complete dosage and administration information, including dose modifications for adverse reactions.

Dosage and Administration[1] (cont'd)

Recommended Premedications[1]

Prior to initial infusion of RYBREVANT® (Week 1, Days 1 and 2), administer premedications to reduce the risk of IRRs, as detailed in the table below:

Medication	Dose	Route of Administration	Dosing Window Prior to RYBREVANT® Administration
Antihistamine*	Diphenhydramine (25 to 50 mg) or equivalent	Intravenous	15 to 30 minutes
		Oral	30 to 60 minutes
Antipyretic*	Acetaminophen (650 to 1,000 mg)	Intravenous	15 to 30 minutes
		Oral	30 to 60 minutes
Glucocorticoid†	Dexamethasone (20 mg) or equivalent	Intravenous	45 to 60 minutes
Glucocorticoid‡	Dexamethasone (10 mg) or equivalent	Intravenous	45 to 60 minutes

*Required at all doses.
†Required at initial dose (Week 1, Day 1).
‡Required at second dose (Week 1, Day 2); optional for subsequent doses.

Glucocorticoid administration is required for Week 1, Days 1 and 2 doses only and upon re-initiation after prolonged dose interruptions, then as necessary for subsequent infusions. Administer both antihistamine and antipyretic prior to all infusions.

Administration[1]

Administer the diluted RYBREVANT® solution by intravenous infusion using an infusion set fitted with a flow regulator and with an in-line, sterile, nonpyrogenic, low protein-binding PES filter (pore size 0.2 micrometer).

Administration sets must be made of either PU, PBD, PVC, PP, or PE.

The administration set with filter **must** be primed with either 5% dextrose injection or 0.9% sodium chloride injection prior to the initiation of each RYBREVANT® infusion.

Do not infuse RYBREVANT® concomitantly in the same intravenous line with other agents.

Administer RYBREVANT® as a single agent infusion every 2 weeks intravenously until disease progression or unacceptable toxicity according to the infusion rates on page 12.

Administer RYBREVANT® via a peripheral line on Week 1 and Week 2 to reduce the risk of IRRs during initial treatment.

RYBREVANT® may be administered via central line for subsequent weeks.

For the initial infusion, prepare RYBREVANT® as close to administration time as possible to allow for the possibility of extended infusion time in the event of an IRR.

Dosage and Administration[1] (cont'd)

Infusion Rates of RYBREVANT® as a Single Agent

Body Weight Less Than 80 kg

Week	Dose (per 250 mL bag)	Initial Infusion Rate	Subsequent Infusion Rate*
Week 1 (split-dose infusion)			
Week 1, Day 1	350 mg	50 mL/hr	75 mL/hr
Week 1, Day 2	700 mg	50 mL/hr	75 mL/hr
Week 2	1,050 mg	85 mL/hr	
Week 3	1,050 mg	125 mL/hr	
Week 4	1,050 mg	125 mL/hr	
Week 5	1,050 mg	125 mL/hr	
Week 6	No dose		
Week 7 and every 2 weeks thereafter	1,050 mg	125 mL/hr	

Body Weight Greater Than or Equal to 80 kg

Week	Dose (per 250 mL bag)	Initial Infusion Rate	Subsequent Infusion Rate*
Week 1 (split-dose infusion)			
Week 1, Day 1	350 mg	50 mL/hr	75 mL/hr
Week 1, Day 2	1,050 mg	35 mL/hr	50 mL/hr
Week 2	1,400 mg	65 mL/hr	
Week 3	1,400 mg	85 mL/hr	
Week 4	1,400 mg	125 mL/hr	
Week 5	1,400 mg	125 mL/hr	
Week 6	No dose		
Week 7 and every 2 weeks thereafter	1,400 mg	125 mL/hr	

*In the absence of IRRs, increase the initial infusion rate to the subsequent infusion rate after 2 hours based on patient tolerance. Total infusion time is approximately 4 to 6 hours for Day 1 and 6 to 8 hours for Day 2. Subsequent infusion time is approximately 2 hours.

Please see Important Safety Information on pages 36–41 and read full Prescribing Information for RYBREVANT®.

NOTE: All content in the Coding section applies to both RYBREVANT® as a single agent and RYBREVANT® + chemotherapy unless otherwise specified.

