RYBREVANT®
(amivantamab-vmjw)

Injection for IV Use | 350 mg/7 mL (50 mg/mL)

Access & Reimbursement Guide

Please read full Important Safety Information on pages 27-28, and read full Prescribing Information for RYBREVANT®.

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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 Janssen Biotech, Inc., that these codes will be appropriate or that reimbursement will be made. It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. We strongly recommend you consult the payer organization for its reimbursement policies.

INDICATION

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

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

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

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

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

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Companion Diagnostic Test (CDx) for *EGFR* Alterations

Select patients for treatment with RYBREVANT® based on the presence of *EGFR* exon 20 insertion mutations. Information on FDA-approved tests is available at: http://www.fda.gov/CompanionDiagnostics.

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

Coverage

Biomarker testing is typically a covered benefit, but requirements and patient cost-sharing may vary by payer:

Payer Type	Prior Authorization Requirement	Lab: In-network Requirement	Patient Cost-Sharing	Verification of Benefits Recommended
Medicare ("Original")	No	Must participate in Medicare	20%*	Yes
Medicare Advantage	Often	Yes	Yes†	Yes
Commercial	Often	Usually	Yes‡	Yes
Medicaid	Unknown	Must participate in Medicaid	Yes§	Yes

*Patient cost-sharing may be offset by Medicare Supplement (Medigap) insurance or other secondary payer.
†Up to 20% until patients reach their plan's annual out-of-pocket limit.
‡Varies by payer and plan.
§Often nominal; varies by state program and patient income level.

Companion Diagnostic Test (CDx) for *EGFR* Alterations (continued)

Coding

When verifying benefits, you may be asked to identify the code for the requested test. The following codes and descriptors are provided for your reference:

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

Ordering

Contact your reference laboratory to see if they can run an *EGFR* exon 20 test.

Dosing and Administration[1]

Recommended Dosage[1]

The recommended doses of RYBREVANT®, based on baseline body weight, are provided in Table 1. Administer RYBREVANT® weekly for 4 weeks, with the initial dose as a split infusion in Week 1 on Day 1 and Day 2, then administer every 2 weeks starting at Week 5 until disease progression or unacceptable toxicity. Administer premedications before each RYBREVANT® infusion as recommended. Administer diluted RYBREVANT® intravenously according to the infusion rates in Table 3.

Dosing Schedule for RYBREVANT®

Weeks	Schedule
Weeks 1 to 4	Weekly (total of 4 doses)
	Week 1 - split infusion on Day 1 and Day 2
	Weeks 2 to 4 - infusion on Day 1
Week 5 onwards	Every 2 weeks starting at Week 5

Table 1: Recommended Dose of RYBREVANT®

Body Weight at Baseline*	Recommended Dose	Number of 350 mg/7 mL RYBREVANT® Vials
Less than 80 kg	1050 mg	3
Greater than or equal to 80 kg	1400 mg	4

*Dose adjustments not required for subsequent body weight changes.

Recommended Premedications[1]

Prior to initial infusion of RYBREVANT® (Week 1, Days 1 and 2), administer premedication as described in Table 2 to reduce the risk of infusion-related reactions:

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Infusion-Related Reactions (continued)

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

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Dosing and Administration[1] (continued)

Table 2: Premedications

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 (10 mg) or Methylprednisolone (40 mg) or equivalent	Intravenous	45 to 60 minutes

*Required at all doses.
‡Required at initial dose (Week 1, Days 1 and 2); optional for subsequent doses.

Administer both antihistamine and antipyretic prior to all infusions. Glucocorticoid administration required for Week 1, Days 1 and 2 doses only and as necessary for subsequent infusions.

Administration[1]

Administer the diluted solution by intravenous infusion using an infusion set fitted with a flow regulator and with an in-line, sterile, non-pyrogenic, low protein-binding polyethersulfone (PES) filter (pore size 0.2 micrometer) primed with diluent only. Administration sets must be made of either polyurethane (PU), polybutadiene (PBD), polyvinyl chloride (PVC), polypropylene (PP), or polyethylene (PE).

