RYBREVANT Faspro™

(amivantamab and hyaluronidase-lpuj)

Subcutaneous injection | 160 mg/2,000 units per mL

Access and Reimbursement Guide

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO*.

Introduction

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all CPT® and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Johnson & Johnson that these codes will be appropriate or that reimbursement will be made. It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. We strongly recommend you consult the payer organization for its reimbursement policies.

INDICATIONS[1]

RYBREVANT *FASPRO* (amivantamab and hyaluronidase-lpuj) is indicated:

- in combination with 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.

Johnson & Johnson is pleased to provide you with this detailed information to assist you in obtaining reimbursement for RYBREVANT *FASPRO* on behalf of your patients. We have developed this Access and Reimbursement Guide to provide coding information, access routes, and Important Safety Information that we hope will be helpful to you and your practice.

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

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

RYBREVANT *FASPRO* is contraindicated in patients with known hypersensitivity to hyaluronidase or to any of its excipients.

WARNINGS AND PRECAUTIONS for RYBREVANT *FASPRO* include: Hypersensitivity & ARRs, ILD/Pneumonitis, VTE, Dermatologic Adverse Reactions, Hepatotoxicity, Ocular Toxicity, and Embryo-Fetal Toxicity.

FDA, U.S. Food and Drug Administration.

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO* and LAZCLUZE® (lazertinib).

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Once you have made the clinical decision to prescribe RYBREVANT *FASPRO*, Johnson & Johnson has resources to help you support your patients.

J&J

withMe

Access and Affordability Resources Plus Personalized Support for Your Patients

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 *FASPRO*, providing benefits investigation support, prior authorization (PA) support, information on the exceptions and appeals process, and reimbursement information

Affordability resources for your patients

Help patients discover ways to afford their RYBREVANT *FASPRO* – regardless of their insurance type or even if they have no insurance at all

Personalized, free, 1-on-1 support for your patients throughout their treatment journey

Each patient's treatment journey is unique. We're here to help by providing personalized 1-on-1 support from oncology-trained nurses*

J&J withMe completes the benefits investigation for your patients; we:

- Perform a benefits investigation for pharmacy benefit requests, typically within 4 to 6 business hours
- Verify medical benefits, typically within 1 to 2 business days
- Review the benefits with you and your patients†
- Inform your patients about cost support options and offer care coordination support
- Keep you informed of any issues that come up, with timely alerts

J&J withMe can provide PA assistance‡; we:

- Research patients' health plan for PA requirements
- Provide payer-specific PA form for online completion by the provider in the portal
- Monitor status of the PA submission and notify your office 30 days before PA expiration

J&J withMe offers reimbursement information and other support resources:

- Payer considerations checklists§
- Coding and billing information§
- Customized Letter of Medical Necessity and Exception Letter on **Portal.JNJwithMe.com**. Sample letter templates are also available§
- Prescription triage to specialty pharmacy
- Information on the appeals process for administrative denials§
- Appeals research and tracking on **Portal.JNJwithMe.com**

Information about your patients' insurance coverage, cost support options, and treatment support is given by service providers for J&J withMe. The information you get does not require you or your patients to use any Johnson & Johnson product. Because the information we give you comes from outside sources, J&J withMe cannot promise the information will be complete.

The patient support and resources provided by J&J withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe RYBREVANT *FASPRO*.

*Care Navigators do not provide medical advice.

†Healthcare professionals may request that patients not be called concerning insurance benefits investigation by requesting a limitation of services. However, patients may request these services by contacting J&J withMe.

‡We do not fill out any information that requires the medical judgment of the prescriber, and only the prescriber can determine whether to pursue a PA.

§Available at **JNJwithMe.com**.

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Helping Your Patients Access RYBREVANT *FASPRO* Every Step of the Way

1 **Complete a benefits investigation** and connect your patients to a J&J withMe Care Navigator.*

Patient Enrollment Form

2 **Submit PA or medical exception request**

If request is denied, review the reason for denial and consider submitting an appeal.

Prior Authorization Checklist

Exception Considerations Checklist

Sample Letter of Medical Necessity and Exception Template

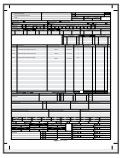
3 **Acquire RYBREVANT *FASPRO* via buy-and-bill**

Where to Order

4 **Submit a reimbursement claim for RYBREVANT *FASPRO* and procedure and track progress**

Track claim status and initiate appeals process, if denied.

CMS-1500



CMS-1450

Appeal Process Consideration Checklist

5 **Schedule the patient's next appointment**

Confirm the patient's health insurance has not changed and arrange the next appointment.

*Patients can also initiate enrollment themselves by visiting Account.JNJwithMe.com OR calling 833-JNJ-wMe1 **(833-565-9631)**, Monday through Friday, 8:00 am–8:00 pm ET.

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Coding Summary for RYBREVANT *FASPRO*

Information	Code type	Code and descriptor	Outpatient hospital	Physician office
Diagnosis	ICD-10-CM	**C34.00** Malignant neoplasm of unspecified main bronchus **C34.01** Malignant neoplasm of right main bronchus **C34.02** Malignant neoplasm of left main bronchus **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	✓	✓
RYBREVANT *FASPRO*	11-Digit NDC (5-4-2) Format	**57894-0510-01** One single-dose vial containing 1,600 mg of amivantamab and 20,000 units of hyaluronidase per 10 mL (160 mg and 2,000 units per mL) **57894-0514-01** One single-dose vial containing 2,240 mg of amivantamab and 28,000 units of hyaluronidase per 14 mL (160 mg and 2,000 units per mL) **57894-0515-01** One single-dose vial containing 2,400 mg of amivantamab and 30,000 units of hyaluronidase per 15 mL (160 mg and 2,000 units per mL) **57894-0522-01** One single-dose vial containing 3,520 mg of amivantamab and 44,000 units of hyaluronidase per 22 mL (160 mg and 2,000 units per mL)	As required by payer	As required by payer
	Revenue Codes	**0636** Pharmacy, drugs requiring detailed coding	✓	N/A
	HCPCS Level II	**J9062** Injection, amivantamab 5 mg and hyaluronidase-lpuj	As required by payer	As required by payer
Procedure	Revenue Codes	**0331** Chemotherapy administration, injection	✓	N/A
	CPT® Category I	**96401** Chemotherapy administration, subcutaneous or intramuscular; nonhormonal antineoplastic **81235** *EGFR* (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)	✓	✓

Special Considerations	
Procedure Coding	• Subcutaneous injection volume of RYBREVANT *FASPRO* should not exceed 15 mL per site, sometimes requiring multiple injections to achieve the prescribed dose • In the event pain is not alleviated by pausing or slowing down delivery rate, a second injection site may be chosen on the opposite side of the abdomen to deliver the remainder of the dose • If multiple injections are required on a single date of service, Medicare's Medically Unlikely Edit (MUE) program permits CPT® 96401 to be reported for more than 1 injection: – up to 4 units in the facility setting (HOPD) – up to 3 units in the physician office setting

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage for any specific service on an insurance claim. Payers such as Medicare Administrative Contractors (MACs) and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and which payment rules are to be applied to such claims.