Coding

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.[6]

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[8]	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
C34.2	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 NSCLC with *EGFR* exon 20 insertion mutations post platinum-based chemotherapy, also consider[7]:	
Z92.21	Personal history of antineoplastic chemotherapy

*These codes are not intended to be promotional or to encourage or suggest the 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.

EGFR, epidermal growth factor receptor; FDA, U.S. Food and Drug Administration; NSCLC, non-small cell lung cancer.

Coding for RYBREVANT®

HCPCS Codes

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[8]

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 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
5	1,750 mg	875
6	2,100 mg	1,050

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.

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)[9] and claims for many private payers.[10] 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	Each single-dose vial contains 350 mg/7 mL (50 mg/mL) RYBREVANT®

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.

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
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

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). The 1,750 mg dose requires 5 vials (7 mL x 5 = 35 NDC units). The 2,100 mg dose requires 6 vials (7 mL x 6 = 42 NDC units). Accurate NDC coding typically requires reporting the following components in this order[9]:

- 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**
- 1,750 mg dose - **N457894050101 ML35**
- 2,100 mg dose - **N457894050101 ML42**

Coding for Administration

CPT® Codes

Current Procedural Terminology (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.[5]

RYBREVANT® + chemotherapy for 2L NSCLC with *EGFR*+ mutations* after progression on an *EGFR* TKI or 1L NSCLC with *EGFR* exon 20 insertion mutations

When administering RYBREVANT® in combination with carboplatin and pemetrexed, infuse pemetrexed first, carboplatin second, and RYBREVANT® last.[1] Only 1 "initial" service code should be reported for a given date, unless protocol requires that 2 separate IV sites must be used.[5] When coding multiple drug administration services on the same date, follow CPT® guidelines and the infusion hierarchy:

- **Physician office:** the initial infusion is the key or primary reason for the encounter, irrespective of the temporal order in which infusions or injections occur[5]
- **Hospital outpatient department (HOPD):** chemotherapy services are primary to therapeutic, prophylactic, and diagnostic services, which are primary to hydration; infusions are primary to IV pushes, which are primary to injections[5]

**EGFR+* includes exon 19 deletions and exon 21 L858R substitution mutations.
1L, first line; 2L, second line; IV, intravenous; TKI, tyrosine kinase inhibitor.

Please see Important Safety Information on pages 36–41 and read full Prescribing Information for RYBREVANT®.

Coding for Administration (cont'd)

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[5]	Description[5]
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

*These codes are not intended to be promotional or to encourage or suggest the 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.

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 provider-based departments (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[11]

Code	Name	Descriptions
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

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 Outpatient Prospective Payment System (OPPS) since hospitals' assignment of cost varies. 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.[12] The following revenue codes may be applicable to CMS-1450 claims for RYBREVANT® and its administration:

Revenue Codes and Descriptions[13]

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

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 healthcare professional (HCP) on the same day of the procedure or other service[5]	• Patient requires distinct E/M service in addition to drug administration procedure[5] • Must be substantiated with documentation[5] • Append the modifier to the relevant E/M code[5]	✓ Required by Medicare	✓ Required by Medicare
PO*	Excepted service provided at an off-campus, outpatient, PBD of a hospital[12]	• Report with every HCPCS code for all outpatient hospital items and services furnished in an excepted off-campus PBD of a hospital[13]	N/A	✓ Required by Medicare
PN*	Nonexcepted service provided at an off-campus, outpatient, PBD of a hospital[12]	• Report on each claim line for nonexcepted items and services including those for which payment will not be adjusted, such as separately payable drugs[13] • Modifier PN will trigger a payment rate under the Medicare Physician Fee Schedule (PFS)[13]	N/A	✓ Required by Medicare
JW	Drug amount discarded/ not administered to any patient[14]	• Unused drug remains after applicable dose is administered from single-use vial[15] • CMS issued a discarded drug policy and requires use of the JW modifier; other payer policies may vary[15] • 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[15]	✓ Required by Medicare	✓ Required by Medicare
JZ	No discarded drug amounts[14]	• Applies to single-dose containers of drugs for which the JW modifier would be required if there were discarded amounts[15] • Append the modifier to the HCPCS drug code on the claim line with the administered amount[15]	✓ 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.[13]

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[12]

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

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.[15]

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.[15]

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.[15] If the incremental infusion time is 30 minutes or less, the time is not to be billed separately.[15] 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).[16] Payer policies may vary.