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

Administer RYBREVANT® via a peripheral line on Week 1 and Week 2 given the high incidence of infusion-related reactions 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 infusion-related reaction.

Administer RYBREVANT® infusion intravenously according to the infusion rates in Table 3.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Interstitial Lung Disease/Pneumonitis

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

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Dosing and Administration[1] (continued)

Table 3: Infusion Rates for RYBREVANT® Administration[1]

1050 mg Dose			
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	1050 mg	85 mL/hr	
Week 3	1050 mg	125 mL/hr	
Week 4	1050 mg	125 mL/hr	
Subsequent weeks*	1050 mg	125 mL/hr	

1400 mg Dose			
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	1050 mg	35 mL/hr	50 mL/hr
Week 2	1400 mg	65 mL/hr	
Week 3	1400 mg	85 mL/hr	
Week 4	1400 mg	125 mL/hr	
Subsequent weeks*	1400 mg	125 mL/hr	

*Starting at Week 5, patients are dosed every 2 weeks.
†Increase the initial infusion rate to the subsequent infusion rate after 2 hours in the absence of infusion-related reactions.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Interstitial Lung Disease/Pneumonitis (continued)

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

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Coding for Diagnosis

ICD-10-CM Diagnosis Codes

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 7th character, if applicable.[2]

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.

Table 4: ICD-10-CM Diagnosis Codes[3] for Consideration*

Code	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

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

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

Coding for RYBREVANT®

HCPCS Codes

Drugs are typically reported with Healthcare Common Procedure Coding System (HCPCS) codes assigned by the Centers for Medicare & Medicaid Services (CMS). Effective January 1, 2022, the HCPCS code for RYBREVANT® is:

- **J9061 - Injection, amivantamab-vmjw, 2 mg.** [4,5]

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

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. Table 5 illustrates the correlation between RYBREVANT® vials, milligrams, and HCPCS units used for billing:

Table 5: RYBREVANT® HCPCS Billing Units

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

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage 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.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Dermatologic Adverse Reactions

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

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Coding for RYBREVANT® (continued)

National Drug Code (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),[6] Medicaid fee-for-service claims,[6] and claims for many private payers.[7,8] 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:

Table 6: 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-use 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.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Dermatologic Adverse Reactions (continued)

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

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

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Coding for RYBREVANT® (continued)

NDC Units of Measure

Reporting 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®:

Table 7: RYBREVANT® NDC Units

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

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 1050 mg dose requires 3 vials (7 mL x 3 = 21 NDC units). The 1400 mg dose requires 4 vials (7 mL x 4 = 28 NDC units).

Accurate NDC coding typically requires reporting the following components on the claim[8]:

- the 11-digit NDC in a 5-4-2 configuration
- the correct NDC unit of measure (ie, ML)
- the number of NDC units dispensed
- the qualifier "N4" preceding the NDC

Using the same RYBREVANT® examples illustrated above, here is how NDC coding would appear on a claim:

- 1050 mg dose - **N457894050101 ML21**
- 1400 mg dose - **N457894050101 ML28**

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Dermatologic Adverse Reactions (continued)

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

Coding for Administration

CPT® Codes for Administration

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 any particular claim based on the patient's condition, the items and services that are furnished, and any specific payer requirements.

The CPT® codes commonly associated with the administration of RYBREVANT® (amivantamab-vmjw) are:

- 96413 – Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug[9]
- 96415 – Each additional hour (list separately in addition to code for primary procedure)[9]

These codes, often referred to as "complex" infusion codes, apply to the parenteral administration of chemotherapy and also anti-neoplastic agents provided for treatment of non-cancer diagnoses, or to substances such as certain monoclonal antibodies and other biologic response modifiers.[9] Complex drug administration services require special considerations to prepare, dose, or dispose, and typically entail professional skill and patient monitoring significantly beyond that required for therapeutic infusions.[9]

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Ocular Toxicity

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

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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.