CPT®, Current Procedural Terminology; FDA, U.S. Food and Drug Administration; HCPCS, Healthcare Common Procedure Coding System; HOPD, hospital outpatient department; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

CPT® is a registered trademark of the American Medical Association.

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Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO*.

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Coverage

The identification of actionable biomarkers, as well as treatment with matched therapies, have been associated with favorable patient outcomes.[2] A biomarker test may be called a *companion diagnostic test* if it is paired with a specific treatment. Companion diagnostics provide results of genetic variations and are essential for the safe and effective use of a corresponding therapeutic product.[3]

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 fda.gov/CompanionDiagnostics

FDA, U.S. Food and Drug Administration.

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Patient Selection

Before initiation of RYBREVANT *FASPRO*, *EGFR* mutation status in tumor tissue or plasma specimens must be established based on an FDA-approved test. Testing may be performed at any time from initial diagnosis until the initiation of therapy; 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 are provided in the table below.

Companion Diagnostics for Treatment With RYBREVANT *FASPRO*[5,6]

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.

For broad *EGFR* gene analysis of common variants, see CPT® code 81235.[6]

Note: Johnson & Johnson is not the manufacturer of companion diagnostics approved for RYBREVANT *FASPRO*.

Ordering

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

CPT®, Current Procedural Terminology; DNA, deoxyribonucleic acid; EGFR, epidermal growth factor receptor; FDA, U.S. Food and Drug Administration; RNA, ribonucleic acid.

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Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO* and LAZCLUZE.

RYBREVANT Faspro™
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Select Important Dosage and Administration Information[1]

- RYBREVANT *FASPRO* is contraindicated in patients with known hypersensitivity to hyaluronidase or to any of its excipients
- **RYBREVANT *FASPRO* is for subcutaneous use only.** Do not administer RYBREVANT *FASPRO* intravenously
- RYBREVANT *FASPRO* must be administered by a healthcare professional
- To reduce the risk of medication errors, prior to administration, check the vial labels to ensure that the drug being prepared and administered is subcutaneous RYBREVANT *FASPRO* and not intravenous amivantamab
- RYBREVANT *FASPRO* has different recommended dosage and administration than intravenous amivantamab products. Do not substitute RYBREVANT *FASPRO* for or with intravenous amivantamab products
- RYBREVANT *FASPRO* is not indicated for use in pediatric patients
- Discard unused portion

Recommended Premedications[1]

Prior to the initial injection of RYBREVANT *FASPRO* (Week 1 Day 1), administer premedications as described in the table below to reduce the risk of ARRs.

Glucocorticoid administration is required at the initial dose at Week 1 Day 1 only, and upon re-initiation after prolonged dose interruptions, then as necessary for subsequent injections. Administer both antihistamine and antipyretic prior to all RYBREVANT *FASPRO* doses.

Medication	Dose	Route of Administration	Dosing Window Prior to RYBREVANT *FASPRO* Administration	Frequency
Antihistamine	Diphenhydramine (25 mg to 50 mg) or equivalent	Intravenous	15 to 30 minutes	All doses
		Oral	30 to 60 minutes	
Antipyretic	Acetaminophen (650 mg to 1,000 mg) or equivalent	Intravenous	15 to 30 minutes	All doses
		Oral	30 to 60 minutes	
Glucocorticoid	Dexamethasone (20 mg) or equivalent	Intravenous	45 to 60 minutes	Initial dose*
		Oral	At least 60 minutes	
Glucocorticoid	Dexamethasone (10 mg) or equivalent	Intravenous	45 to 60 minutes	Optional for subsequent doses
		Oral	60 to 90 minutes	

*Required at initial dose (Week 1, Day 1) or at the next subsequent dose in the event of an ARR.

ARR, administration-related reaction.

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Every-4-Week Dosing—RYBREVANT *FASPRO* + LAZCLUZE (lazertinib) or as a Single Agent[1]

The recommended dosages, dose volume, and vial selection of RYBREVANT *FASPRO* in combination with LAZCLUZE or as a single agent, based on baseline body weight, are provided below.

Every-4-Week Dosing

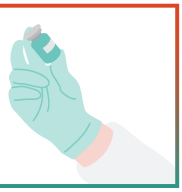
Body Weight at Baseline*	Recommended Dose	Dosing Schedule
<80 kg	1,600 mg amivantamab and 20,000 units hyaluronidase	Weekly (total of 4 doses) from Weeks 1 to 4 • Weeks 1 to 4—Injection on Day 1
	3,520 mg amivantamab and 44,000 units hyaluronidase	Every 4 weeks starting at Week 5 onwards
≥80 kg	2,240 mg amivantamab and 28,000 units hyaluronidase	Weekly (total of 4 doses) from Weeks 1 to 4 • Weeks 1 to 4—Injection on Day 1
	4,640 mg amivantamab and 58,000 units hyaluronidase	Every 4 weeks starting at Week 5 onwards

Vial Selection and Dose Volume for Q4W Dosing†

Q4W DOSING

STEP 1

Select the right vial for the starting dose based on patient weight at baseline



STEP 2

Determine dose volume needed

<80 kg	WEEKS 1–4 (once weekly)	1,600 mg amivantamab	ONE 10-mL VIAL	Administer 10 mL
	SUBSEQUENT DOSES* (Q4W from Week 5)	3,520 mg amivantamab	ONE 22-mL VIAL	Administer 22 mL‡
≥80 kg	WEEKS 1–4 (once weekly)	2,240 mg amivantamab	ONE 14-mL VIAL	Administer 14 mL
	SUBSEQUENT DOSES* (Q4W from Week 5)	4,640 mg amivantamab	ONE 14-mL VIAL ONE 15-mL VIAL	Administer 29 mL§‖

*Dose adjustments not required for subsequent body weight changes.

†Following weekly doses from Weeks 1 to 4. For patients currently following a Q2W dosing regimen, switch to subcutaneous and/or Q4W dosing at their next scheduled dose after initial weekly dosing has been completed (on or after Week 5).

‡Divide the 22-mL dose volume approximately equally into 2 syringes (each injection volume should not exceed 15 mL).

§Divide the 29-mL dose volume approximately equally into 2 syringes (each injection volume should not exceed 15 mL).

‖For the 29-mL dose volume, use one 2,240 mg amivantamab and 28,000 units hyaluronidase/14-mL vial and one 2,400 mg amivantamab and 30,000 units hyaluronidase/15-mL vial to minimize waste. If a different combination of vials is used, discard unused portion.

Q2W, every 2 weeks; Q4W, every 4 weeks.

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO* and LAZCLUZE.