Sample Claim Forms

CMS-1500 and CMS-1450

RYBREVANT® + chemotherapy for 2L NSCLC with *EGFR*+ mutations* after progression on an *EGFR* TKI or 1L NSCLC with *EGFR* exon 20 insertion mutations

RYBREVANT® as a single agent for NSCLC with *EGFR* exon 20 insertion mutations post platinum-based chemotherapy

**EGFR*+ includes exon 19 deletions and exon 21 L858R substitution mutations.

1L, first line; 2L, second line; CMS, Centers for Medicare & Medicaid Services; *EGFR*, epidermal growth factor receptor; NSCLC, non-small cell lung cancer; TKI, tyrosine kinase inhibitor.

Please see Important Safety Information on pages 36–41 and read full Prescribing Information for RYBREVANT®.

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

Filing Healthcare Claims

Physician Office Claims (Form CMS-1500)

Form CMS-1500 is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from suppliers and noninstitutional providers that qualify for a waiver from the Administrative Simplification Compliance Act requirement for electronic submission of claims. It has also been adopted by the TRICARE Program. 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/clm104c26.pdf

The 837P (Professional) is the standard format used by healthcare providers and suppliers to transmit healthcare claims electronically. The American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N 837P (Professional) Version 5010A1 is the current electronic claim version. Data elements in the CMS uniform electronic billing specifications are consistent with the hard copy data set to the extent that 1 processing system can handle both. Medicare Administrative Contractors (MACs) may include a crosswalk between the ASC X12N 837P and the CMS-1500 on their websites.

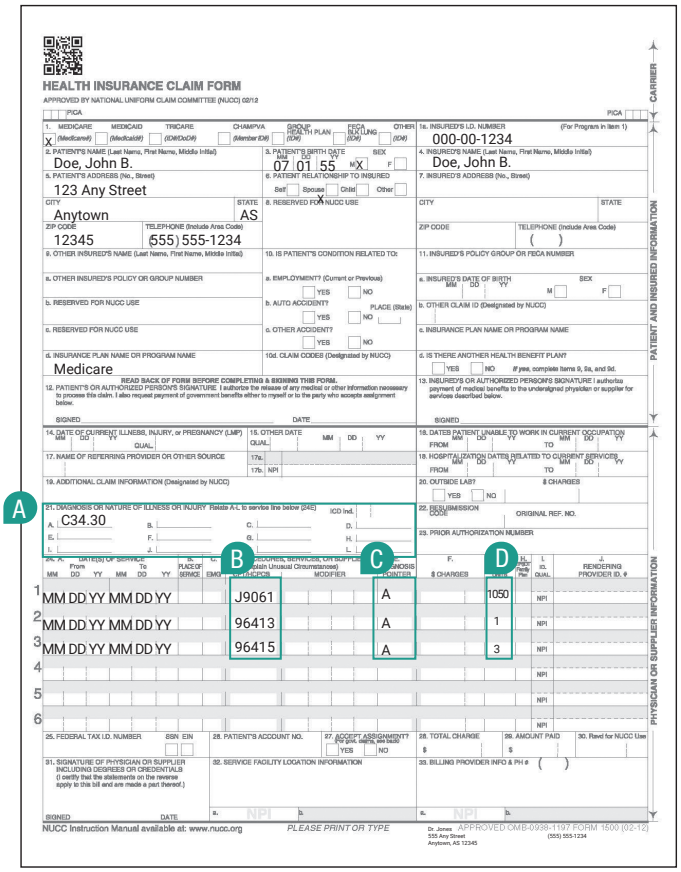
Hospital Outpatient Claims (Form CMS-1450)

Form CMS-1450, also known as the UB-04, is a uniform institutional provider bill suitable for use in billing multiple third-party payers. It is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from hospitals, including Hospital Outpatient Departments (HOPDs). Because the form serves many payers, a particular payer may not need some data elements. 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

The 837I (Institutional) is the standard format used by institutional providers to transmit healthcare claims electronically. The ANSI ASC X12N 837I (Institutional) Version 5010A2 is the current electronic claim version. Data elements in the uniform electronic billing specifications are consistent with the hard copy data set to the extent that 1 processing system can handle both. MACs may include a crosswalk between the ASC X12N 837I and the CMS-1450 on their websites.