Place of Service (POS) Codes

The POS code set provides setting information necessary to appropriately pay professional service claims. The place of service 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)[6]. 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.

Table 8: Place of Service Codes[10]

Code	Name	Descriptor
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 provider 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 (continued)

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 Outpatient Prospective Payment System (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.[11] The following revenue codes may be applicable to CMS-1450 claims for RYBREVANT® and its administration:

Code	Descriptor
0335	Chemotherapy administration – IV (intravenous)[12]
0510	Clinic, general[12]
0636	Pharmacy, drugs requiring detailed coding[12]

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Embryo-Fetal Toxicity

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

Please read full Important Safety Information on pages 27-28, and read full Prescribing Information for RYBREVANT®.

Other Coding Considerations (continued)

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 table summarizes modifiers that may be applicable to RYBREVANT® coding and billing in physician offices and hospital outpatient departments.

Table 9: Summary of CPT® and HCPCS Modifiers

Modifier	Description	Indication and Placement	CMS-1500 Item 24D	CMS-1450 Locator Box 44
25	Significant, separately identifiable evaluation and management (E/M) service by the same physician or other qualified healthcare professional (HCP) on the same day of the procedure or other service[9]	• Patient requires distinct E/M service in addition to the infusion procedure[9] • Must be substantiated with relevant documentation[9] • Append the modifier to the relevant E/M code[9]	✓ Required by Medicare	✓ Required by Medicare
JG	Drug or biological acquired with 340B Drug Pricing Program Discount[11]	• Must be reported by providers that are NOT excepted* from the 340B payment policy[11] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[11]	N/A	✓ Required by Medicare
TB	Drug or biological acquired with the 340B Drug Pricing Program Discount, reported for informational purposes[11]	• Must be reported by providers that ARE excepted* from the 340B payment policy[11] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[11]	N/A	✓ Required by Medicare

*The following provider types are excepted from the 340B payment policy: rural sole community hospitals, children's hospitals, and Prospective Payment System (PPS)-exempt cancer hospitals.

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

Other Coding Considerations (continued)

Same Day Evaluation and Management 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. The policy states:

CPT® code 99211 cannot be paid if it is billed, with or without modifier 25, with a chemotherapy or nonchemotherapy drug administration code.[13]

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.[13]

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.[13] If the incremental infusion time is 30 minutes or less, the time is not to be billed separately. 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 (ie, when drug is not flowing, or 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 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 for free-of-charge drugs, it may be necessary to include drug information on the claim and enter "$0.01" charges.[14] Payer policies may vary.

Filing Healthcare Claims

Physician Office Claims (CMS-1500)

The 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 the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 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 ANSI 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 may include a crosswalk between the ASC X12N 837P and the CMS-1500 on their websites.

Hospital Outpatient Claims (CMS-1450)

The 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 it serves many payers, a particular payer may not need some data elements. For detailed guidance on completing the CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 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 one processing system can handle both. Medicare Administrative Contractors 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