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Every-2-Week Dosing—RYBREVANT *FASPRO* + LAZCLUZE (lazertinib) or as a Single Agent[1]

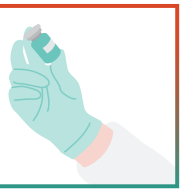
Every-2-Week Dosing

Body Weight at Baseline*	Recommended Dose	Dosing Schedule
<80 kg	1,600 mg amivantamab and 20,000 units hyaluronidase	Weekly (total of 4 doses) from Weeks 1 to 4 • Weeks 1 to 4–Injection on Day 1
		Every 2 weeks starting at Week 5 onwards
≥80 kg	2,240 mg amivantamab and 28,000 units hyaluronidase	Weekly (total of 4 doses) from Weeks 1 to 4 • Weeks 1 to 4—Injection on Day 1
		Every 2 weeks starting at Week 5 onwards

Vial Selection and Dose Volume for Q2W Dosing

Q2W DOSING

STEP 1
Select the right vial for the starting dose based on patient weight at baseline



STEP 2
Determine dose volume needed

<80 kg	WEEKS 1–4 (once weekly)	1,600 mg amivantamab	ONE 10-mL VIAL	Administer 10 mL
	SUBSEQUENT DOSES* (Q2W from Week 5)	1,600 mg amivantamab	ONE 10-mL VIAL	Administer 10 mL
≥80 kg	WEEKS 1–4 (once weekly)	2,240 mg amivantamab	ONE 14-mL VIAL	Administer 14 mL
	SUBSEQUENT DOSES* (Q2W from Week 5)	2,240 mg amivantamab	ONE 14-mL VIAL	Administer 14 mL

When given in combination with LAZCLUZE, administer RYBREVANT *FASPRO* any time after LAZCLUZE when given on the same day. Refer to the LAZCLUZE Prescribing Information for recommended LAZCLUZE dosing information. Administer RYBREVANT *FASPRO* in combination with LAZCLUZE until disease progression or unacceptable toxicity.

*Dose adjustments not required for subsequent body weight changes.

Patients receiving Q2W dosing (RYBREVANT *FASPRO* or RYBREVANT®) may switch to RYBREVANT *FASPRO* Q4W dosing at their next scheduled dose on or after Week 5.

Q2W, every 2 weeks; Q4W, every 4 weeks.

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO* and LAZCLUZE.

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Every-3-Week Dosing—RYBREVANT *FASPRO* + Chemotherapy (Carboplatin and Pemetrexed)[1]

The recommended dosages of RYBREVANT *FASPRO*, administered in combination with carboplatin and pemetrexed, based on baseline body weight are provided below. Administer RYBREVANT *FASPRO* until disease progression or unacceptable toxicity.

Every-3-Week Dosing

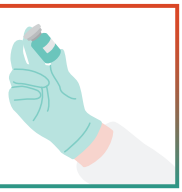
Body Weight at Baseline*	Recommended Dose	Dosing Schedule
<80 kg	1,600 mg amivantamab and 20,000 units hyaluronidase	First dose at Week 1 Day 1
	2,400 mg amivantamab and 30,000 units hyaluronidase	Weekly (total of 2 doses) from Weeks 2 to 3 • Weeks 2 to 3—Injection on Day 1
		Every 3 weeks starting at Week 4 onwards
≥80 kg	2,240 mg amivantamab and 28,000 units hyaluronidase	First dose at Week 1 Day 1
	3,360 mg amivantamab and 42,000 units hyaluronidase	Weekly (total of 2 doses) from Weeks 2 to 3 • Weeks 2 to 3—Injection on Day 1
		Every 3 weeks starting at Week 4 onwards

When used in combination with carboplatin and pemetrexed, RYBREVANT *FASPRO* should be administered in the following order: pemetrexed first, carboplatin second, and RYBREVANT *FASPRO* last. See manufacturers' Prescribing Information for complete information.

Vial Selection and Dose Volume for Q3W Dosing

Q3W DOSING

STEP 1
Select the right vial for the starting dose based on patient weight at baseline



STEP 2
Determine dose volume needed

<80 kg	WEEK 1 (Day 1)	1,600 mg amivantamab	ONE 10-mL VIAL	Administer 10 mL
	SUBSEQUENT DOSES*†	2,400 mg amivantamab	ONE 15-mL VIAL	Administer 15 mL
≥80 kg	WEEK 1 (Day 1)	2,240 mg amivantamab	ONE 14-mL VIAL	Administer 14 mL
	SUBSEQUENT DOSES*†	3,360 mg amivantamab	ONE 22-mL VIAL	Administer 21 mL‡§

*Dose adjustments not required for subsequent body weight changes.

†Including Week 2, Day 1 and Week 3, Day 1 doses. Initiate Q3W dosing starting at Week 4.

‡Divide the 21-mL dose volume approximately equally into 2 syringes (each injection volume should not exceed 15 mL).

§For the 21-mL dose volume, the entire contents of the 3,520 mg amivantamab and 44,000 units hyaluronidase/22 mL vial will not be needed. Discard unused portion.

Q3W, every 3 weeks.

If switching from RYBREVANT Q3W dosing to RYBREVANT *FASPRO* Q3W dosing, switch patients at their next scheduled dose on or after Week 4.

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO*.

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Concomitant and Prophylactic Medications[1]

When initiating treatment with RYBREVANT *FASPRO* in combination with LAZCLUZE (lazertinib), administer anticoagulant prophylaxis to prevent VTE events for the first 4 months of treatment. If there are no signs or symptoms of VTE during the first 4 months of treatment, consider discontinuation of anticoagulant prophylaxis at the discretion of the healthcare provider.

When initiating treatment with RYBREVANT *FASPRO*, prophylactic and concomitant medications are recommended to reduce the risk and severity of dermatologic adverse reactions. Administer an oral antibiotic, an antibiotic lotion to the scalp, a non-comedogenic skin moisturizer on the face and whole body (except scalp), wash hands and feet with 4% chlorhexidine solution, and limit sun exposure. Advise patients to wear protective clothing and use broad-spectrum UVA/UVB sunscreen to reduce the risk of dermatologic adverse reactions. Refer to the RYBREVANT *FASPRO* Prescribing Information for complete information.

Refer to the LAZCLUZE Prescribing Information for information about concomitant medications.

Preparation and Administration[1]

RYBREVANT *FASPRO* is for subcutaneous administration by a healthcare provider.

Do not administer RYBREVANT *FASPRO* intravenously.

Divide doses requiring greater than 15 mL into approximately equal volumes in 2 syringes and administer at separate injection sites. Do NOT exceed 15 mL in each syringe.

Recommended Dosing Volumes

RYBREVANT *FASPRO* Total Dose (amivantamab/ hyaluronidase)	Total Dose Volume	Recommended RYBREVANT *FASPRO* Vial (amivantamab/hyaluronidase) Selection			
		Number of 1,600 mg and 20,000 units/10 mL vials	Number of 2,240 mg and 28,000 units/14 mL vials	Number of 2,400 mg and 30,000 units/15 mL vials	Number of 3,520 mg and 44,000 units/22 mL vials
1,600 mg/20,000 units	10 mL	1	0	0	0
2,240 mg/28,000 units	14 mL	0	1	0	0
2,400 mg/30,000 units	15 mL	0	0	1	0
3,360 mg/42,000 units	21 mL*†	0	0	0	1
3,520 mg/44,000 units	22 mL†	0	0	0	1
4,640 mg/58,000 units	29 mL†‡	0	1	1	0

*For the 21-mL dose volume, the entire contents of the 3,520 mg amivantamab and 44,000 units hyaluronidase/22 mL vial will not be needed. Discard unused portion.