For more information on electronic claims, please see the CMS website at:
https://www.cms.gov/medicare/billing/electronicbillingeditrans/healthcareclaims.html

Physician Office Sample Claim Form (CMS-1500) for RYBREVANT® 2,100 mg + Chemotherapy



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

When administering RYBREVANT® in combination with carboplatin and pemetrexed, infuse pemetrexed first, carboplatin second, and RYBREVANT® last. Follow the manufacturers' Prescribing Information for complete dosing information about the other drugs.[1] When coding multiple drug administration services on the same date, follow CPT® guidelines and the infusion hierarchy. For professional claims (Form CMS-1500), the initial infusion is the key or primary reason for the encounter reported, irrespective of the temporal order in which infusions or injections are administered.[5]

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.

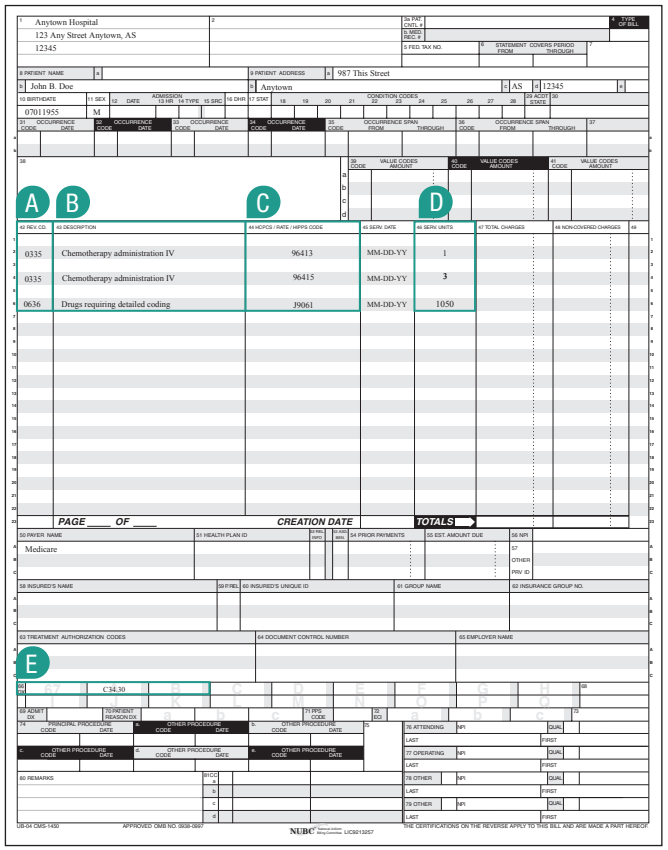
RYBREVANT®
J9061 – Enter the amount of drug in HCPCS units according to the drug-specific descriptor and dose:
- 2 mg = 1 unit
- 2,100 mg = 1,050 units

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. Fiscal Intermediaries (FIs)/MACs and/or state Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Hospital Outpatient Department Sample Claim Form (CMS-1450) for RYBREVANT® 2,100 mg + Chemotherapy



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
- 2,100 mg = 1,050 units

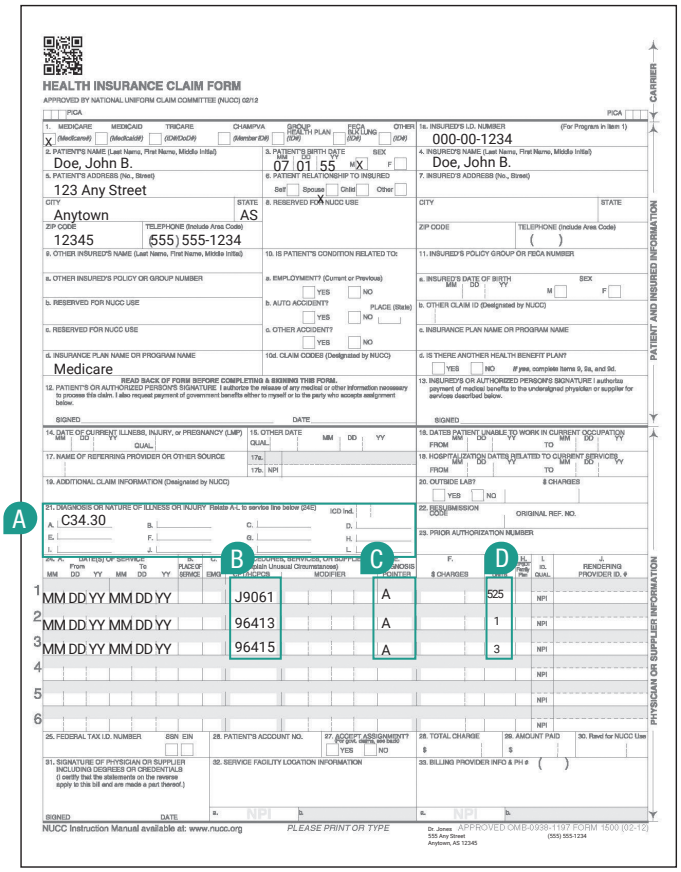
When administering RYBREVANT® in combination with carboplatin and pemetrexed, infuse pemetrexed first, carboplatin second, and RYBREVANT® last. Follow the manufacturers' Prescribing Information for complete dosing information about the other drugs.[1] When coding multiple drug administration services on the same date, follow CPT® guidelines and the infusion hierarchy. For facility claims (Form CMS-1450), chemotherapy services are primary to therapeutic, prophylactic, diagnostic services, which are primary to hydration; infusions are primary to intravenous pushes, which are primary to injections.[5]