RYBREVANT® (amivantamab-vmjw)
Physician Office Sample Claim Form: CMS-1500

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

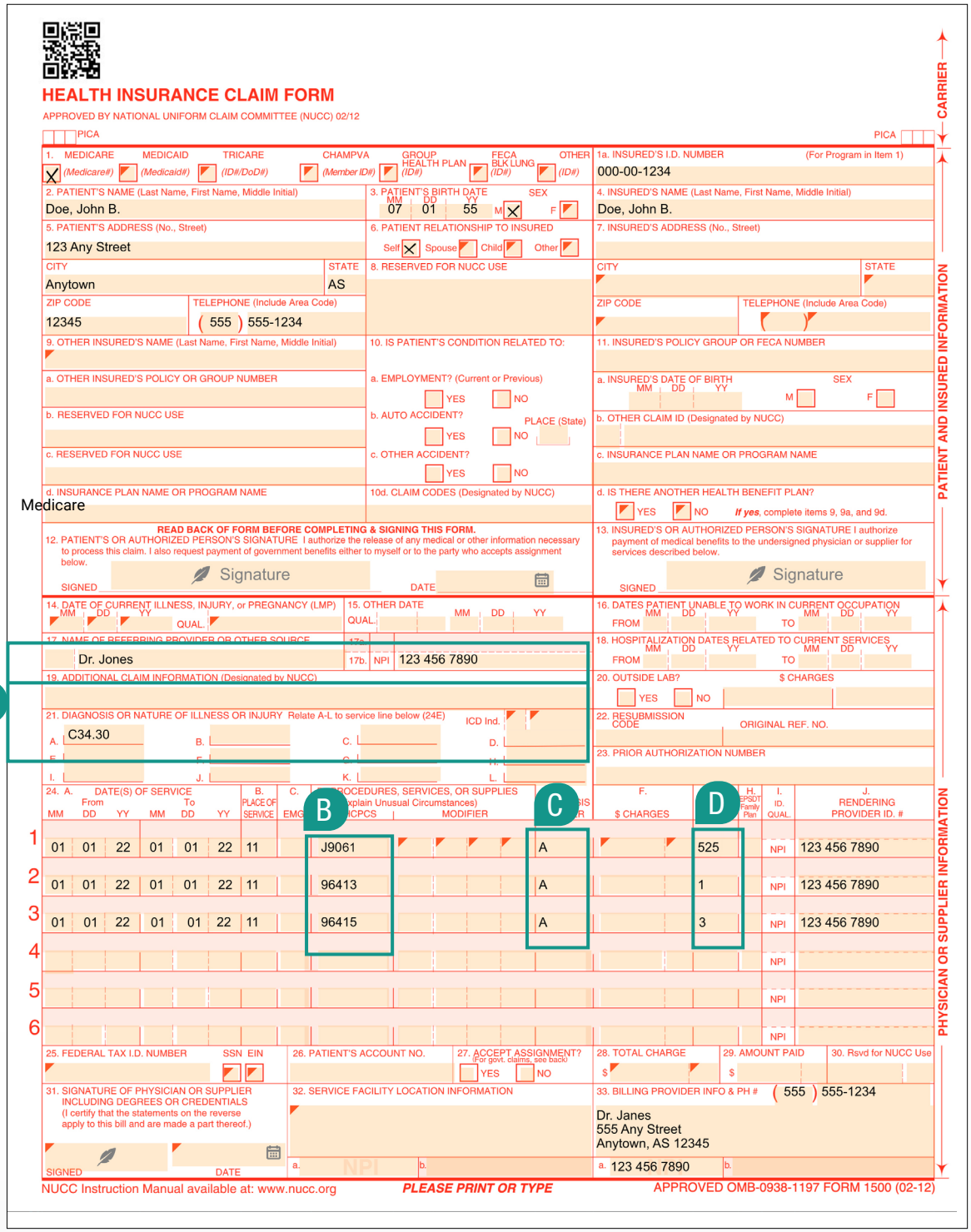
Item 24G – Enter the units for items/services provided.

RYBREVANT®
J9061 – Enter the amount of drug in HCPCS units according to the drug-specific descriptor and dose:
- 2-mg = 1 unit
- 1050-mg dose = 525 units
- 1400-mg dose = 700 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 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)/Medicare Administrative Contractors (MACs) and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

Physician Office Claim (CMS-1500) Sample Claim: RYBREVANT® 1050-mg



HEALTH INSURANCE CLAIM FORM

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

PICA

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

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

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

CITY | STATE

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

ZIP CODE | TELEPHONE (Include Area Code)

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

10d. CLAIM CODES (Designated by NUCC)

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

Medicare

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 Signature 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 Signature

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: Dr. Jones

17a.