†Divide the dose volume approximately equally into 2 syringes (each syringe should not exceed 15 mL).

‡For the 29-mL dose volume, use one 2,240 mg amivantamab and 28,000 units hyaluronidase/14 mL vial and one 2,400 mg amivantamab and 30,000 units hyaluronidase/15 mL vial to minimize waste. If a different combination of vials is used, discard unused portion.

UVA, ultraviolet A; UVB, ultraviolet B; VTE, venous thromboembolism.

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO* and LAZCLUZE.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

Coding

ICD-10-CM Diagnosis Coding 16

HCPCS Codes 17

National Drug Codes 18

CPT® Codes 20

Other Coding Considerations 21

Physician Office Sample Claim Form (CMS-1500)
for RYBREVANT *FASPRO* (1,600 mg Amivantamab and 20,000 Units Hyaluronidase) 26

Hospital Outpatient Department Sample Claim Form (CMS-1450)
for RYBREVANT *FASPRO* (2,240 mg Amivantamab and 28,000 Units Hyaluronidase) 27

CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO*.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

ICD-10-CM Diagnosis Coding

ICD-10-CM diagnosis codes use 3 to 7 alphanumeric 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.[7]

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. Please consult your ICD-10-CM codebook for additional applicable codes.*

ICD-10-CM Diagnosis Code[8]	Description[8]
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
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 *FASPRO* as a single agent, also consider[8]:	
Z92.21	Personal history of antineoplastic chemotherapy

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

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

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO*.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

HCPCS Codes

HCPCS Code[9]
Drugs are typically reported with HCPCS codes assigned by the Centers for Medicare & Medicaid Services (CMS). The HCPCS code for RYBREVANT *FASPRO* is **J9062** **injection, amivantamab 5 mg and hyaluronidase-lpuj** Each 5-mg injection represents 1 unit of J9062.

Because requirements may vary, it is advisable to check with your payer prior to submitting claims reporting J9062.

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage for any specific service on an insurance claim. Payers such as Medicare Administrative Contractors (MACs) and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and which payment rules are to be applied to such claims.

HCPCS, Healthcare Common Procedure Coding System.

National Drug Codes

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 crossover claims)[10] and claims for many private payers.[11] 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 whether an NDC is needed, as well as the format the payer requires. To convert the 10-digit format to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below.

FDA-Specified 10-Digit NDC[1] (5-3-2 format)	11-Digit NDC (5-4-2 format)	Description[1]
57894-510-01	57894-0510-01	One single-dose vial containing 1,600 mg of amivantamab and 20,000 units of hyaluronidase per 10 mL (160 mg and 2,000 units/mL)
57894-514-01	57894-0514-01	One single-dose vial containing 2,240 mg of amivantamab and 28,000 units of hyaluronidase per 14 mL (160 mg and 2,000 units/mL)
57894-515-01	57894-0515-01	One single-dose vial containing 2,400 mg of amivantamab and 30,000 units of hyaluronidase per 15 mL (160 mg and 2,000 units/mL)
57894-522-01	57894-0522-01	One single-dose vial containing 3,520 mg of amivantamab and 44,000 units of hyaluronidase per 22 mL (160 mg and 2,000 units/mL)

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

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

National Drug Codes (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 *FASPRO*[1]:

Dose to Be Billed	11-Digit NDC (5-4-2 Format)	Packaging	NDC Unit of Measure	NDC Unit
1,600 mg	57894-0510-01	1,600 mg of amivantamab and 20,000 units of hyaluronidase per 10-mL vial (liquid)	ML	10
2,240 mg	57894-0514-01	2,240 mg of amivantamab and 28,000 units of hyaluronidase per 14-mL vial (liquid)	ML	14
2,400 mg	57894-0515-01	2,400 mg of amivantamab and 30,000 units of hyaluronidase per 15-mL vial (liquid)	ML	15
3,520 mg	57894-0522-01	3,520 mg of amivantamab and 44,000 units of hyaluronidase per 22-mL vial (liquid)	ML	22

Accurate NDC coding typically requires reporting the following components in this order[10,12]:

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

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

- 1,600-mg dose – **N457894051001 ML10**
- 2,240-mg dose – **N457894051401 ML14**
- 2,400-mg dose – **N457894051501 ML15**
- 3,520-mg dose – **N457894052201 ML22**

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

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO*.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

CPT® Codes

CPT® codes are the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. Drug administration services are reported on claim forms in both the physician office (CMS-1500) and hospital outpatient (CMS-1450) sites of care using the CPT® coding system. Healthcare providers are responsible for selecting appropriate codes for each individual claim based on the patient's condition, the items and services that are furnished, and any specific payer requirements.

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

Payer requirements for drug administration codes may vary. Consider verifying the correct administration coding with the payer. The following CPT® code may be used to report the administration of RYBREVANT *FASPRO* injection for subcutaneous use.

CPT® Code[6]	Description[6]
96401	Chemotherapy administration, subcutaneous or intramuscular; nonhormonal antineoplastic
81235	*EGFR* (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)

Report separate codes for each parenteral method of administration when chemotherapy is administered by different techniques. When coding multiple drug administration services on the same date, follow CPT® guidelines and the infusion hierarchy:

- Physician's office: The initial infusion is the key or primary reason for the encounter, irrespective of the temporal order in which infusions or injections occur[6]
- Hospital outpatient department: 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[6]
- The administration of medications (eg, antiemetics, steroidal agents) administered independently or sequentially as supportive management of chemotherapy administration should be separately reported

CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; IV, intravenous.

Other Coding Considerations

When coding and billing for RYBREVANT *FASPRO* 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 information about the setting, which is necessary to appropriately pay professional service claims. The POS is the location of the provider's face-to-face encounter with the patient. POS codes are required on all claims for professional services (billed on CMS-1500, Item 24B). The physician practice setting is indicated with POS code 11. To differentiate between on-campus and off-campus PBDs, CMS created POS code 19 and revised the description for outpatient hospitals in 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[6]

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

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

Other Coding Considerations (cont'd)

Revenue Codes

Many payers require use of American Hospital Association revenue codes to bill for services provided in hospital outpatient departments. Revenue codes consist of a leading zero followed by 3 other digits and are used on CMS-1450 claim forms to assign costs to broad categories of hospital revenue centers. Codes used for Medicare claims are available from Medicare contractors. Generally, CMS does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under the OPPS since hospitals' assignments 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 is assigned in the cost report.[13] The following revenue codes may be applicable to CMS-1450 claims for RYBREVANT *FASPRO* and its administration.