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 state Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

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



HEALTH INSURANCE CLAIM FORM

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

1. MEDICARE X (Medicare#) | MEDICAID (Medicaid#) | TRICARE (ID#/DoD#) | CHAMPVA (Member ID#) | GROUP HEALTH PLAN (ID#) | FECA BLK LUNG (ID#) | OTHER (ID#)

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

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, John B.

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

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, John B.

5. PATIENT'S ADDRESS (No., Street): 123 Any Street

6. PATIENT RELATIONSHIP TO INSURED: Self X | Spouse | Child | Other

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

CITY: Anytown | STATE: AS

8. RESERVED FOR NUCC USE

ZIP CODE: 12345 | TELEPHONE (Include Area Code): (555) 555-1234

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial):

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER:

a. OTHER INSURED'S POLICY OR GROUP NUMBER:

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY | SEX M F

b. RESERVED FOR NUCC USE:

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC):

c. RESERVED FOR NUCC USE:

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME:

d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare

10d. CLAIM CODES (Designated by NUCC):

6. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE: I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED: DATE:

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE: I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED:

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. C34.30 B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	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 SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

Dr. Jones
555 Any Street
Anytown, AS 12345

APPROVED OMB-0938-1197 FORM 1500 (02-12)

(555) 555-1234

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

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.

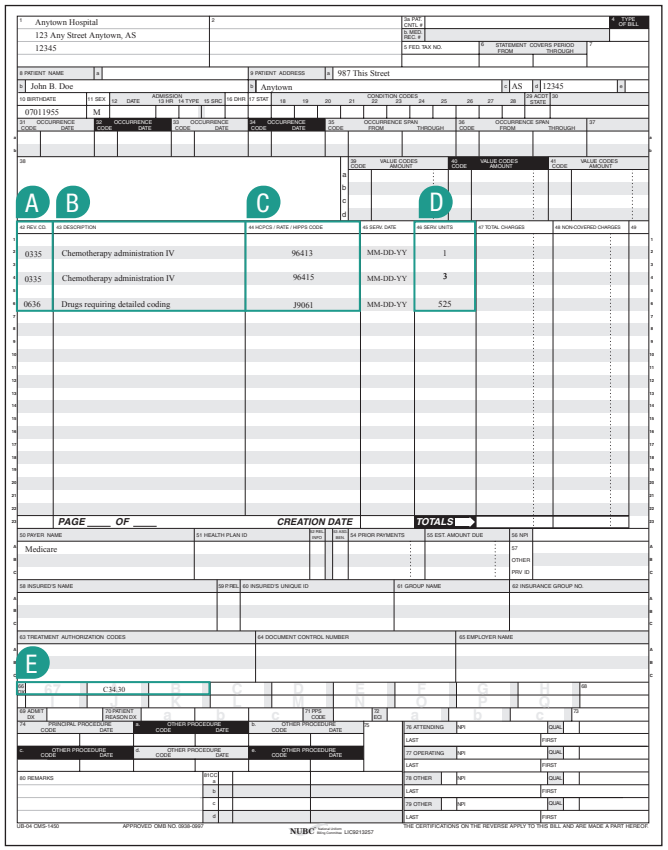
D **Item 24G** – Enter the units for items/services provided.