17b. NPI 123 456 7890

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 | PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS | MODIFIER | DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. #

	24A From	24A To	24B	24C	24D CPT/HCPCS	MODIFIER	24E	24F $ CHARGES	24G	24H	24I	24J
1	01 01 22	01 01 22	11		J9061		A		525		NPI	123 456 7890
2	01 01 22	01 01 22	11		96413		A		1		NPI	123 456 7890
3	01 01 22	01 01 22	11		96415		A		3		NPI	123 456 7890
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 # (555) 555-1234

Dr. Janes
555 Any Street
Anytown, AS 12345

a. 123 456 7890 b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

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

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

A

B

C

D

RYBREVANT® (amivantamab-vmjw) Hospital Outpatient Department Sample Claim Form: CMS-1450

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
- 1050-mg dose = 525 units
- 1400-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 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)/Medicare Administrative Contractors (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 (CMS-1450) Sample Claim: RYBREVANT® 1400-mg

1 Anytown Hospital 123 Any Street Anytown, AS 12345	2	3a PAT. CNTL #	4 TYPE OF BILL
		b. MED. REC. #	
		5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM THROUGH 7

8 PATIENT NAME	a		9 PATIENT ADDRESS	a	987 This Street			
b John B. Doe			b Anytown			c AS	d 12345	e

10 BIRTHDATE	11 SEX	12 ADMISSION DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT	CONDITION CODES 18 19 20 21 22 23 24 25 26 27 28	29 ACDT STATE	30
07011955	M									

31 OCCURRENCE CODE DATE	32 OCCURRENCE CODE DATE	33 OCCURRENCE CODE DATE	34 OCCURRENCE CODE DATE	35 OCCURRENCE SPAN CODE FROM THROUGH	36 OCCURRENCE SPAN CODE FROM THROUGH	37
a						a
b						b

38

39 VALUE CODES CODE AMOUNT	40 VALUE CODES CODE AMOUNT	41 VALUE CODES CODE AMOUNT
a		
b		
c		
d		

A B C D

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1								1
2	0335	Cherna adrninistration IV	96413	01-01-22	1			2
3								3
4	0335	Cherna adrninistration IV	96415	01-01-22	3			4
5								5
6	0636	Drugs requiring detailed coding	J9061	01-01-22	700			6
7–22								7–22
23		PAGE ____ OF ____	CREATION DATE		TOTALS			23

	50 PAYER NAME	51 HEALTH PLAN ID	52 REL. INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	
A	Medicare						57	A
B							OTHER	B
C							PRV ID	C

	58 INSURED'S NAME	59 P REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
A					
B					
C					

	63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME
A			
B			
C			

E

66 DX: C34.30

A B C D E F G H 68
I J K L M N O P Q

69 ADMIT DX	70 PATIENT REASON DX	a b c	71 PPS CODE	72 ECI	a b c	73

74 PRINCIPAL PROCEDURE CODE DATE	a. OTHER PROCEDURE CODE DATE	b. OTHER PROCEDURE CODE DATE	75
c. OTHER PROCEDURE CODE DATE	d. OTHER PROCEDURE CODE DATE	e. OTHER PROCEDURE CODE DATE	

80 REMARKS	81CC		
	a		
	b		
	c		
	d		

76 ATTENDING	NPI	QUAL	
LAST		FIRST	
77 OPERATING	NPI	QUAL	
LAST		FIRST	
78 OTHER	NPI	QUAL	
LAST		FIRST	
79 OTHER	NPI	QUAL	
LAST		FIRST	

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC® National Uniform Billing Committee LIC9213257 THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

Please read full Important Safety Information on pages 27-28, and read full Prescribing Information for RYBREVANT®.

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

Access Letter Templates

Some payers may require that treating physicians complete a Letter of Medical Necessity or request a medical exception before patients can obtain coverage for a specific therapy. We have provided sample letters below. Please visit **JanssenCarePath.com/RYBREVANT-LMN** and **JanssenCarePath.com/RYBREVANT-LOE** for digital sample letter templates.