Revenue Codes and Descriptions[14]

Code	Description
0331	Chemotherapy administration – injection
0510	Clinic, general
0636	Pharmacy, drugs requiring detailed coding

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

Other Coding Considerations (cont'd)

CPT® and HCPCS Modifiers

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

Summary of CPT® and HCPCS Modifiers

Modifier	Description	Indication and Placement	Physician Claims (CMS-1500)	CMS-1450 Locator Box 44
25	Significant, separately identifiable E/M service by the same physician or other qualified HCP on the same day of the procedure or other service[6]	• Patient requires distinct E/M service in addition to drug administration procedure[6] • Must be substantiated with documentation[6] • Append the modifier to the relevant E/M code[6]	✓ Required by Medicare	✓ Required by Medicare
PO*	Excepted service provided at an off-campus, outpatient, PBD of a hospital[17]	• 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[17]	• 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 PFS[13]	N/A	✓ Required by Medicare
JW	Drug amount discarded/not administered to any patient[11]	• 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[11]	• 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 a remote location of the hospital.[13]

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

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO*.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

Other Coding Considerations (cont'd)

340B Modifier

Effective January 1, 2025, CMS requires all 340B-covered entities that submit claims for separately payable Part B drugs and biologics to report the TB modifier on claim lines for drugs acquired through the 340B program. All 340B-covered entities that previously reported the JG modifier should now report only the TB modifier.[16]

2025 Reporting Requirements

Modifier[13]	Description[13]	Indication and Placement[16]
TB	Drug or biologic acquired with 340B drug pricing program discount, reported for informational purposes	• Must be reported by all 340B entities submitting claims for separately payable drugs and biologics • To be reported on the same line as the drug HCPCS code for all 340B-acquired drugs

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

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO*.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

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, via a chemotherapy administration or nonchemotherapy drug infusion code[17]

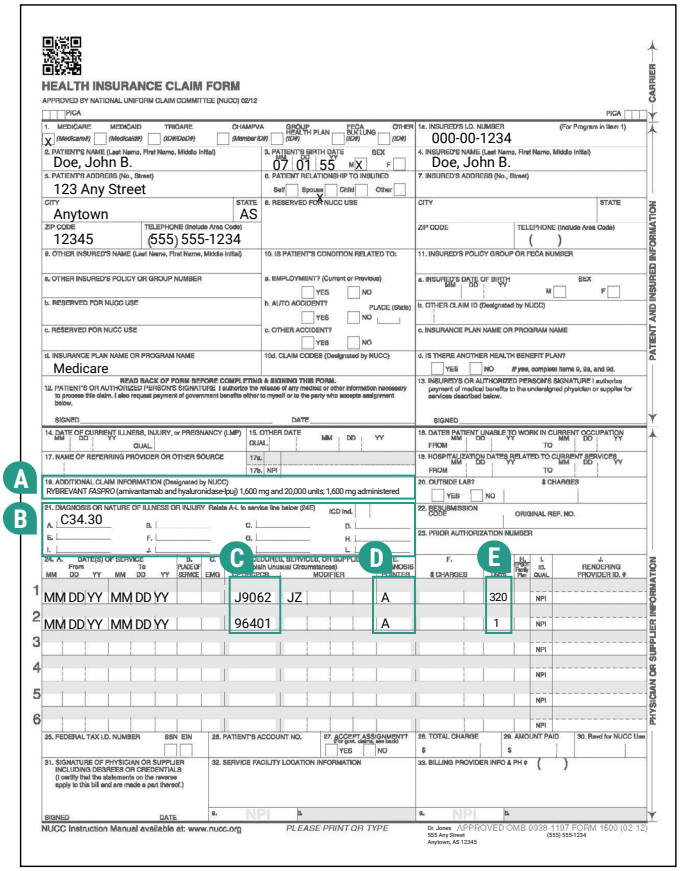
Thus, CPT® 99211 cannot be paid on the same day as an office-based injection of RYBREVANT *FASPRO*. If a chemotherapy service and a significant, separately identifiable E/M service are provided on the same day, a different diagnosis is not required.[17]

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 had the provider purchased it. When reporting drug administration services with no drug charge, it is common to require the drug HCPCS code on the same claim. To accommodate claim-processing edits, it may also be necessary to include a nominal charge of $0.01 (one cent).[18] Payer policies may vary.

CPT®, Current Procedural Terminology; E/M, evaluation and management; HCPCS, Healthcare Common Procedure Coding System.

Physician Office Sample Claim Form (CMS-1500) for RYBREVANT *FASPRO* (1,600 mg amivantamab and 20,000 units hyaluronidase)



HEALTH INSURANCE CLAIM FORM

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

1. MEDICARE X — 1a. INSURED'S I.D. NUMBER: 000-00-1234
2. PATIENT'S NAME: Doe, John B.
3. PATIENT'S BIRTH DATE: 07 01 55 — SEX: M X F
4. INSURED'S NAME: Doe, John B.
5. PATIENT'S ADDRESS: 123 Any Street
6. PATIENT RELATIONSHIP TO INSURED: Self X
7. INSURED'S ADDRESS
CITY: Anytown — STATE: AS — ZIP CODE: 12345 — TELEPHONE: (555) 555-1234
11. INSURED'S POLICY GROUP OR FECA NUMBER
11d. IS THERE ANOTHER HEALTH BENEFIT PLAN?
d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare

A — 19. ADDITIONAL CLAIM INFORMATION: RYBREVANT FASPRO (amivantamab and hyaluronidase-lpuj) 1,600 mg and 20,000 units; 1,600 mg administered

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

24A. DATE(S) OF SERVICE	C. PROCEDURES, SERVICES, OR SUPPLIES	MODIFIER	D. DIAGNOSIS POINTER	F. $ CHARGES	E. DAYS OR UNITS	RENDERING PROVIDER ID. #
1 MM DD YY MM DD YY	J9062	JZ	A		320	NPI
2 MM DD YY MM DD YY	96401		A		1	NPI
3						NPI
4						NPI
5						NPI
6						NPI

25. FEDERAL TAX I.D. NUMBER — 26. PATIENT'S ACCOUNT NO. — 27. ACCEPT ASSIGNMENT? YES — 28. TOTAL CHARGE $ — 29. AMOUNT PAID $ — 30. Rsvd for NUCC Use
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS — 32. SERVICE FACILITY LOCATION INFORMATION — 33. BILLING PROVIDER INFO & PH #

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

A **Item 19** – Enter the drug name, strength, and amount administered

B **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

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

RYBREVANT *FASPRO*
J9062 - Injection, amivantamab 5 mg and hyaluronidase-lpuj

Modifier
JZ modifier indicates no discarded amount from a single-dose container*

Drug Administration
96401 – Chemotherapy administration, subcutaneous or intramuscular; nonhormonal antineoplastic

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

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

RYBREVANT *FASPRO*
J9062 – Enter **320** units

Injection Services
96401 – Enter **1** unit for each injection (for practitioners, Medicare allows up to 3 units of 96401 per date of service[19])

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage for any specific service on an insurance claim. Payers such as Medicare Administrative Contractors (MACs) and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and which payment rules are to be applied to such claims.