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 = 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 state Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

Hospital Outpatient Department Sample Claim Form (CMS-1450) for RYBREVANT® as a Single Agent 1,050 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
- 1,050 mg = 525 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 state Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

Appendices and References

Access Letter Templates

Some payers may require that treating physicians complete a Letter of Medical Necessity or request an exception before patients can obtain coverage for a specific therapy. We have provided sample letters below. Prior authorizations, exceptions, and appeals information and sample letter templates are available at janssencarepath.com/hcp/rybrevant/insurance-coverage/

Sample Letter of Medical Necessity

[Insert Physician Letterhead]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address]
[Insert City, State Zip]

RE: Member Name: [Insert Member Name]
Member Number: [Insert Member Number]
Group Number: [Insert Group Number]

REQUEST: Authorization for treatment with RYBREVANT® (amivantamab-vmjw)
DIAGNOSIS: [Insert Diagnosis] [Insert ICD]
DOSE AND FREQUENCY: [Insert Dose & Frequency]
REQUEST TYPE: ☐ Standard ☐ EXPEDITED

Dear [Insert Name of Medical Director]:

I am writing to request a **formulary exception** for the above-mentioned patient to receive treatment with RYBREVANT® for [insert indication]. My request is supported by the following:

Summary of Patient's Diagnosis
[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

Summary of Patient's History
[Insert:

- Previous therapies/procedures, including dose and duration, and response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type: Inpatient, hospital outpatient, outpatient clinic, private practice, or other
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with RYBREVANT®

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment
[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of RYBREVANT®, I believe treatment with RYBREVANT® at this time is medically necessary, and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for RYBREVANT® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,
[Insert Physician Name and Participating Provider Number]

Enclosures [Include full Prescribing Information and the additional support noted above]

This letter is available at:
https://asset.janssencarepath.com/document/rybrevant-letter-of-medical-necessity.docx

PLEASE NOTE: These are sample letters. Use of these letters does not guarantee reimbursement.

Access Letter Templates (cont'd)

Sample Letter for a Medical Exception Request

[Insert Physician Letterhead]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address]
[Insert City, State Zip]

RE: Member Name: [Insert Member Name]
Member Number: [Insert Member Number]
Group Number: [Insert Group Number]

REQUEST: Authorization for treatment with RYBREVANT® (amivantamab-vmjw)
DIAGNOSIS: [Insert Diagnosis] [Insert ICD]
DOSE AND FREQUENCY: [Insert Dose & Frequency]
REQUEST TYPE: ☐ Standard ☐ EXPEDITED

Dear [Insert Name of Medical Director]:

I am writing to request a **formulary exception** for the above-mentioned patient to receive treatment with RYBREVANT® for [insert indication]. My request is supported by the following:

Summary of Patient's Diagnosis
[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

Summary of Patient's History
[Insert:

- Previous therapies/procedures, including dose and duration, and response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type: Inpatient, hospital outpatient, outpatient clinic, private practice, or other
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with RYBREVANT®

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment
[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of RYBREVANT®, I believe treatment with RYBREVANT® at this time is medically necessary, and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for RYBREVANT® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,
[Insert Physician Name and Participating Provider Number]

Enclosures [Include full Prescribing Information and the additional support noted above]

This letter is available at:
https://asset.janssencarepath.com/document/rybrevant-letter-of-exception.docx

PLEASE NOTE: These are sample letters. Use of these letters does not guarantee reimbursement.

Specialty Distributors

Authorized Specialty Distributor Network

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

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

Once you have made the clinical decision to prescribe RYBREVANT®, 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®, 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®—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® 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–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 36–41 and read full Prescribing Information for RYBREVANT®.

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

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); 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.

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Please read full Prescribing Information for LAZCLUZE™.

RYBREVANT® (amivantamab-vmjw)
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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.

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.

Please read full Prescribing Information for RYBREVANT®.
Please read 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)

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 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.

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Please read full Prescribing Information for LAZCLUZE™.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Dermatologic Adverse Reactions (cont'd)

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. 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.

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Please read full Prescribing Information for LAZCLUZE™.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Embryo-Fetal Toxicity (cont'd)

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).

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%),

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Please read full Prescribing Information for LAZCLUZE™.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Adverse Reactions (cont'd)

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.

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.

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Please read full Prescribing Information for LAZCLUZE™.

cp-213274v6

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