Sample Letter of Medical Necessity: RYBREVANT® (amivantamab-vmjw)

[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 or name of individual responsible for prior authorization]:

I am writing to support my request for an **authorization** 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 (eg, inpatient, hospital outpatient, outpatient clinic, private practice, or other) and rationale (eg, compliance or closely monitoring patients)
- 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]

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

Access Letter Templates (continued)

Sample Letter for Medical Exception: RYBREVANT® (amivantamab-vmjw)

[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]

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
AmerisourceBergen	1-800-746-6273	1-800-547-9413	https://www.asdhealthcare.com
Cardinal Health Specialty Pharmaceutical Distribution	Physician Offices: 1-877-453-3972 Hospitals/All Others: 1-866-677-4844	1-614-652-7043	https://specialtyonline.cardinalhealth.com https://orderexpress.cardinalhealth.com
Cardinal PR 120 (Puerto Rico)	1-787-625-4200	1-787-625-4398	https://cardinalhealth.pr
CuraScript Specialty Distribution (Priority Healthcare)	1-877-599-7748	1-800-862-6208	https://curascriptsd.com/
McKesson Pharmaceutical Solutions & Services	1-877-625-2566	1-888-752-7626	https://connect.mckesson.com
McKesson Specialty Health	Oncology: 1-800-482-6700 Multispecialty: 1-855-477-9800	Oncology: 1-800-289-9285 Multispecialty: 1-800-800-5673	https://www.mckessonspecialtyhealth.com
AmerisourceBergen Oncology Supply	1-800-633-7555	1-800-248-8205	https://www.oncologysupply.com

NOTE: Janssen Biotech, Inc., does not endorse the use of any of the listed specialty distributors in particular.

Janssen CarePath

Janssen CarePath is your one source for access, affordability, and treatment support for your patients

Access support to help navigate payer processes

Janssen CarePath helps verify insurance coverage for your patients taking RYBREVANT® and provides reimbursement information.

Our offerings include:

- Benefits investigation support
- Prior authorization support and status monitoring
- Information on the exceptions and appeals process
- Coding and billing information, if needed
- Triage to specialty pharmacy providers, if needed
- Provider Portal at JanssenCarePathPortal.com for online benefits investigation, prior authorization support, and other resources
  - — Online Secure Messaging to ask a question, request a status update, or send missing information related to an existing case

Affordability support to help your patients start and stay on the treatment you prescribe

Janssen CarePath can help you find out what affordability assistance may be available for your patients taking RYBREVANT®.

Treatment support to help your patients get informed and stay on RYBREVANT®

Janssen CarePath provides additional support to your patients, including patient education, web-based resources, and personalized reminders.

Call a Janssen CarePath Care Coordinator at 877-CarePath (877-227-3728), Monday–Friday, 8:00 AM to 8:00 PM ET

Sign Up or Log In to the Provider Portal at JanssenCarePathPortal.com

Visit JanssenCarePath.com

Please read full Important Safety Information on pages 27-28, and read full Prescribing Information for RYBREVANT®.

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

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

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

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

Interstitial Lung Disease/Pneumonitis

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

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

Dermatologic Adverse Reactions

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

Please read full Important Safety Information on pages 27-28, and read full Prescribing Information for RYBREVANT®.

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

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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

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

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

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

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

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

cp-213274v2

References:
Amivantamab Access & Reimbursement Guide 2022

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12. Noridian Healthcare Solutions. Revenue Codes. Accessed November 19, 2021. https://med.noridianmedicare.com/web/jfa/topics/claim-submission/revenue-codes

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14. Centers for Medicare & Medicaid Services. Billing and Coding: Patients Supplied Donated or Free-of-Charge Drug (A55044). Accessed November 21, 2021. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55044&Cntrctr=364

Please read full Important Safety Information on pages 27-28, and read full Prescribing Information for RYBREVANT®.

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