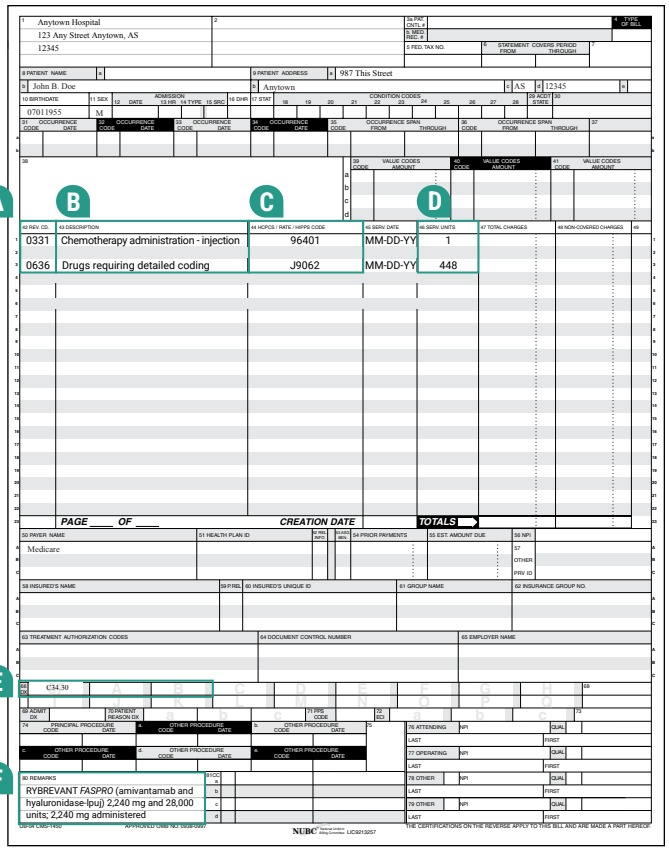
*For doses resulting in discarded amounts, CMS does not use fractional billing units. Therefore, the JW modifier should not be used when the dose of the drug administered is less than the billing unit.[20]

CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO*.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

Hospital Outpatient Department Sample Claim Form (CMS-1450) for RYBREVANT *FASPRO* (2,240 mg amivantamab and 28,000 units hyaluronidase)



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 *FASPRO*
J9062 - Injection, amivantamab 5 mg and hyaluronidase-lpuj

Drug Administration
96401 – Chemotherapy administration, subcutaneous or intramuscular; nonhormonal antineoplastic

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

RYBREVANT *FASPRO*
J9062 – Enter **1** unit

Injection Services
96401 – Enter **448** units for each injection

For facilities, Medicare allows up to 4 units of 96401 per date of service[21]

E **Locator Box 66** – 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

F **Locator Box 80** – Enter the drug name, strength, and amount administered

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage for any specific service on an insurance claim. Payers such as Medicare Administrative Contractors (MACs) and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and which payment rules are to be applied to such claims.

CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; FI, Fiscal Intermediary; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO*.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

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Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO*.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

Where to Order

Specialty Pharmacy

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

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

Specialty Distributors

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

Specialty Pharmacy for LAZCLUZE				
Name	**Phone Number**	**Fax**	**Website**	**ePrescribe**
Onco360	877-662-6633	877-662-6355	Onco360.com	OncoMed dba Onco360 or NPI# 1679618151
Specialty Authorized Distribution Network				
Name	**Phone Number**	**Fax**	**Website**	**Drug Fulfillment**
BioCare Specialty Distribution	800-304-3064	N/A	biocare-us.com	RYBREVANT *FASPRO*, RYBREVANT and LAZCLUZE
Cardinal Health Specialty Pharmaceutical Distribution	**Physician offices:** 877-453-3972 **Hospitals/All others:** 855-855-0708	614-652-7043	specialtyonline.cardinalhealth.com orderexpress.cardinalhealth.com	RYBREVANT *FASPRO*, RYBREVANT and LAZCLUZE
Cardinal Health P.R. 120 (Puerto Rico)	787-625-4200	787-625-4398	cardinalhealth.pr	RYBREVANT *FASPRO*, RYBREVANT and LAZCLUZE
Cencora (AmerisourceBergen)	800-746-6273	800-547-9413	asdhealthcare.com	RYBREVANT *FASPRO*, RYBREVANT and LAZCLUZE
Cencora Oncology Supply (AmerisourceBergen Oncology Supply)	800-633-7555	800-248-8205	oncologysupply.com	RYBREVANT *FASPRO*, RYBREVANT and LAZCLUZE
CuraScript SD (Priority Healthcare)	877-599-7748	800-862-6208	curascriptsd.com	RYBREVANT *FASPRO* and RYBREVANT
McKesson Plasma and Biologics	877-625-2566	888-752-7626	connect.mckesson.com	RYBREVANT *FASPRO*, RYBREVANT and LAZCLUZE
McKesson Specialty Health	**Oncology:** 800-482-6700 **Multispecialty:** 855-477-9800	**Oncology:** 855-824-9489 **Multispecialty:** 800-800-5673	mckessonspecialtyhealth.com	RYBREVANT *FASPRO*, RYBREVANT and LAZCLUZE
Morris & Dickson Specialty Distribution	800-388-3833	318-798-6007	morrisdickson.com mdspecialtydist.com	RYBREVANT *FASPRO*, RYBREVANT and LAZCLUZE

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

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

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO*, RYBREVANT, and LAZCLUZE.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

Onco360 Pharmacy Patient Support

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

Onco Care Coordinators

A patient can expect a welcome call within the first 3 days of receiving their LAZCLUZE prescription. They will validate the patient's insurance information and provide any support to ensure medication access: benefits investigation, insurance verification, prior authorization support, exception requests/appeal support, and patient financial assistance.

Once insurance is confirmed, LAZCLUZE will be shipped to the patient's preferred location at the beginning of every treatment cycle. Patients can expect a refill reminder before medication is shipped.

Onco360 Pharmacist

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

Onco360 Nurse

Each patient will receive a call from an oncology nurse at the beginning of treatment and get in-depth education on adverse event management, advice on how to stay on treatment, and when to contact their doctor. The nurse will also check in at the end of each treatment cycle to ensure there were no barriers to adherence.

Patients can contact a nurse Monday to Friday, 8 am to 8 pm Eastern time to discuss any concerns they have about LAZCLUZE.

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO* and LAZCLUZE.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

Coverage Decisions

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

Medical Necessity

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

When third-party payers consider coverage requests for RYBREVANT *FASPRO*, they will first determine whether the therapy is covered under their policies. Next, they will look for evidence supporting medical necessity, which may include, but not be limited to:

- Patient diagnosis and alignment with indications for requested therapy
- FDA-approved biomarker test results: positive for genetic abnormalities consistent with one of the indications for RYBREVANT *FASPRO*
- Summary of the patient's current medical condition and history
- Rationale for requested therapy and expected outcome(s)

View a sample Letter of Medical Necessity for RYBREVANT *FASPRO*.

FDA, U.S. Food and Drug Administration; PA, prior authorization.

Coverage Decisions (cont'd)

Prior Authorization

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

Items you may want to prepare for a PA request:

- Letter of Medical Necessity
- Prescribing information for the requested drugs
- Relevant biomarker test results
- Patient history and physical findings, including:
  - Diagnosis (ICD-10-CM)
  - Previous therapies/procedures and response to the interventions
  - Current symptoms/condition

Exception Request

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

View a sample Exception Request letter for RYBREVANT *FASPRO*.

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

Coverage Decisions (cont'd)

Appeals

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

Tips for Filing an Appeal

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

PA, prior authorization.

Once the clinical decision has been made to prescribe RYBREVANT *FASPRO* or RYBREVANT in combination with LAZCLUZE, Johnson & Johnson has resources to help you support patients.

RYBREVANT-based regimens* are accessible with coverage on the majority of commercial and Medicare plans†

NOTE: Medicare patient costs for all Part D drugs in 2026 have a $2,100 OOP limit due to the Part D reform (IRA)

Accessible

- RYBREVANT has **>95% coverage across Medicare and commercial plans‡**

Affordable

- Eligible commercial plans pay **$0 per dose and prescription fill§**
  - The J&J withMe Savings Program is expanding to include reimbursement support for certain direct oral anticoagulant (DOAC) medicines for VTE prophylaxis for your patients prescribed either RYBREVANT FASPRO or RYBREVANT in combination with LAZCLUZE
- Over 85% of **Medicare patients paid $0 OOP for RYBREVANT** and approximately 73% **paid $0 OOP for LAZCLUZE**

Comprehensive Support

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

The patient support and resources provided by J&J withMe and RYBREVANT withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe a J&J medicine.

*RYBREVANT and/or LAZCLUZE.

†Source: Managed Markets Insight and Technology, LLC™, a trademark of MMIT, as of 10/25. Collected as of 10/25 and may change.

‡This percentage may not represent 100% of formulary lives due to data limitations. Majority: >51% number of covered lives.

§Maximum program benefit per calendar year shall apply. Offer subject to change or end without notice. Program does not cover the cost to give patients their treatment. See program requirements at **Ryb-Laz.JNJwithMeSavings.com**.

IRA, Inflation Reduction Act; OOP, out of pocket; VTE, venous thromboembolism.

Please see full Important Safety Information. Please read full Prescribing Information for RYBREVANT *FASPRO*.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

INDICATIONS

RYBREVANT *FASPRO* (amivantamab and hyaluronidase-lpuj) is indicated:

- in combination with LAZCLUZE (lazertinib) for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with 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

CONTRAINDICATIONS

RYBREVANT *FASPRO* is contraindicated in patients with known hypersensitivity to hyaluronidase or to any of its excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity and Administration-Related Reactions with RYBREVANT *FASPRO*

RYBREVANT *FASPRO* can cause hypersensitivity and administration-related reactions (ARR); signs and symptoms of ARR include dyspnea, flushing, fever, chills, chest discomfort, hypotension, and vomiting. The median time to ARR onset is approximately 2 hours.

RYBREVANT FASPRO *with LAZCLUZE*

In PALOMA-3 (n=206), all Grade ARRs occurred in 13% of patients, including 0.5% Grade 3. Of the patients who experienced ARRs, 89% occurred with the initial dose (Week 1, Day 1).

Premedicate with antihistamines, antipyretics, and glucocorticoids and administer RYBREVANT *FASPRO* as recommended. Monitor patients for any signs and symptoms of administration-related reactions during injection in a setting where cardiopulmonary resuscitation medication and equipment are available. Interrupt RYBREVANT *FASPRO* injection if ARR is suspected. Resume treatment upon resolution of symptoms or permanently discontinue RYBREVANT *FASPRO* based on severity.

Interstitial Lung Disease/Pneumonitis

RYBREVANT *FASPRO* can cause severe and fatal interstitial lung disease (ILD)/pneumonitis.

RYBREVANT FASPRO *with LAZCLUZE*

In PALOMA-3, ILD/pneumonitis occurred in 6% of patients, including Grade 3 in 1%, Grade 4 in 1.5%, and fatal cases in 1.9% of patients. 5% of patients permanently discontinued RYBREVANT *FASPRO* and LAZCLUZE due to ILD/pneumonitis.

Please read full Prescribing Information for RYBREVANT *FASPRO* and LAZCLUZE.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Interstitial Lung Disease/Pneumonitis (cont'd)

Intravenous Amivantamab with LAZCLUZE

In MARIPOSA, ILD/pneumonitis occurred in 3.1% of patients, including Grade 3 in 1.0% and Grade 4 in 0.2% of patients. There was one fatal case of ILD/pneumonitis and 2.9% of patients permanently discontinued intravenous amivantamab and LAZCLUZE due to ILD/pneumonitis.

Intravenous Amivantamab with Carboplatin and Pemetrexed

Based on the pooled safety population, ILD/pneumonitis occurred in 2.1% of patients with 1.8% of patients experiencing Grade 3 ILD/pneumonitis. 2.1% discontinued intravenous amivantamab due to ILD/pneumonitis.

Intravenous Amivantamab as a Single Agent

In CHRYSALIS, ILD/pneumonitis occurred in 3.3% of patients, with 0.7% of patients experiencing Grade 3 ILD/pneumonitis. Three patients (1%) permanently discontinued intravenous amivantamab due to ILD/pneumonitis.

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

Venous Thromboembolic (VTE) Events with Concomitant Use with LAZCLUZE

RYBREVANT *FASPRO* in combination with LAZCLUZE can cause serious and fatal venous thromboembolic (VTE) events, including deep vein thrombosis and pulmonary embolism. Without prophylactic anticoagulation, the majority of these events occurred during the first four months of treatment.

RYBREVANT FASPRO *with LAZCLUZE*

In PALOMA-3 (n=206), all Grade VTE occurred in 11% of patients and 1.5% were Grade 3. 80% (n=164) of patients received prophylactic anticoagulation at study entry, with an all Grade VTE incidence of 7%. In patients who did not receive prophylactic anticoagulation (n=42), all Grade VTE occurred in 17% of patients. In total, 0.5% of patients had VTE leading to dose reductions of RYBREVANT *FASPRO* and no patients required permanent discontinuation. The median time to onset of VTEs was 95 days (range: 17 to 390).

Intravenous Amivantamab with LAZCLUZE

In MARIPOSA (n=421), VTEs occurred in 36% of patients 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 intravenous amivantamab, and 7% of patients had VTE leading to dose interruptions of LAZCLUZE; 1% of patients had VTE leading to dose reductions of intravenous amivantamab, and 0.5% of patients had VTE leading to dose reductions of LAZCLUZE; 3.1% of patients had VTE leading to permanent discontinuation of intravenous amivantamab, 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).

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Venous Thromboembolic (VTE) Events with Concomitant Use with LAZCLUZE (cont'd)

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 *FASPRO* and LAZCLUZE based on severity. Once anticoagulant treatment has been initiated, resume RYBREVANT *FASPRO* 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 *FASPRO*. Treatment can continue with LAZCLUZE at the same dose level at the discretion of the healthcare provider. Refer to the LAZCLUZE Prescribing Information for recommended LAZCLUZE dosage modification.

Dermatologic Adverse Reactions

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

RYBREVANT FASPRO *with LAZCLUZE*

In PALOMA-3, rash occurred in 80% of patients, including Grade 3 in 17% and Grade 4 in 0.5% of patients. Rash leading to dose reduction occurred in 11% of patients, and RYBREVANT *FASPRO* was permanently discontinued due to rash in 1.5% of patients.

Intravenous Amivantamab with LAZCLUZE

In MARIPOSA, rash occurred in 86% of patients, 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 intravenous amivantamab and 30% for LAZCLUZE, rash leading to dose reductions occurred in 23% of patients for intravenous amivantamab and 19% for LAZCLUZE, and rash leading to permanent discontinuation occurred in 5% of patients for intravenous amivantamab and 1.7% for LAZCLUZE.

Intravenous Amivantamab with Carboplatin and Pemetrexed

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

Intravenous Amivantamab as a Single Agent

In CHRYSALIS, rash occurred in 74% of patients, including Grade 3 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% and permanent discontinuation due to rash occurred in 0.7% of patients. Toxic epidermal necrolysis occurred in one patient (0.3%).

When initiating treatment with RYBREVANT *FASPRO* and LAZCLUZE, prophylactic and concomitant medications are recommended to reduce the risk and severity of dermatologic adverse reactions. Instruct patients to limit sun exposure during and for 2 months after treatment. Advise patients to wear protective clothing and use broad spectrum UVA/UVB sunscreen.

Please read full Prescribing Information for RYBREVANT *FASPRO* and LAZCLUZE.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Dermatologic Adverse Reactions (cont'd)

If skin reactions develop, administer supportive care including 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 *FASPRO* in combination with LAZCLUZE, withhold, reduce the dose, or permanently discontinue both drugs based on severity. For patients receiving RYBREVANT *FASPRO* as a single agent or in combination with carboplatin and pemetrexed, withhold, dose reduce or permanently discontinue RYBREVANT *FASPRO* based on severity.

Hepatotoxicity

LAZCLUZE in combination with amivantamab can cause severe hepatotoxicity (including increased ALT and AST).

Intravenous Amivantamab with LAZCLUZE

In MARIPOSA, based on adverse reaction data, hepatotoxicity occurred in 49% of patients treated with LAZCLUZE, including Grade 3 in 9.3% of patients and Grade 4 in 0.5%. LAZCLUZE was interrupted for an adverse reaction of hepatotoxicity in 8% of patients, the dose was reduced in 1.4% and permanently discontinued in 0.2%.

Perform liver function tests (including ALT, AST, and total bilirubin) before initiation of LAZCLUZE and during treatment, as clinically indicated. Withhold, reduce the dose, or permanently discontinue LAZCLUZE and amivantamab based on severity.

Ocular Toxicity

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

RYBREVANT FASPRO *with LAZCLUZE*

In PALOMA-3, all Grade ocular toxicity occurred in 13% of patients, including 0.5% Grade 3.

Intravenous Amivantamab with LAZCLUZE

In MARIPOSA, ocular toxicity occurred in 16%, including Grade 3 or 4 ocular toxicity in 0.7% of patients.

Intravenous Amivantamab with Carboplatin and Pemetrexed

Based on the pooled safety population, ocular toxicity occurred in 16% of patients. All events were Grade 1 or 2.

Intravenous Amivantamab as a Single Agent

In CHRYSALIS, keratitis occurred in 0.7% and uveitis occurred in 0.3% of patients. All events were Grade 1-2.

Promptly refer patients presenting with new or worsening eye symptoms to an ophthalmologist. Withhold, dose reduce or permanently discontinue RYBREVANT *FASPRO* and continue LAZCLUZE based on severity.

Please read full Prescribing Information for RYBREVANT *FASPRO* and LAZCLUZE.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

IMPORTANT SAFETY INFORMATION (cont'd)

Embryo-Fetal Toxicity

Based on animal models, RYBREVANT *FASPRO*, and LAZCLUZE can cause fetal harm when administered to a pregnant woman. Verify pregnancy status of females of reproductive potential prior to initiating RYBREVANT *FASPRO*. Advise pregnant women and females of reproductive potential of the potential risk to the fetus. Advise patients of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of RYBREVANT *FASPRO*, and for 3 weeks after the last dose of LAZCLUZE.

ADVERSE REACTIONS

RYBREVANT FASPRO *with LAZCLUZE*

In PALOMA-3 (n=206), the most common adverse reactions (≥20%) were rash (80%), nail toxicity (58%), musculoskeletal pain (50%), fatigue (37%), stomatitis (36%), edema (34%), nausea (30%), diarrhea (22%), vomiting (22%), constipation (22%), decreased appetite (22%), and headache (21%). The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocyte count (6%), decreased sodium (5%), decreased potassium (5%), decreased albumin (4.9%), increased alanine aminotransferase (3.4%), decreased platelet count (2.4%), increased aspartate aminotransferase (2%), increased gamma-glutamyl transferase (2%), and decreased hemoglobin (2%).

Serious adverse reactions occurred in 33% of patients, with those occurring in ≥2% of patients including ILD/pneumonitis (6%); and pneumonia, VTE and fatigue (2.4% each). Death due to adverse reactions occurred in 5% of patients treated with RYBREVANT *FASPRO*, including ILD/pneumonitis (1.9%), pneumonia (1.5%), and respiratory failure and sudden death (1% each).

Intravenous Amivantamab with LAZCLUZE

In MARIPOSA (n=421), the most common adverse reactions (ARs) (≥20%) were rash (86%), nail toxicity (71%), infusion-related reactions (IRRs) (intravenous amivantamab) (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%), and nausea (21%). 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 ARs occurred in 49% of patients, with those occurring in ≥2% of patients including VTE (11%), pneumonia (4%), ILD/pneumonitis and rash (2.9% each), COVID-19 (2.4%), and pleural effusion and IRRs (intravenous amivantamab) (2.1% each). Fatal ARs occurred in 7% of patients 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).

Intravenous Amivantamab with Carboplatin and Pemetrexed

In MARIPOSA-2 (n=130), the most common ARs (≥20%) were rash (72%), IRRs (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%).

Please read full Prescribing Information for RYBREVANT *FASPRO* and LAZCLUZE.

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

In MARIPOSA-2, serious ARs occurred in 32% of patients, with those occurring in >2% of patients including dyspnea (3.1%), thrombocytopenia (3.1%), sepsis (2.3%), and PE (2.3%). Fatal ARs occurred in 2.3% of patients; these included respiratory failure, sepsis, and ventricular fibrillation (0.8% each).

In PAPILLON (n=151), the most common ARs (≥20%) were rash (90%), nail toxicity (62%), stomatitis (43%), IRRs (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 ARs occurred in 37% of patients, with those occurring in ≥2% of patients including rash, pneumonia, ILD, PE, 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.

Intravenous Amivantamab as a Single Agent

In CHRYSALIS (n=129), the most common ARs (≥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 ARs occurred in 30% of patients, with those occurring in ≥2% of patients including PE, pneumonitis/ILD, dyspnea, musculoskeletal pain, pneumonia, and muscular weakness. Fatal adverse reactions occurred in 2 patients (1.5%) due to pneumonia and 1 patient (0.8%) due to sudden death.

LAZCLUZE DRUG INTERACTIONS

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

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

Please see full Prescribing Information for RYBREVANT *FASPRO* and LAZCLUZE.

cp-491010v2

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Subcutaneous injection | 160 mg/2,000 units per mL

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